

IN THE COURT OF ARBITRATION FOR SPORT

FLOYD LANDIS

Appellant,

V.

UNITED STATES ANTI-DOPING AGENCY

Respondent.

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CAS 2007/A/1394

UNITED STATES ANTI-DOPING AGENCY'S RESPONSE BRIEF

The United States Anti-Doping Agency ("USADA"), through its undersigned counsel, hereby submits its response to Appellant's appeal brief ("Appellant's Brief").

I. INTRODUCTION

Appellant, Floyd Landis, brings this appeal seeking to overturn the ruling of the American Arbitration Association ("AAA") Panel, which decided on September 20, 2007, that he had committed an Anti-Doping Rules Violation based on the presence of exogenous testosterone in a sample collected from Appellant after Stage 17 of the 2006 Tour de France (the "Tour").

The Majority Decision reached by the AAA Panel came after one of the most exhaustive proceedings in the history of anti-doping adjudication, culminating in a nine day hearing. Despite the voluminous and unprecedented scope of discovery that Appellant was granted by the AAA Panel and the length of the hearing, the elements of this case are not overly complex.

The elements of the case against Appellant center on the determination by the Laboratoire National de Dépistage du Dopage ("LNDD") in Paris that his Sample contained

exogenous testosterone. LNDD's Adverse Analytical Finding report was based on the detected presence of exogenous testosterone or its precursors or metabolites in Appellant's sample using Carbon Isotope Ratio Mass Spectrometry ("IRMS") analysis. As discussed below, the fundamental science in this case has been reviewed at length and leads to only one conclusion – on a day that Appellant made a seemingly spectacular ride in the Tour, he was doing so with exogenous testosterone in his system. In short, he was cheating and he got caught.

To the extent this case is unique in any way, it is only because of the unprecedented scope of attacks by Appellant after his positive test was announced. Appellant is known in cycling circles as an intense competitor and he attacked those whom he viewed as his opposition in this case with an equal ferocity. These attacks included efforts to encourage Congress to pull funding from USADA unless the case against him was dropped, threats of federal lawsuits against USADA, and press conferences and other public statements attacking anti-doping officials, laboratory employees and witnesses.¹

While publicly proclaiming that he wanted the "truth to come out," the record of the proceeding below establishes that Appellant and his team continually tried to prevent the truth from being heard. For example, after declaring that it would not make any sense to dope during just one stage of the Tour, Appellant did everything possible to prevent USADA from analyzing the remaining B Samples from his other Tour doping tests with the more thorough IRMS method. Not surprisingly, when Appellant's obstructionist efforts were rejected by the AAA

¹ These public attacks, which often contained blatantly false information, were made by Appellant specifically because he knew that USADA's rules prevented USADA from responding publicly until after the AAA Hearing had closed and a doping violation had been declared.

Panel and the samples were tested, four more of Appellant's Tour Samples were revealed to contain exogenous testosterone.²

Why are these previous bad acts by Appellant relevant to this appeal, which should be narrowly focused on the science that clearly establishes Appellant's doping? The answer is that, while this Brief will not devote further time to Appellant's improper behavior during prior proceedings, these facts, as set forth in the transcript of the AAA Hearing and the record provide an important context for what the Panel will hear from Appellant during this proceeding. Whether it is the Tour or this arbitration, Appellant and his team have displayed a classic "win at all costs" mentality.

Unfortunately, this background is also relevant to these proceedings because Appellant's approach remains apparent in his Brief. Appellant seeks to convince this Panel that LNDD employees are incompetent and dishonest, that USADA's expert witnesses are corrupt and unethical, that the Panel's scientific expert only provided one-sided advice, and that Appellant is somehow the victim of a complicated international web of conspiracy and incompetence that has unfairly accused him of doping. Appellant has consistently taken the position that everyone is at fault but him.

Fortunately for those who truly value clean sport, Appellant's doping was discovered. It was discovered by the diligent employees of LNDD whom Appellant now seeks to cast as the

² The extent of Appellant's team's commitment to suppressing the truth became clear in the well-documented incident where Appellant was forced to fire his long-time business manager in the middle of the AAA Hearing because the manager had called and threatened a witness, three-time Tour Champion, Greg LeMond, the night before Mr. LeMond was to testify. Indeed, Appellant was also forced to admit at the AAA Hearing that he had made his own threats against Mr. LeMond. Specifically, he had posted a message on an internet forum threatening to expose Mr. LeMond's history as a sexual abuse survivor if Mr. LeMond talked about a conversation he had with the Appellant where they discussed the doping allegations against Appellant.

villains in this situation. It was detected by a valid scientific method that has been the downfall of many other athletes who thought that they could beat the system and get away with doping.

Finally, Appellant was held accountable for his doping behavior by the AAA Panel, which gave him a full, fair and complete opportunity to raise every defense possible to the evidence against him. Specifically, after carefully considering the voluminous briefing and the evidence submitted over nine days of hearing, the AAA Panel concluded that LNDD's Adverse Analytical Finding based on IRMS analysis was scientifically sound. In its 84-page Arbitration Award ("AAA Panel Decision"), the AAA Panel, with the assistance of its independent scientific expert, thoroughly and painstakingly explained that none of Appellant's myriad attacks undercut the reliability of LNDD's IRMS findings. The AAA Panel Decision concluded that Appellant's primary arguments were "scientifically totally unacceptable and fundamentally flawed."

Despite the AAA Panel's exhaustive scientific analysis supporting the IRMS findings, Appellant asks this Panel to conclude that the "[IRMS] test results are worse than unreliable, they are a farce." Thus, a ruling in Appellant's favor would, by necessity, require this Panel to conclude that the AAA Panel grossly misunderstood and misapplied the scientific principles in this case.

USADA respectfully submits that after this Panel has had the opportunity to review the complete record from the AAA Hearing, hear directly from the relevant witnesses and judge their credibility, and has completed the admittedly difficult task of mastering the scientific issues in this case, this Panel will also reach the inescapable conclusion that, despite any attempt by Appellant to confuse the issues, the scientific evidence in this case establishes that there was exogenous testosterone in Appellant's Stage 17 Sample.

II. STATEMENT OF FACTS

A. The 2006 Tour de France

Appellant was the first place finisher of the 2006 Tour, which took place between July 1 and July 23, 2006. The Tour was on the racing calendar of the Union Cycliste Internationale (“UCI”) and doping control during the Tour was conducted pursuant to the UCI Anti-Doping Rules (the “UCI Rules”). Doping control samples collected during the Tour were sent, upon collection, to the LNDD in Paris for analysis.

Appellant provided eight samples on different days during the course of the Tour. Appellant’s Stage 17 Sample was collected on July 20, 2006, and was assigned Sample Number 995474. That sample was collected at approximately 5:55 p.m. at the Doping Control Station in Morzine, Avoriaz, see Ex. 27, and was received by LNDD less than four hours later, at 9:35 p.m. See Ex. 24 at USADA0023-0024. Appellant testified during the AAA Hearing that he signed his doping control forms with the understanding that his signature indicated his assent to the doping control process, and the process had no irregularities. See Landis Testimony, Tr. at 1632:1-1635:25. Appellant did not submit any evidence or testimony challenging the validity and integrity of collection and transport of Appellant’s samples to LNDD. (Declarations from Alexia, Bordaberry, Rahali, and Tollenaere addressing this issue are part of the record and are included for convenience as Ex. 135.³)

³ Exs. 1-134 were part of the hearing below. USADA will continue to refer to those exhibits by their original numbers, and new exhibits will be numbered in sequence. An exhibit list for all exhibits is attached, and all exhibits are attached to the transmission of this Brief in electronic format.

On July 25, 2006, LNDD reported Appellant's Stage 17 Sample to UCI as an Adverse Analytical Finding based on the detected presence of exogenous testosterone or its precursors or metabolites in Appellant's sample IRMS analysis.

The inspection and analysis of Appellant's Stage 17 B Sample took place at LNDD on August 3-5, 2006. Appellant was represented at the B Sample inspection and analysis by two attorneys and an expert. That expert, Dr. Douwe de Boer, in a written statement to LNDD summarizing his observations, stated: "The impression of the expert regarding the analytical performance of the B-sample analysis was that the LNDD worked in a transparent and professional way and according to transparent and professional procedures." Ex. 25 at USADA0368.⁴

The reliability of the use of IRMS by laboratories accredited by the World Anti-Doping Agency ("WADA") to detect the use of exogenous testosterone has been upheld in numerous cases. Further, LNDD's method for IRMS analysis was specifically approved as part of its accreditation by the International Organization for Standardization ("ISO"), which took place six months before Appellant's Stage 17 Sample was analyzed.

Here, LNDD's IRMS confirmation of the presence of exogenous testosterone metabolites in Appellant's Stage 17 Sample was also corroborated by two different investigations that were conducted during the course of the AAA proceedings. First, at Appellant's insistence, the electronic data files ("EDFs") of Appellant's Stage 17 Sample were reanalyzed on a second

⁴ Dr. de Boer's only caveat with respect to the IRMS analysis was that it had not been possible for him to see LNDD's documentation regarding IRMS uncertainty and the historical data regarding Blank Urine pool number 4. LNDD's uncertainty documentation was produced during the course of the AAA proceedings. LNDD's documentation regarding Blank Urine pool number 4 was also produced and confirms that the analytical results for the Blank Urines analyzed as a control during the analysis of Appellant's Stage 17 Sample were the same as the expected results based on the historical analysis of Blank Urine pool number 4.

instrument using different software, pursuant to the instructions of Appellant's expert, Dr. Davis. The result of this reanalysis was that Appellant's Stage 17 Sample continued to be positive regardless of which instrument was used or the way the data were analyzed. Second, at USADA's request and over Appellant's objections, the AAA Panel authorized the B specimens of Appellant's other seven Tour samples to be analyzed using IRMS. Evidence of exogenous testosterone use, satisfying the WADA criteria for positivity, was present in four of those seven samples.⁵ A more detailed chronology of events can be found beginning at page 4 of USADA's Proposed Findings of Fact and Conclusions of Law.

B. Summary of Prior Proceedings

The history of the case before the AAA is discussed at length in the AAA Panel Decision. Therefore, we will not repeat a recitation of facts in the body of this Brief. However, USADA would like to draw this Panel's attention to several aspects of the prior proceeding that may be particularly germane as this case goes forward on appeal.

⁵ USADA argued in the AAA Hearing that Appellant's Stage 17 positive test established by IRMS analysis was also corroborated by the 11:1 T/E ratio found in that sample. Although the Paris laboratory performs a T/E ratio analysis in both the screening and confirmation phases of sample analysis, it relies on the IRMS method, not T/E ratio, to confirm the presence of exogenous testosterone. The AAA Panel correctly concluded that LNDD's T/E ratio analysis did not satisfy all the technical requirements of the International Standard for Laboratories ("ISL") for a stand-alone confirmation of the use of exogenous testosterone. This apparently led the Panel to decide that it would not look to T/E ratio as corroborating evidence either. While USADA believes, and as was supported by testimony during the AAA Hearing, that the T/E ratio evidence is sufficiently reliable to be used as corroborating evidence, to further simplify the issues in this appeal, USADA respectfully submits that the Panel does not need to rely on the T/E ratio as further corroboration of the doping violation established by the IRMS evidence. Additionally, there are a number of other corroborative issues including, but not limited to, admissions and blood results, that while not the focus of this Brief may become relevant depending on the content of Appellant's witness statement and the defenses he asserts during the hearing.

After voluminous briefing and nine days of hearings the AAA Panel correctly concluded that LNDD's Adverse Analytical Finding based on IRMS analysis was scientifically sound. In its 84-page decision, the AAA Panel carefully explained why each of Appellant's attacks on LNDD's IRMS finding was unpersuasive. Appellant is reasserting those same attacks in this appeal. Among his limited new arguments is the claim that the AAA Panel was wrong in concluding that LNDD used the same columns in its GC/MS and GC/C/IRMS instruments and therefore the Panel was incorrect in concluding that the relevant peaks in the GC/C/IRMS chromatogram could be properly identified. As will be explained in Section VII.B of this Brief, the AAA Panel was in fact correct in concluding that the same column had been used in both instruments and that, contrary to Appellant's claims, the relevant peaks in the GC/C/IRMS chromatogram can be correctly identified.

One distinctive characteristic of this case is that LNDD has produced documents requested by Appellant that go far beyond what is required in the ISL. The WADA Technical Document TD2003LDOC (Ex. 11), provides a specific list of the only documentation that a laboratory is required to produce in support of an Adverse Analytical Finding that has been challenged by an athlete. All information required in TD2003LDOC is found in LNDD's A Sample documentation package (223 pages) and B Sample documentation package (147 pages). However, in this case, in response to Appellant's requests and directions from the AAA Panel, LNDD produced more than 1800 pages of additional documentation describing its analytical methods and the use of these methods. The panel and the parties went through an extended process of narrowing and refining the additional information which Appellant was seeking. Finally, in response to a direct request from the AAA Panel, Appellant acknowledged that, but

for four specific issues, he had received all of the documents which he had requested and which LNDD had been directed to produce. See Ex. 136 (Apr. 5, 2007, Corr.).

Unfortunately, in the AAA Hearing, Appellant attempted to use the fruits of this unprecedented and voluminous discovery to create confusion and to obfuscate the clear evidence of Appellant's doping violation. Hearings in doping cases should be a search for the truth. In the AAA Hearing, Appellant employed a different strategy. Instead of properly raising all of his criticisms of LNDD's analysis in his 182 pages of pre-hearing briefs, Appellant held back many of what turned out to be his central arguments in order to surprise USADA and its witnesses at the AAA Hearing. This was a conscious defense strategy.⁶ Predictably, a number of the questions which Appellant raised during the AAA Hearing could have been answered more fully had the particular issue been raised in a timely fashion.

As a first example, Appellant's IRMS Retention Time and Relative Retention Time arguments, which made up a significant part of the testimony of Appellant's witness, Dr. Meier-Augenstein, and which are featured prominently in this appeal, were not raised prior to the examination of witnesses during the AAA Hearing.⁷ This omission is unexplainable other than

⁶ Appellant's counsel made this clear during the course of the discovery hearing before the AAA Panel when he stated:

And by the way, one of the things that we did, both for time and effort – frankly, because we didn't want to lay out the entirety of our case out. We didn't put down every issue that we know exists in our brief. You will see many more when it comes to trial.

Ex. 101, Discovery Hearing Tr. at 184:3-8.

⁷ In his Pre-Trial Brief, Appellant did argue that the retention times in the T/E portion of the case were not in compliance with the WADA Technical Document. He did not raise this issue with respect to the IRMS analysis.

as a surprise tactic because those arguments are based on LNDD's documentation package which was produced to Appellant eight and a half months before the AAA Hearing.

As a second example, Appellant claims in his Brief that either USADA or LNDD forged a document to support the laboratory result. Appellant argues that "notably, USADA *did not even contest the evidence that this document was a forgery.*" Appellant's Br. at 75 (citing AAA Dissent at ¶ 30, emphasis in original). The document in question is a reference solution log for methyltestosterone (a substance used in the T/E analysis but not IRMS) which was produced to Appellant in March 2007. This supposedly fraudulent document was never mentioned in any of Appellant's pre-hearing submissions. Appellant chose not to raise this document during the AAA Hearing with any witness, let alone the six employees of LNDD, whom Appellant insisted be present for the AAA Hearing. Instead, Appellant chose to raise this document for the very first time in closing argument, while dramatically accusing USADA and LNDD of forging evidence. The obvious reason USADA did not respond to Appellant's accusation is because the issue was intentionally not raised by Appellant until after USADA had no chance to respond.

Significantly, this document was not "forged," but is instead a recopied version of the original reference solution log. The original is in the possession of LNDD and contains five non-substantive clerical errors. A copy is produced herewith as Ex. 137, LNDD 2006. The document was recopied in 2007 by Agnes Gaillard, which explains why the document is all in the same handwriting (and why the wrong year is visible in the forensic corrections).⁸ If LNDD was truly interested in forging evidence, it likely would not have produced a document that maintains forensic corrections; rather, one would imagine the staff member would simply start

⁸ Ms. Gaillard also filled in two pieces of information that she noticed were missing on the original form, using records that the laboratory keeps elsewhere. See Ex. 138, LNDD 2007 and 2008, which the laboratory printed for inclusion with this Brief.

over and recopy the document to fix the recopying error. In truth, this recopied document is a very trivial matter that has no impact on the question of whether Appellant committed a doping violation. Appellant's counsel did not raise this document during the evidentiary portion of the hearing because they knew it had no evidentiary value.

Based on this prior tactic by Appellant's counsel of valuing surprise over substance, USADA respectfully submits that it is important that the Panel hold both parties accountable for compliance with CAS Rule R56, which requires that the parties "shall not be authorized to supplement their argumentation nor to produce new exhibits, nor to specify further evidence on which they intend to rely after the submission of the grounds for appeal and of the answer," absent exceptional circumstances or agreement of the Panel or parties. See Ex. 139, CAS Rules.

Appellant also claims to have objected to the appointment of Dr. Francesco Botrè as the AAA Panel's expert. Appellant's original objection suggested that Dr. Botrè would be restricted in his ability to offer advice to the Panel by the WADA Code of Ethics. Ex. 70.⁹ See Appellant's Br. at 79. Dr. Botrè is the Director of the WADA-accredited laboratory in Rome. Appellant seriously mischaracterizes the facts. As the AAA Panel pointed out in its decision,

⁹ Appellant made the same argument to the AAA Panel, which he now puts forth in his Appeal Brief before agreeing to Dr. Botrè as the Panel's expert. See Suh letter of 4/13/07, Ex. 70. This argument has been waived. Further, Appellant's argument is totally without substantive merit. Appellant's claim that the WADA Code of Ethics somehow constrained Dr. Botrè to only give one-sided advice to the Panel is based on Sections 3.3 and 3.4 of the Code of Ethics found within Section 3 of that Code, entitled "Testing." These sections provide that in the context of performing forensic testing, a lab director should not provide expert testimony that would call into question the work performed in the anti-doping program. Section 4 of the Code of Ethics provides that when lab directors do testify, they are required to testify truthfully. Dr. Botrè was providing advice to the Panel as its expert. He did not do any sample testing, nor did he provide expert testimony. Like other WADA lab directors who have assisted CAS panels as panel experts in the past, Dr. Botrè was serving in an advisory capacity. It is insulting to both Dr. Botrè and to the AAA Panel for Appellant to suggest that Dr. Botrè did anything other than perform his services honestly and fairly.

Appellant initially objected to any WADA-accredited laboratory director serving as the Panel's expert. However, after the Panel on its own initiative identified Dr. Botrè as a potential expert and after a lengthy telephone conference among the Panel, counsel for the parties, and Dr. Botrè, during which both parties had the opportunity to question Dr. Botrè, Appellant withdrew his objection to Dr. Botrè as the panel-appointed expert, as evidenced by the email excerpt below.

From: Suh, Maurice [MSuh@gibsondunn.com]
Sent: Thursday, April 19, 2007 10:21 AM
To: Patrice M. Brunet; Carmen Frobos (E-mail); Chris Campbell (E-mail); Howard Jacobs (E-mail); Ho, James C.; Janette Henry (E-mail); Matthew Barnett; Richard McLaren (E-mail); Richard R. Young; Richard Young's assistant (E-mail); Rosalie Brunel (E-mail); Travis Tygart (E-mail); Davis, Trish
Subject: RE: Teleconference call with Dr Botrè

Dear Messrs. Brunet, Campbell and McLaren:

Thank you for the opportunity to speak with Dr. Botre. We have no objection to Dr. Botre serving as the Panel's expert.

Ex.143, Apr. 19, 2007 Corr.; see also AAA Panel Decision at ¶ 63.

III. APPLICABLE LAW AND BURDEN OF PROOF

The parties are in agreement that the UCI Rules are the controlling rules in this proceeding.¹⁰ The UCI Rules recite that UCI has accepted the World Anti-Doping Code (“World Code”) and that the World Code is incorporated into UCI’s Anti-Doping Rules. Ex. 1, Intro. at 1.

The UCI Rules specifically provide that the International Standards adopted by the World Anti-Doping Agency (“WADA”) are equally controlling under the UCI Rules: It is important to note that under the UCI Rules the athlete has the burden to prove that there has been a violation of the ISL:

¹⁰ See ¶ 1 of USADA’s Pre-Hearing Brief and fn. 1 of Appellant’s Rebuttal Brief in re: Retesting of Urine Specimens That Have Previously Tested Negative for Prohibited Substances.

Compliance with the International Standards (as opposed to other alternative standards, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standards were performed properly.

Ex. 1 at 48 (Definition of International Standard); AAA Panel Decision at ¶ 9.

The AAA Panel correctly applied the proper burden of proof in the AAA Panel Decision:

The effect of the UCI Regulations in Article 16 is to make it unnecessary for USADA to prove intent, fault, negligence, or knowing use on the part of the Athlete in order to establish an anti-doping rule violation. The principle of strict liability is well established in doping cases. . . . Therefore, the initial burden is met by USADA in this matter, by filing the LNDD's Lab reports with the Panel, as evidence in this proceeding. . . . Article 18 of the UCI Regulations provides that WADA-accredited laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratory analysis {ISL}.

AAA Panel Decision at ¶ 150 (citations omitted). As noted by the AAA Panel in its decision:

Article 18 goes on to provide that the Rider may only successfully rebut the presumption favouring the Lab by showing a deviation or departure from an IS [International Standard]. This is the only relevant evidence to determine if the Athlete's attempt to rebut the presumption of Article 18 may be successful. Proving some other procedure, practice or alternative standard is of no consequence in rebutting the presumption favouring the Lab.

AAA Panel Decision at ¶ 151.

IV. ISSUES ON APPEAL

A. Questions Before the Panel

While there is no restriction on this Panel's ability to hear evidence, the standard approach is for the appeal hearing to focus on a narrower set of refined issues. Here, Appellant has done little to narrow the issues from the AAA Hearing. Accordingly, in order to maintain a proper focus on the central questions before this Panel, USADA respectfully submits that for each issue, the application of an analytical filter should be employed.

Specifically, for each issue raised by Appellant, it is his burden to show that:

1. The issue relates to his Stage 17 sample;

2. The issue relates to IRMS analysis; and
3. There has been a violation of the ISL.

As Appellant has elected in both the AAA Hearing and this Hearing to raise an extensive number of issues – many of which are entirely unrelated to his Stage 17 Sample – the filter described above is critical because it allows the parties and the Panel to stay focused on the issues that are actually determinative of this case. Under the controlling law, only violations of the ISL with regard to Appellant's Stage 17 Sample are relevant to his attempts to overturn his Adverse Analytical Finding. Therefore, arguments that do not survive application of this filter may be entirely disregarded by the Panel.

B. The Role Of The ISL And ISO

Appellant's response to the UCI Rule holding that compliance with the ISL is sufficient to establish that the testing was carried out properly is to try and characterize as many of his arguments as possible as violations of the ISL. Often, the result of this effort is that Appellant is forced to base his argument on a distorted and factually unsupported interpretation of the ISL language. Further, Appellant's credibility with respect to interpretation of the ISL is compromised by the fact that none of his experts have had any prior experience with the ISL standards. Appellant's experts have never operated a laboratory subject to the requirements of the ISL; they have never been called upon to interpret the ISL; nor did any of them have any role in drafting the ISL. This contrasts markedly with the testimony of Dr. Ayotte and Dr. Schanzer, the Directors of the Montreal and Cologne WADA-accredited laboratories, who work with and operate under the ISL on a daily basis. Dr. Ayotte was personally involved in drafting several of the ISL provisions most pertinent to this case. The unfamiliarity of Appellant's experts with the ISL was also apparent when compared with the AAA Panel's independent expert, Dr. Francesco Botrè, who advised the AAA Panel throughout the proceeding below.

Finally, as this Panel assesses Appellant's attempts to prove an ISL violation occurred during the analysis of his Stage 17 Sample, it is important that the role of another group of experts be afforded the appropriate weight.

That group of experts is the accreditation team from Comité Français d'Accreditation ("COFRAC"), the ISO accreditation body in France. Unlike Appellant's experts, who have been retained by Appellant specifically within the context of this litigation to try and find ISL violations, the COFRAC inspectors are objective professionals who exhaustively inspect LNDD's methods and procedures in order to determine if LNDD is complying with all relevant standards including the ISL.

COFRAC's assessment of LNDD's capabilities is the most objective and meaningful measurement of LNDD's compliance with the provisions of the ISL. For example, in evaluating Appellant's attacks on LNDD's IRMS method, it is important for the Panel to remember that LNDD's IRMS method was specifically accredited by COFRAC during an ISO accreditation of LNDD approximately six months prior to the testing of Appellant's A Sample. The COFRAC inspection report stated in part that the IRMS method was very well "under control with maximum analytical precautions taken by the section staff," and that LNDD unquestionably had the capacity to implement the methods subject to review, including the IRMS method. Ex. 26 at LNDD0397.

As its core, Appellant's Brief seeks to second-guess the exhaustive undertaking performed by ISO in accrediting LNDD. The AAA Panel squarely rejected Appellant's request that it should step into the shoes of the ISO accreditation team. USADA respectfully submits that this Panel should similarly refuse Appellant's invitation to turn this proceeding into an exercise in accreditation through litigation.

V. USE AND DETECTION OF EXOGENOUS TESTOSTERONE

In the AAA Hearing, Appellant and his experts argued that it would be illogical for a cyclist to dope using testosterone. This argument has no basis in fact, and is exposed as false by both the long history of athletes doping with testosterone and the more immediate history of the use of testosterone by cyclists. For example, Appellant's argument is directly contradicted by the fact that two elite level cyclists and Tour de France riders, Patrik Sinkewitz and Cristian Moreni, each were disciplined for using testosterone leading up to and during the 2007 Tour. In contrast to Appellant, they each admitted what they had done. See Exs. 149 and 151.

A. Doping With Testosterone

Athletes can dope with testosterone or its precursors (e.g., androstenediol, androstenedione, DHEA and testosterone esters), which are metabolized in the body into testosterone. All of these substances are prohibited and are found on the WADA Prohibited List (Ex. 5) which is incorporated into the UCI Rules. Ex. 1 at Art. 21.¹¹

Until the late 1990s, the method used by WADA-accredited laboratories (previously International Olympic Committee ("IOC")-accredited laboratories) to detect testosterone abuse was the ratio of testosterone (T) over epitestosterone (E). Individuals naturally excrete testosterone and epitestosterone in approximately the same quantities. Thus, a typical T/E ratio is approximately 1:1. However, a few individuals have been found to have a naturally elevated T/E ratio. To identify those individuals whose T/E ratio is naturally elevated, anti-doping organizations compare the results of the sample having an elevated T/E ratio against prior or subsequent samples from the same athlete to determine whether the athlete is consistently

¹¹ For ease of reference this Brief will simply refer to "testosterone administration" as inclusive of the administration of testosterone and its precursors.

elevated (meaning the athlete has a naturally elevated T/E ratio) or whether the subject sample is a spike in T/E ratio (meaning the athlete doped). The T/E ratio considered to be doping or to trigger further investigation has varied. The current ratio triggering the reporting of an Adverse Analytical Finding and requiring further investigation is 4:1. See Ex. 9 at § 2.

B. Use of IRMS to Detect Testosterone

Starting in the late 1990s, several of the IOC-accredited laboratories began applying the IRMS method to identify the use of exogenous testosterone by determining the origin of testosterone metabolites. This is because, from an anti-doping perspective, there are several limitations to the T/E ratio approach as the exclusive method for detecting doping. First, some athletes' T/E ratios are not very responsive to exogenous testosterone abuse. Thus, they can dope without the ratio ever exceeding 4:1.¹² Second, the T/E ratio approach is not particularly effective in detecting doping with low doses of testosterone. Third, an athlete can attempt to mask doping with testosterone by also doping with an appropriate quantity of epitestosterone so that the ratio does not exceed 4:1.

WADA Technical Document TD2004EAAS instructs WADA-accredited laboratories to use the 4:1 T/E ratio as a method to routinely screen for suspicious samples. The use of exogenous testosterone may then be confirmed using IRMS. However, conducting a screen or having a positive screen is not a necessary precursor to IRMS analysis.

¹² For example, in USADA v. Hartman, the athlete's sample screened negative using T/E ratio analysis and was reported by the UCLA laboratory as a negative sample. Several weeks later the laboratory went back and conducted IRMS analysis on the sample and detected exogenous testosterone which the athlete subsequently admitted that he had taken. See Ex. 13 at ¶¶ 1, 4.1 and 4.2. See also the Cologne studies (Exs. 34 and 152), where a number of the research subjects who were administered testosterone did not produce samples with T/E ratios greater than 4:1.

IRMS analysis is now a well established method in the anti-doping field. The detection of exogenous testosterone administration using the IRMS method was deemed conclusive proof of doping as early as the 1999 Olympic Movement Anti-Doping Code (“OMADC”). “Evidence obtained from metabolic profiles and/or isotopic ratio measurements may be used to draw definitive conclusions regarding the use of anabolic androgenic steroids.” See Ex. 7 at Art. 4(2). The WADA 2006 Prohibited List, which is made applicable to this case through the UCI Rules, is equally clear that IRMS findings are definitive proof of doping:

In all cases, and at any concentration, the *Athlete’s* sample will be deemed to contain a *Prohibited Substance* and the laboratory will report an *Adverse Analytical Finding* if, based on any reliable analytical method (e.g. IRMS), the laboratory can show that the *Prohibited Substance* is of exogenous origin. In such case, no further investigation is necessary.

If a laboratory reports, using an additional reliable analytical method (e.g. IRMS), that the *Prohibited Substance* is of exogenous origin, no further investigation is necessary and the *Sample* will be deemed to contain such *Prohibited Substance*.

Ex. 5 at 3-4.

C. The Science of IRMS

The cells of all living things are composed of molecules containing carbon. Some of the carbon atoms in a molecule have six protons and six neutrons in the nucleus (^{12}C), while other carbon atoms may have six protons and seven neutrons in the nucleus (^{13}C). As a general statement, there are about ninety-nine ^{12}C atoms for every ^{13}C atom. The ratio of the ^{12}C to ^{13}C atoms in any organic material can be measured by IRMS.¹³ That ratio is compared to the ratio of an accepted international standard (Pee Dee belemnite, a limestone found in South Carolina, known as “PDB”) and expressed as delta value per mil (“delta value”). The accepted delta value

¹³ Before its application to doping control, IRMS had long been used to detect fraudulent substitution of synthetic products in place of natural compounds in the food, flavor and fragrance industries. For example, see Ex. 40 at USADA1234 (Journal of Food and Chemistry article about maple syrup adulteration).

of PDB is zero. Because corn has relatively fewer ^{13}C carbon atoms than PDB, the delta value for corn may be -23. Because soybeans contain even fewer ^{13}C atoms than corn, the delta value for soybean may be -29.

The delta value of the steroids found in the urine of any individual reflects the different delta values of the content of plants eaten by that individual and the plants which were eaten by the animals whose meat was eaten by the individual. The delta value of steroids found in the urine of an individual who eats corn and corn-fed beef would be different than the delta value of the steroids found in the urine of an individual who eats primarily rice and fish. While differences between individuals based on diet is to be expected, there should be no significant difference in the delta values of the different steroids within a single individual's body because all of the steroids made by that person's body should have come from the same organic sources.

Synthetic testosterone is made primarily from soy products or yams. Both have low delta values and consequently the delta values of synthetic testosterone and its precursors range from -27 to -32, which is much lower than the delta value that would be expected from any normal diet. In IRMS analysis the laboratory compares the delta values of metabolites of testosterone found in an athlete's urine (which would come from both naturally produced testosterone and synthetic testosterone if the athlete doped with testosterone) with the delta values of endogenous reference compounds from a different metabolic pathway which would not be altered by the administration of exogenous testosterone. The laboratory calculates the difference between the delta values of the target metabolites and endogenous reference compounds, obtaining what is called a "delta-delta" value. Simply put, the administration of exogenous testosterone will affect the delta values of one or more downstream metabolites of testosterone, but will not affect the delta value of an endogenous reference compound from other steroid metabolic pathways. Thus a

significant difference between the delta value of the endogenous reference compound and a testosterone metabolite establishes exogenous testosterone administration.¹⁴ This is illustrated in Figure 1 and Figure 2 below.

Figure 1.
Simplified Illustration of IRMS Test for
Testosterone
(No Doping with Exogenous Testosterone)

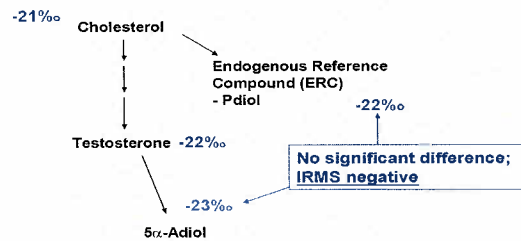
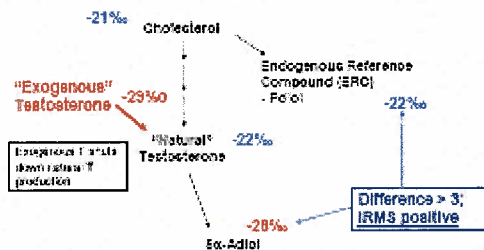


Figure 2.
Simplified Illustration of IRMS Test for
Testosterone
(Doping with Exogenous Testosterone)



¹⁴ WADA Technical Document TD2004EAAS defines a significant difference as three delta units or more. Ex. 9 at 3.

D. WADA Positivity Criteria

In August 2004, WADA issued Technical Document 2004EAAS (Ex. 9), which established a positivity criteria for the IRMS method. The positivity criteria established in TD2004EAAS is as follows:

The results will be reported as consistent with the administration of a steroid when the $^{13}\text{C}/^{12}\text{C}$ value measured for the metabolite(s) differs significantly i.e. by 3 delta units or more from that of the urinary reference steroid chosen. In some Samples, the measure of the $^{13}\text{C}/^{12}\text{C}$ value of the urinary reference steroid(s) may not be possible due to their low concentration. The results of such analyses will be reported as 'inconclusive' unless the ratio measured for the metabolite(s) is below -28‰ based on non-derivatised steroid.

Ex. 9 at 3.

As is apparent from the language of TD2004EAAS and as confirmed in the testimony of Dr. Ayotte, who was the member of the WADA Laboratory Committee most responsible for TD2004EAAS, a sample should be reported as an Adverse Analytical Finding for the administration of exogenous testosterone when the $^{13}\text{C}/^{12}\text{C}$ value for a single metabolite differs by 3 delta units or more from the applicable endogenous reference steroid. See Ayotte Testimony, Tr. at 816:1-818:25. Appellant presented no evidence at the AAA Hearing that casts doubt on this interpretation of TD2004EAAS.

Importantly, once WADA establishes positivity criteria in a technical document, the criteria become the relevant standard for determining whether any analytical result is an Adverse Analytical Finding. See, e.g., Ex. 105, Canadian Anti-Doping Program and Christopher Sheppard at ¶ 53. The World Code, accepted by UCI and the rest of the Olympic Movement, gives WADA the power to establish positivity criteria and other technical standards for the laboratories through the adoption of the ISL and Technical Documents.

International Standards for different technical and operational areas within the anti-doping program will be developed in consultation with the *Signatories* and governments and approved

by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of the anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*.

Ex. 4, World Code Intro. at 2 (emphasis in the original).

Once promulgated, Technical Documents become part of the *International Standard* for Laboratories.

Ex. 8, International Standard for Laboratories Art. 1.0 at 5.

Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly.

Ex. 4, World Code Definition of International Standard at 74; Ex. 1, UCI Rules at 48.¹⁵

Accordingly, it is well-settled that LNDD was required to apply the positivity criteria established by WADA and that in validating its method as fit for purpose, it was not required to independently validate the WADA criteria. Contrary to Appellant's attempt to mischaracterize Dr. Ayotte's testimony on this point (Appellant's Br. at 77), she clearly testified that LNDD was entitled to rely on the WADA positivity criteria without conducting its own validation of the WADA criteria. See Ayotte Testimony, Tr. at 818:20-819:8.

¹⁵ Appellant claims in his appeal that USADA's briefs were misleading in stating that Appellant's sample would have been reported as an Adverse Analytical Finding by the UCLA laboratory. USADA's statements were accurate. As Dr. Catlin, the director of the UCLA laboratory until September 2006, testified regarding Appellant's sample: "I would have reported it as positive, and I would write a side letter to the client, or certainly that client would be USADA, and I would explain that the sample is positive according to WADA criteria. But, I would also point out that we had written some time ago, a long time ago, a letter to clients. And if you read that letter, you would find the criteria in there are not met and by those criteria would be negatives so I would be giving USADA fair warning that there could be an issue they have to deal with." Catlin Testimony, Tr. at 1194:14-25.

E. CAS Panels Have Repeatedly Found Doping Based on IRMS

Between 2000 and present, at least ten CAS Panels and National Tribunals have found that IRMS analysis is a reliable and definitive method to detect doping with testosterone. For example:

In Susin v. FINA, the CAS Panel held that even though the T/E ratio in the athlete's B specimen was not reliable because it may have been affected by bacterial degradation, IRMS analysis provided definitive proof of doping:

Based upon the above analysis, the Panel has concluded that:
(a) the IRMS analysis provides conclusive scientific evidence of an exogenous administration of testosterone and; (b) the Panel is entitled to rely upon the IRMS analysis as an independent and sufficient basis for finding that the Appellant committed a doping offence under FINA Rule DC 2.1(a).

Ex. 14, Susin v. FINA at ¶ 220).

IAAF v. Dos Santos involved a Brazilian runner whose sample had an IRMS delta-delta difference between an endogenous reference compound and a testosterone metabolite of approximately -6, which is similar to Appellant's delta-delta value for the 5alpha metabolite.

Ex. 15 at ¶¶ 11, 162. The CAS Panel concluded:

The IRMS analysis provides additional direct and conclusive scientific evidence of an exogenous administration of the prohibited substance testosterone by the Athlete.

Ex. 15, IAAF v. Dos Santos, CAS Panel at ¶ 88; see also Ex. 17, IAAF v. Czech Athletic Federation and Z at ¶¶ 27-30; Ex. 21, UCI v. S, DCU and DIF at ¶ 29; Ex. 18, UCI v. Moller at ¶¶ 11, 13; Ex. 19, UCI v. Bakker and KNWU at ¶¶ 10.2.6-10.2.14; Ex. 20, UCI v. Skelde at 21.

Like the AAA Panel in the case appealed here, several CAS Panels have upheld positive test findings based on IRMS results where there were problems with the corresponding T/E

analysis. See AAA Panel Decision at ¶ 147; and Ex. 16, WADA v. Wium at ¶¶ 6.10-6.14; Ex 14, Susin v. FINA at ¶ 220.

Importantly, there has never been a CAS case where the panel has not upheld the scientific reliability of the IRMS method to detect exogenous testosterone. Even in UCI v. Landaluce, Ex. 22, where the doping determination was overturned because the same laboratory personnel had participated in analyzing the A and B Samples in violation of the ISL, the Panel clearly rejected the various challenges raised to LNDD's IRMS method. See Ex. 22, UCI v. Landaluce at ¶¶ 71, 79, 83, 87.

VI. APPELLANT'S SAMPLE CONTAINED EXOGENOUS TESTOSTERONE

Despite the nearly unlimited discovery that was conducted by the Appellant in this case and the exhaustive nine day hearing conducted before the AAA Panel, this is not an unusually complicated scientific case. Instead, like the other cases discussed above, this anti-doping rule violation rests on a positive IRMS test. Specifically, the IRMS analysis conducted on Appellant's sample establishes that there was exogenous testosterone in his system during Stage 17 of the Tour. As is set forth below, the IRMS analysis methods used by LNDD were scientifically sound, as were the results of that analysis. Like a number of athletes before him, Appellant thought that he could dope with exogenous testosterone without getting caught and like a number of athletes before him, his doping was detected by IRMS. This is the very reason that IRMS analysis is an important tool in the fight against doping.

Despite Appellant's attempts to escape the consequences of his doping, an analysis of the IRMS evidence in this case only confirms the value of the IRMS method in catching those who otherwise might get away with doping.

A. LNDD's IRMS Method

The IRMS method used by LNDD and other WADA-accredited anti-doping laboratories consists of three main steps: sample preparation, pre-IRMS compound identification, and IRMS analysis.

The first of the three steps in the LNDD IRMS test is sample preparation, which is a lengthy process. In this process, the compounds of interest (the testosterone metabolites and endogenous reference compounds)¹⁶ are extensively purified and isolated from other substances which might interfere with the analysis. To improve the chromatographic behavior, LNDD converts the purified analytes into acetate derivatives. In order to further improve the purity of each selected analyte, the mixture is again separated into three fractions (F1, F2 and F3).

- F1 contains 11-keto etio
- F2 contains andro and etio
- F3 contains 5alpha, 5beta, and pdiol

A Blank Urine quality control is processed simultaneously with F1, F2 and F3. The Blank Urine is pooled from individuals who have not used steroids. The IRMS analytical results of the Blank Urine are monitored by the lab over time to verify assay performance and IRMS instrument accuracy. In other words, if on any one day the Blank Urine results are as expected, that is one element of proof that the assay is performing correctly on that day. Finally, an internal standard, 5-alpha-androstanol acetate ("5alpha AC"), is added to each fraction to establish a retention time anchor for compound identification.

¹⁶ The testosterone metabolites are: androsterone ("andro"); etiocholanolone ("etio"); 5-beta-androstane-3-alpha,17-beta-diol ("5beta"); and 5-alpha-androstane-3-alpha,17-beta-diol ("5alpha"). The endogenous reference compounds are 11-ketoetiocholanolone ("11-ketoetio") and 5-beta-pregnane-3-alpha, 20-alpha-diol ("pdioI,")

The second of the three steps in the LNDD IRMS test is pre-IRMS compound identification using Gas Chromatography/Mass Spectrometry (“GC/MS”). This step serves two main purposes: a) proving the identity of each analyte and b) demonstrating the purity of the peak corresponding to each analyte. GC separates the compounds present in a mixture and MS identifies them. The first element of compound identification is the GC retention time. Retention time is the time it takes for the compound to pass through the instrument to the detector. The second is the molecular fingerprint recorded by the MS, which fragments the molecule into ions. Compound identification in the GC/MS process is achieved by matching GC retention times and MS mass spectra between the compound in the sample and a reference standard. Compounds can also be identified by relative retention time, which is a comparison of the retention time of the compound and the retention time of one or more known standards.

The third of the three steps in the LNDD IRMS method is analysis of the sample on the GC/C/IRMS instrument. LNDD runs control samples in the same batch with the athlete’s sample to confirm that the instrument is operating properly. In this step, LNDD measures a delta value for each of the four testosterone metabolites and two endogenous reference compounds. LNDD then calculates the difference in delta values (delta-delta values) between each metabolite and its corresponding endogenous reference compound: etio and 11ketoetio; andro and 11ketoetio, 5beta and pdiol; and 5alpha and pdiol.

The positivity criteria set forth in LNDD’s standard operating procedure, (Ex. 24 at USADA0186), is actually more conservative, in favor of the athlete, than the WADA criteria. To account for uncertainty in its IRMS measurements, which LNDD determined in a study to be ± 0.8 delta units (Ex. 26 at LNDD0456), LNDD only reports a sample as an Adverse Analytical

Finding if the difference between a testosterone metabolite and its endogenous reference compound is -3.8 delta units or more.

B. IRMS Analysis of Appellant's Stage 17 Sample Establishes Doping

LNDD reported Appellant's Stage 17 Sample as an Adverse Analytical Finding because the presence of exogenous testosterone was found in both Appellant's A and B Samples using IRMS analysis. See Mongongu Testimony, Tr. at 448-52; Frelat Testimony, Tr. at 679-80.

This Panel can be confident that LNDD's IRMS method correctly detected the presence of an exogenous testosterone metabolite in Appellant's urine for several important reasons. First, LNDD's IRMS method was specifically accredited by ISO. Second, the various controls run by LNDD establish that its GC/C/IRMS instrument was operating properly when Appellant's samples were analyzed. Finally, LNDD complied with the ISL, which sets the standard for valid IRMS analysis. Moreover, this is not a close or borderline case. The difference between the delta value of the 5alpha testosterone metabolite in Appellant's urine and the corresponding endogenous reference compound (pdicol) was more than double the -3 delta unit difference that WADA has established as the criteria for reporting a sample positive for exogenous testosterone use.

C. IRMS Results

The IRMS results reported by LNDD for the A and B specimens of Appellant's Stage 17 Sample collected on July 20, 2006, are as follows:

Appellant's Testosterone Metabolites				
	5alpha	5beta	Andro	Etio
Appellant's A Sample	-27.72	-23.73	-25.05	-23.63
Appellant's B Sample	-27.43	-23.69	-25.29	-23.80

Appellant's Endogenous Reference Compounds		
	pdiol	11-ketoetio
Appellant's A Sample	-21.58	-21.06
Appellant's B Sample	-21.05	-21.78

The difference in delta value between Appellant's testosterone metabolites and the corresponding endogenous reference compound are as follows:

	5alpha diol-pdiol	5beta diol-pdiol	Andro-11keto	Etio-11Keto	LNDD Page#
Appellant's A Sample	-6.14	-2.15	-3.99	-2.58	USADA0186
Appellant's B Sample	-6.39	-2.65	-3.51	-2.02	USADA0352

LNDD reported Appellant's sample as an Adverse Analytical Finding because the difference between the 5alpha metabolite and the pdiol endogenous reference compound in Appellant's A Sample was -6.14 delta units and in his B Sample it was -6.39 delta units, more than twice the difference established in the WADA positivity criteria.

1. LNDD's Methods are Accredited by ISO

As Dr. Ayotte explained, when COFRAC specifically listed LNDD's IRMS method under LNDD's scope of accreditation, it meant that LNDD's IRMS method and paperwork had been carefully reviewed by the assessors and found to be compliant with the good quality management principles of ISO document 17025 and the requirements of the ISL. It also meant that laboratory personnel were qualified and had demonstrated control of their methods. Tr. at 815:5-816:15. (For example, in Ex. 26 at LNDD0401 at the top of the page, COFRAC makes specific reference to TD2004EAAS and makes a minor suggestion on reporting of IRMS results consistent with TD2004EAAS. See also Ex. 26 at LNDD0076, which makes clear that the

certification is based on examination against the WADA requirement documents, as well as ISO 17025.

When Appellant argues that LNDD's operating procedures violate the ISL, Appellant is necessarily arguing that ISO, in granting accreditation for those procedures, must have misinterpreted the ISL. ISO is an independent accreditation body whose only interest is in documenting compliance or noncompliance with the ISL and ISO 17025. The AAA Panel correctly found that LNDD's IRMS analysis procedures were ISL and ISO compliant.

2. Quality Controls Establish that the GC/C/IRMS Instrument was Working Properly.

Appellant's Brief speculates that the GC/C/IRMS instrument may not have been operating properly during the analysis of Appellant's A or B Samples. This claim is entirely put to rest by the instrument checks performed before the analysis of these samples and the precision and accuracy of the result of controls run contemporaneously with the samples. The verification of IRMS instrument performance that occurred prior to and during Appellant's sample analysis was not only excellent on the day of the A confirmation and on the day of the B confirmation, but it was also reproducible between those two days and was exceptionally consistent with prior measurements using the same standards and controls. This is demonstrated by the results obtained for the Mix Cal IRMS standard, the Mix Cal Acetate standard, and the Blank Urine standard during the analysis of Appellant's A and B Samples. The results for each of these controls is discussed separately below.

LNDD analyzed Appellant's sample and the corresponding controls in the following sequence:

IRMS injection sequence, USADA Ex. 24 at 0155	
Injection	Purpose of injection
1 stabilite 1	A reference gas (CO ₂ , carbon dioxide) is injected 3 times to check instrument stability.
2 stabilite 2	
3 stabilite 3	
4 Mix cal IRMS 003-1	3 injections are made from 1 vial containing a standard mixture of 4 alkanes, to check instrument precision.
5 Mix cal IRMS 003-2	
6 Mix cal IRMS 003-3	
7 Mix cal Acetate 001A-100 ng inj	The 1 st of 2 injections is made from 1 vial containing a mixture of 4 steroids standards, to establish instrument accuracy.
8 Blu 1 pool 4 F3/45ul inj 2ul	Injection of Blank Urine, fraction F3 containing 5alpha, 5beta, and pdiol, to check that the delta-delta values measured today agree with those measured the first time this Blank Urine pool was ever analyzed. An internal standard is also added to the sample to serve as a retention time anchor.
9 178/07 995474 F3/45ul inj 2ul	Injection of sample 995474, fraction F3 containing 5alpha, 5beta, and pdiol. An internal standard is also added to the sample to serve as a retention time anchor.
10 Blu 1 pool 4 F1/50ul inj 1ul	Injection of Blank Urine, fraction F1 containing 11-ketoetio, to check that the delta/delta values measured today agree with those measured the first time this Blank Urine pool was ever analyzed. An internal standard is also added to the sample to serve as a retention time anchor.
11 178/07 995474 F1/50ul inj 1ul	Injection of sample 995474, fraction F1 containing 11-ketoetio. An internal standard is also added to the sample to serve as a retention time anchor.
12 Blu 1 pool 4 F2/500ul inj 1ul	Injection of Blank Urine, fraction F2 containing andro and etio, to check that the delta-delta values measured today agree with those measured the first time this Blank Urine pool was ever analyzed. An internal standard is also added to the sample to serve as a retention time anchor.
13 178/07 995474 F2/400ul inj 1ul	Injection of sample 995474, fraction F2 containing andro and etio. An internal standard is also added to the sample to serve as a retention time anchor.
14 Mix Cal Acetate 001A-2	The 2 nd of 2 injections is made from 1 vial containing a mixture of 4 steroids standards, to establish instrument accuracy.

3. Stability Check

Before IRMS analysis of the sample, the analysts conducted verification of the acceptable range and tuned the GC/C/IRMS instrument performance. The analysts checked that the instrument pressure was within the acceptable range and that the instrument was focused on the target masses. The analysts then conducted stability checks by injecting carbon dioxide several times in a row to make sure that repeated measurements were reproducible within the specified tolerance. See Ex. 24 at USADA0174; Ex. 25 at USADA0353.

4. Mix Cal IRMS Control

The Mix Cal IRMS control contains four different alkane standards (decane, undecane, dodecane, methyldecanoate), compounds made of only carbon and hydrogen atoms, commonly used to verify analytical instrument performance. LNDD checks precision by injecting three times in a row from one vial of Mix Cal IRMS to ensure that the delta value triplicate results are reproducible within acceptable limits. For each of the four alkanes, LNDD calculates the mean delta value and standard deviation. The criterion for acceptability as set forth by LNDD is that the standard deviation must be less than or equal to ± 0.5 delta units for at least three of the four alkanes in the mix. USADA Ex. 24 at 0174. This criterion was met on the day of the A confirmation and on the day of the B confirmation. There is also good consistency between the A confirmation and the B confirmation data. See Figure 3.

Figure 3

MIX CAL IRMS Delta values (per mil)

A Sample IRMS confirmation					
Data filename	decane	undecane	dodecane	methyldecanoate	Delta values: USADA page
DATA_004	-32.52	-28.45	-31.96	-31.51	0178
DATA_005	-32.74	-28.28	-32.13	-31.76	0179
DATA_006	-32.56	-28.65	-31.95	-31.59	0180
B Sample IRMS confirmation					
Data filename	decane	undecane	dodecane	methyldecanoate	Delta values: USADA page
DATA_006	-32.30	-27.78	-31.79	-31.30	0357
DATA_007	-32.44	-27.99	-31.93	-31.44	0358
DATA_008	-32.33	-27.81	-31.80	-31.22	0359

5. Mix Cal Acetate Control

LNDD's Mix Cal Acetate control is a mixture of four steroids: 5alpha AC, Etio, 5beta and 11-Ketoetio. The delta value of each of the four steroids in LNDD's Mix Cal Acetate control mix was previously verified by an external reference laboratory, Eurofins. The exact values established by Eurofins are found at Ex 26 at LNDD 0298, 0301, 0304, 0307. LNDD uses the Mix Cal Acetate control to check instrument accuracy. LNDD's criterion for acceptability is that at least three of the four measurements from the control must agree with the Eurofins measurement ± 0.5 delta units. This criterion was met on the day of Appellant's A Sample analysis and on the day of Appellant's B Sample analysis. In addition, the A Sample results and B Sample results were consistent with each other.

Figure 4. Accuracy of Mixed Cal Acetate δ Values

	5 α -Androstanol	Etiocholanolone	5 β -Androstanediol	11-Ketoetiocholanolone
"True" Value from Eurofins	-30.46 ‰	-19.91 ‰	-33.81 ‰	-16.30 ‰
7/24 before Appellant's sample	-30.29 ‰	-20.01 ‰	-33.70 ‰	-16.69 ‰
7/24 after Appellant's sample	-30.56 ‰	-20.22 ‰	-33.90 ‰	-16.76 ‰
8/4 before Appellant's sample	-30.40 ‰	-19.98 ‰	-33.71 ‰	-16.74 ‰
8/4 after Appellant's sample	-30.25 ‰	-19.95 ‰	-33.63 ‰	-16.68 ‰

The Mix Cal Acetate results from the controls run before and after Appellant's A and B Samples were not only consistent with each other and the verified values established by Eurofins, they are also consistent with all other results from this Mix Cal Acetate control batch for over 75 samples analyzed between May 29, 2006 through October 6, 2006. Ex. 26 at LNDD 0448-0450.¹⁷

The four steroids in the Mix Cal Acetate standard have delta values spread over a large range from approximately -16 delta units to -33 delta units. This large spread proves that LNDD's measurements are accurate not only at -16 delta units but also at -33 delta units and for every value in between. All six delta values for the testosterone metabolites and endogenous reference compounds measured in Appellant's sample all fall within that -16 to -33 delta unit range. The most negative is 5alpha at -27.72 delta units, the least negative is pdiol at -21.05 delta units.

6. Blank Urine Control

LNDD checked overall assay quality by injecting a Blank Urine in the injection sequence from the same Blank Urine pool immediately before each of the three fractions of Appellant's urine was injected. Each fraction of Blank Urine was then analyzed for the same testosterone metabolites and endogenous reference compounds that were identified in Appellant's sample. The initial delta value difference for each of the four testosterone metabolite minus endogenous reference compound comparisons was calculated the first time the Blank Urine pool was analyzed. Ex. 26 at LNDD0309-0310. For each subsequent IRMS confirmation, aliquots of

¹⁷ The values at LNDD0448-0450 represent the Mix Cal Acetate measurements before (not after) each of the 75 samples was analyzed.

Blank Urine from this pool were tested side-by-side with an athlete's sample. LNDD checks assay performance and the accuracy of each day's results by making sure that, of the four delta-delta values for the Blank Urine, at least three agree with LNDD's "initial" values. The criterion for acceptability is that at least three of the four delta-delta values must fall within ± 0.8 delta-delta units of the "initial" difference in the delta-delta value measured by LNDD. This criterion was met on both the day of the IRMS A Sample confirmation and the day of the IRMS B Sample confirmation.

The delta-delta values for testosterone metabolites in the Blank Urines analyzed contemporaneously with Appellant's A and B Samples were not only consistent with each other and the "initial" values for that Blank Urine pool established by LNDD, they were also consistent with the results obtained each of the more than 40 times an aliquot from that Blank Urine pool was used between June and August 2006.

If the IRMS instrument had not functioned properly on the day of the A or B Sample confirmation, at least one of the following would have been observed:

- no signals detected
- impossible to record any data
- failed verification of instrument performance, such as:
 - failed tune
 - failed stability check (i.e., CO₂ data widespread beyond acceptable range)
 - failed precision check (i.e., Mix Cal IRMS outside acceptable range)
 - failed accuracy check (i.e., Mix Cal Acetate delta values outside acceptable range)

- unacceptable Blank Urine data (i.e., delta-delta values outside acceptable range)

None of these failures were observed, and the checks and controls run each day met acceptance criteria.

VII. APPELLANT'S ATTACK ON LNDD'S PEAK IDENTIFICATION IN IRMS DOES NOT ESTABLISH AN ISL VIOLATION

Appellant dedicated the largest section of his brief to trying to establish that LNDD's method for identifying compounds in IRMS violated the ISL. Specifically, Appellant's arguments focus on the column that was used in the IRMS analysis, the retention times generated by the GC/MS and GC/C/IRMS processes, and LNDD's ability to properly identify the analytes of interest in this case. As shown below, Appellant's arguments rest entirely on an erroneous interpretation of TD2003IDCR, and are otherwise unconvincing and insufficient to carry his burden to prove an ISL violation.

A. Appellant's Interpretation of WADA TD2003IDCR is Fatally Flawed

Although Appellant concedes that LNDD correctly identified the peaks for 5alpha, 5beta, andro, etio, pdiol and 11-ketoetio in the GC/MS chromatogram of his urine, he alleges that identification is of no assistance in identifying those same peaks in the chromatogram produced by the GC/C/IRMS instrument. Specifically, Appellant seeks to prove to this Panel that the WADA Technical Document, TD2003IDCR, should be applied to compare retention times between the GC/MS instrument and the IRMS instrument.

In order to successfully maintain this argument, Appellant must provide evidence that establishes the claim made in his brief that the "WADA technical document requires that retention times or relative retention times are consistent between the GC/MS and GC/C/IRMS

phases.” Appellant’s Br. at 30 (emphasis added). As detailed below, Appellant cannot meet this burden because his argument relies on a fundamentally flawed interpretation of the relevant Technical Document that is without any factual or scientific support in the facts and science relevant to this case.

Significantly, this argument is not new, but instead was offered by Appellant at the hearing below. It was considered and squarely rejected by the AAA Panel as “unsound and without any reasonable scientific basis.” AAA Panel Decision at ¶ 188. The AAA Panel found that Appellant’s “interpretation of TD2003IDCR is a complete misapplication of the document” and that the “conclusions of [Appellant] based upon the evidence given by both Dr. Meier-Augenstein and Dr. Davis are scientifically totally unacceptable and fundamentally flawed.” Id. at ¶ 189.

For “Chromatographic separation,” TD2003IDCR requires the following:

For capillary gas chromatography, the retention time (RT) of the analyte shall not differ by more than one (1) percent or ± 0.2 minutes (whichever is smaller) from that of the same substance in a spiked urine sample, Reference Collection sample, or Reference Material analyzed contemporaneously.

Ex. 12 (emphasis in original).

In order to assess Appellant’s argument regarding the language of this Technical Document, it is important to establish what is not in dispute. First, as found by the AAA Panel, there is no dispute that this document requires that when “analyzed contemporaneously,” on the same GC/MS instrument, the retention time of the reference material and the retention time of the same substance in the athlete’s sample should be within one (1) percent or ± 0.2 minutes of one another. Here, it is undisputed that the relevant retention times for the GC/MS instrument and the GC portion of the GC/C/IRMS analysis respectively met this standard. As the panel stated:

Furthermore, as Dr. Meier-Augenstein attested, the RTs measured for the GC/MS instrument and the GC/C/IRMS instrument separately are within the 1% criteria. There is no dispute on this point between the parties.

AAA Panel Decision at ¶ 187 (emphasis added).

Second, the Technical Document does not require that retention times between the GC/MS instrument and the GC/C/IRMS instrument should be within the criteria set forth above. As the panel noted: “Dr. Meier-Augenstein also conceded in his testimony that when you are dealing with two separate machines one would not compare retention times but did claim that one would use relative retention times.” AAA Panel Decision at ¶ 187.

1. TD2003IDCR Does Not Apply to Relative Retention Times Between GC/MS and GC/C/IRMS

Appellant seeks to prove to the Panel that the language Technical Documents requires that the relative retention times between GC/MS and GC/C/IRMS instruments must be within one percent or ± 0.2 minutes. This argument was dismissed by the AAA Panel and should be rejected again for the reasons set forth below.

In order to address this question it is important to first understand the difference between “retention time” and “relative retention time.” The AAA panel defined these terms as follows:

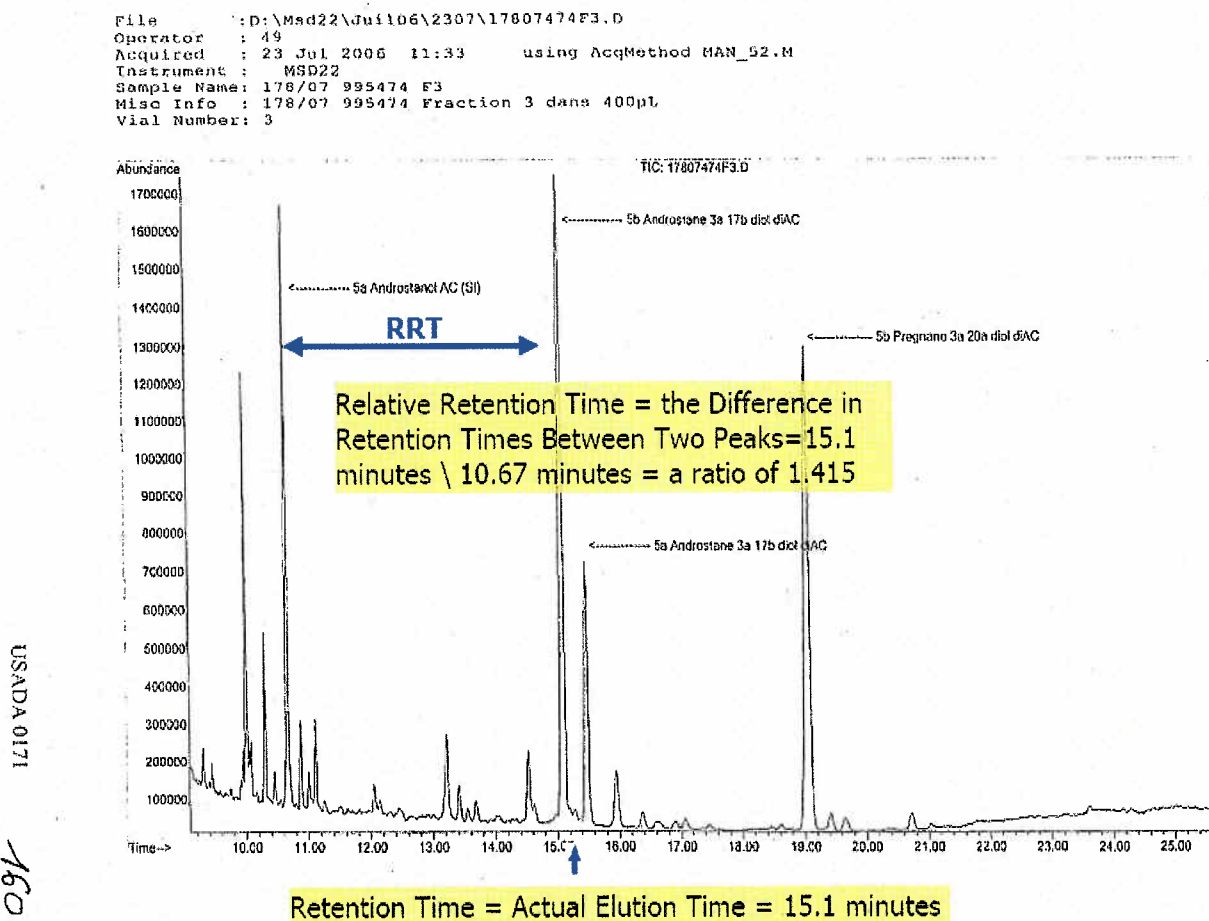
The retention time {“RT”} of a compound is the time that is measured by the instrument (whether GC/MC or GC/IRMS) for the compound to reach the detector. In this particular case, the GC/MS system measures the RT of the target analyte and the internal standard. The relative retention time {“RRT”} is the ratio of the RT of the target analyte to the RT of the internal standard. For example, if the RT of the target analyte is 10 min and the RT of the internal standard is 5 min, then the RRT will be 2.

AAA Panel Decision at ¶ 181.

Additionally, in the scientific literature regarding chromatography, “relative retention time” can also refer to the ratio of the retention times of any two peaks on a chromatogram. Below is a diagram depicting the difference between retention time and relative

retention time. As set forth in this diagram, retention time is a measurement of the time at which the substance elutes from the instrument and is detected by the instrument detector, while relative retention time expresses the temporal relationship of two peaks in the form of a ratio.

Figure 5



Accordingly, retention time and relative retention time measure two distinctly different concepts using different units of measurement and are not used interchangeably in the scientific literature.

In order to address Appellant's argument that the Technical Document requires that the relative retention times between GC/MS and GC/C/IRMS instruments must be within one percent or ± 0.2 minutes it is necessary to first apply the well-settled principles of document

interpretation, by reviewing the plain language of the document. Here, the first test is to review the document for any reference to “relative retention time.” Appellant’s argument cannot survive even this initial inquiry, because nowhere in the Technical Document is the term “relative retention time” used.

Undeterred by the complete lack of support for his argument in the language of the Technical Document, Appellant invites the Panel to retroactively amend the Technical Document in order to add two new requirements that would be beneficial to his argument.

First, Appellant seeks to import the concept of relative retention time into the Technical Document. The fallacy of attempting to import the concept of relative retention time into this standard is self-evident if one tries to apply the one percent \pm 0.2 minutes criteria in the Technical Document to relative retention time values. The criterion was meant to apply to a retention time, which is expressed in either seconds or minutes.¹⁸ However, because relative retention time is expressed as a ratio (e.g., 15 minutes to 10 minutes, equals 1.5) it is impossible to apply the 0.2 minutes standard to a ratio. For example if the relative retention time of a set of known compounds is 1.43, it is not possible for the relative retention time of a second set of the same compounds to be within \pm 0.2 minutes. Accordingly, because one component of the standard (0.2 minutes) does not apply to a measurement of relative retention times and the standard requires that the smaller of either 0.2 minutes or 1 percent must be applied, it is clear on the face of the Technical Document that the drafters did not intend for the document to apply to relative retention times.

¹⁸ For example if the retention time of a known standard is 870 seconds the retention time of the same substance in an athlete’s urine run contemporaneously on the same instrument must be within either 1 percent (8.7 seconds) or 0.2 minutes (12 seconds) of 870 seconds, whichever is smaller.

While no further inquiry is necessary, it is important to note that Appellant's argument would require that the Panel revise the Technical Document to improperly add a second requirement. The second new requirement that Appellant seeks to add to the Technical Document is the requirement that the relative retention time of analytes analyzed in the GC/MS instrument should be within 1% or ± 0.2 minutes of the relative retention time of the analyte analyzed in the GC/C/IRMS instrument, even where such analysis does not occur contemporaneously and takes place on two entirely different instruments. Again, this new requirement simply does not exist in the Technical Document. Accordingly, based on the plain and unambiguous language of the Technical Document, the Panel should reject Appellant's attempt to retroactively revise the relevant WADA standard.

2. Appellant's Incorrect Interpretation of the Technical Document is not Supported by the Evidence

Moreover, even if the Technical Document was ambiguous, which it is not, Appellant's argument still fails because his effort to import these additional criteria lacks any evidentiary support. In his brief, Appellant makes a number of unsupported claims that the testimony of USADA witnesses support his argument. Even a cursory review of the actual testimony of the witnesses establishes that Appellant is mischaracterizing the meaning of testimony in an effort to distort the meaning of the Technical Document. There is no dispute between the parties as to the utility of using both retention time and relative retention times to ensure accuracy and assist with compound identification within the same instrument. The testimony of USADA's witnesses that is cited by Appellant is consistent with the comparison of retention times for the same compound on the same instrument.

However, none of USADA's witnesses testified that the Technical Document requires relative retention times to match between a GC/MS instrument and a GC/C/IRMS instrument.

This fact is apparent even from the testimony excerpts reproduced by Appellant. See Appellant's Br. at 31-33.

Similarly flawed is Appellant's attempt to suggest that his argument is supported by USADA's Pre-Hearing Brief or the AAA Panel Decision. See Appellant's Br. 33-34.

First, Appellant attempts to mischaracterize USADA's Pre-Hearing Brief by suggesting that a section of the brief discussing relative reference time in the context of the "GC" portion of the GC/C/IRMS analysis, somehow stands for the proposition that relative retention times were used in the "IRMS" portion of the analysis. A simple review of the language of the brief reveals the mischaracterization. The key to following the actual intent of that section is in the first sentence of the paragraph quoted by Appellant: "The second of the three steps in the LNDD test is pre-IRMS compound identification by GC/MS, the gold standard for compound identification in analytical chemistry application." USADA Pre-Hearing Br. at ¶ 41.

The next paragraph quoted by Appellant that discusses the value of relative retention time, is undisputedly related to the "second step," which is the "pre-IRMS" analysis.

This point is made even more clear by the next paragraph of USADA's Pre-Hearing Brief, which Appellant failed to quote: "The third of the three steps in the LNDD IRMS test is IRMS analysis." USADA Pre-Hearing Br. at ¶ 43. Therefore, it is clear that USADA was not arguing that LNDD tries to compare relative retention times between GC/MS and GC/C/IRMS.

Similarly flawed is Appellant's argument that paragraph 179 of the AAA Panel's decision supports his interpretation of the Technical Document. Paragraph 179 states:

WADA TD2003IDCR provides that

For capillary gas chromatography, the retention time (RT) of the analyte shall not differ by more than one percent or ± 0.2 minutes (whichever is smaller) from that of the same substance in a spiked urine sample, Reference Collection sample, or Reference Material analyzed contemporaneously.

What the foregoing provision does is to ensure that the technician is calculating the isotopic values of the correct peak. The Technical Document requires that the retention time of the peaks from the GC/MS part of the CIR test process falls within specified time periods of each other: plus or minus .2 minutes or 1%, whichever is smaller. Without this requirement, there is no way to be certain that the peaks selected by the technician in the IRMS chromatographs are in fact the peaks that were previously identified as the target compounds (e.g. 5 Alpha, 5 Beta, Andro, Etiocholanolone (“Étio”), 11-ketoetio and Pdiol).

AAA Panel Decision at ¶ 179 (emphasis added).

Contrary to Appellant’s claim, this paragraph does not support his argument and is instead entirely consistent with USADA’s Pre-Hearing Brief.

Indeed, Paragraph 179 in the AAA Panel’s decision simply expresses the well-settled principle that the Technical Document applies to the “retention time of the peaks from the GC/MS part of the CIR test.” Stated another way, because the GC/MS phase is the phase where the compounds are first identified, it is crucial that the retention times of each compound of interest match a known standard that is analyzed contemporaneously in the same GC/MS instrument.

Accordingly, Appellant’s argument that the Technical Document applies to relative retention times between the GC/MS and GC/IRMS phases finds no support in Paragraph 179 of the AAA Panel’s decision.

In short, Appellant fails to establish a violation of the ISL related to retention times. Instead, Appellant’s effort to create a new ISL standard in order to manufacture a violation of that standard should be squarely rejected by this Panel, as it was by the AAA Panel. “It must be noted, that TD2003IDCR does not apply to RRTs between two different and separate instruments that are not the same type.” AAA Panel Decision at ¶ 182 (emphasis added).

No further analysis of Appellant’s retention time arguments is required by the Panel in order to reach a determination in this case. However, because Appellant dedicated such a

significant portion of his brief to discussing the differences in the retention time values between the GC/MS instrument and the GC/C/IRMS instrument, a number of the issues raised by Appellant are clarified below.

B. LNDD Used the Same Column Type in the GC/MS and GC/C/IRMS Instruments

As part of his effort to attempt to explain the difference between retention times in the two instruments, Appellant raised for the first time in his appeal brief the argument that LNDD appeared to have used a different type of column in the GC/MS instrument than in the GC/C/IRMS instrument. Appellant further claims that this is a violation of the ISL because LNDD's standard operating procedures require that the same column (the DB17ms column) be used in both instruments. Appellant's Br. at 40. This argument fails because LNDD did in fact use the same column – the DB17ms – in each of the two instruments.

Appellant's confusion is caused by a mistake in the printouts of the informational operation summary, which listed a GC column, HP 5 MS, corresponding to the part number an Agilent 19091s-433, in the column identification field for the days that the GC/MS portions of Appellant's IRMS analyses was conducted. See Ex. 24 at USADA0124 (A Sample); Ex. 25 at USADA0303 (B Sample). Significantly, Appellant had these pages well in advance of the first hearing but never elected to raise the issue in any brief or to ask any of the lab personnel questions regarding the apparent discrepancy.¹⁹ Had Appellant inquired into this issue as part of a good faith effort to seek the truth, Appellant would have learned the following:

¹⁹ The apparent discrepancy is with the columns listed in Ex. 24 at USADA0153 and Ex. 25 at USADA0329.

- LNDD's records establish that the proper column name – DB17 – was reflected for the instrument operation summary on Friday, April 21, 2006. See Ex. 140 at LNDD2009.
- The pages that had the wrong column listed were an inadvertent byproduct of a routine service call made to the laboratory by an Agilent service technician from Monday, April 24 to Wednesday, April 26, 2006.
- As part of that service, the Agilent technician temporarily removes LNDD's column (the DB17ms) from the instrument and inserts a 19091s-433 Agilent column into the instrument to aid in the performance of his diagnostics. As part of his procedures he updates the instrument's operating summary to show that his column was used to perform the diagnostics. Importantly, the data entered into the column field of the operating summary is purely for informational purposes and does not impact the instrument analysis in any way.
- The technician, Mr. Gerard Le Petit, will testify that he carries a single 19091s-433 Agilent column with him on these service calls and that, at the completion of the diagnostics he removes his 19091s-433 Agilent column and takes it with him. This is supported by the detailed report of his diagnostics performed from April 24-26, 2006. See Ex. 141.
- He will further testify that it is normal practice to then restore the instrument's operational summary to indicate that he has reinstalled the DB17ms column. It is apparent from the operation summaries printed in conjunction with Appellant's

sample that Mr. Le Petit did not complete the last step and change the name of the column back to DB17ms in the column field of the operating summary.

- Mr. Le Petit is confident that he did not leave the Agilent 19091s-433 column in the instrument on April 26, 2006, because he would not have been able to continue his diagnostics at the next laboratory he visited unless he had this column with him.
- LNDD's records for the instrument show that the column was changed in the instrument on April 27, 2006. See Ex. 142. Appellant's samples were run on this instrument on July 23 and August 6, 2006.
- The next time the column was changed was August 31, 2006. See id. at LNDD 2004.

It should be noted that the fact that the wrong column name appeared in the column field of the operating summary, did not – and could not – have had any impact on the actual analysis that was performed on the instrument. Whether the column field was filled in correctly, incorrectly or left entirely blank would be irrelevant to the operation of the instrument.²⁰

²⁰ Any argument by Appellant that the wrong name appearing in the column field of the operating summary somehow rises to the level of an ISL violation would be deficient for two reasons. First, Appellant will be unable to point to any provision of the ISL that even requires the laboratory to produce the operation summary documents, let alone any provision of the ISL that would be violated by a labeling error. Additionally, there is no argument that the labeling error could have caused the Adverse Analytical Finding, because it is undisputed that the column field in the operation summary is for informational purposes only and does not impact the performance of the instrument.

Based on the foregoing, the Panel can be confident that the same column was used for three reasons. First, Mr. Le Petit took the Agilent 19091s-433 column with him, and LNDD does not use columns with this part number in the lab. Second, the column was changed after Mr. Le Petit's service call. Third, if the wrong column had been used during the time Appellant's samples were analyzed, the GC/MS retention times would not be within the expected range. Because the instrument performed as expected, it is clear that the correct column was used.

While Appellant's confusion on this point is understandable, that confusion could have been cleared up at any time leading up to or during the extensive AAA Hearing had Appellant raised the issue. Now that Appellant has raised the issue, LNDD has provided evidence confirming that the same DB17ms model of column was used in the GC/MS instrument and the GC/C/IRMS instrument used to conduct the analysis of Appellant's A and B samples.

Significantly, Appellant's argument that there was a possibility that the compounds may have changed elution order was based entirely on a theoretical possibility that different columns may cause compounds to elute in a different order depending on the polarity of the columns use. As there is no difference between the two columns this argument is now irrelevant. Indeed, in his brief Appellant concedes that the difference in temperature and method files (discussed below) would cause changes in retention time and relative retention time "but not the order" of the compounds' elution. Appellant's Br. at 36.

C. **The Differences Between the Method Files for GC/MS and GC/C/IRMS are Intentional and Acceptable**

Appellant's attack on the LNDD IRMS method rests on his unsupported claim that the "method files in the GC/MS and the GC/C/IRMS should have been identical." Appellant's Br. at 36 (emphasis in original).

This argument is not only unsupported by any credible evidence, but also displays a fundamental misunderstanding of how retention times are achieved. It is clear that LNDD makes no effort to achieve identical retention times between the GC/MS and GC/C/IRMS instruments; indeed, trying to do so would be an unnecessary, artificial and unscientific endeavor. The specific purpose of LNDD's GC/MS and GC/C/IRMS methods is to be able to identify the target compounds at issue in this case. Further, ISO has reviewed and approved these methods for this purpose.

Retention time is the end product of a number of factors that affect how long after injection a particular compound reaches the detector of the instrument. Here, there is no mystery as to why the retention times are different between the GC/MS and the GC/C/IRMS instruments.

As the AAA Panel correctly noted:

The GC column is, of course, the same in both instruments. However, the thermal ramp {that is the variation of the temperature of the compartment containing the GC column as a function of time} is different. That is evident from the fact that the total time for analysis is 25 minutes for GC/MS and 45 minutes for GC/C/IRMS. The difference in the experimental conditions would itself be enough to consider totally worthless a comparison of the retention times (or relative retention times) between GC/MS and GC/C/IRMS. Thus, the proposition of the Athlete as put by his scientific experts was unsound and without any reasonable scientific basis.

AAA Panel Decision at ¶ 188.

The difference in retention time between LNDD's GC/MS and GC/C/IRMS instruments is obvious and intentional. First, the mechanics of the two instruments between injector and detector are physically different. Second, the operation methods are different, particularly the flow rates. The flow rates of the two instruments are adjusted to make the internal standard elute later in the GC/C/IRMS than in the GC/MS. For LNDD's GC/MS method the flow rate is adjusted so that the internal standard elutes at 10.7 minutes (± 0.5 min). See, e.g., Ex. 84 at LNDD0664 (reproduced in relevant part below). In contrast, to obtain better peak separation,

LNDD's GC/C/IRMS method requires that the flow rate be adjusted so that the internal standard elutes at around 870 seconds (14.5 minutes). See Ex. 25 at USADA0329 (reproduced in relevant part below).

Below are the two standard operating procedures, clearly evidencing the intentional difference in methods:

Figure 6

THE GC/MS SOP:

LNDD	MODE OPÉRATOIRE	Codification : M-AN-52 Version : A Date : 28/10/2005 1 / 2
ANALYSE GC/MS - CONFIRMATION QUALITATIVE DES METABOLITES DE LA TESTOSTERONE ET DE SES PRECURSEURS		

CONDITIONS GC:

Température initiale: 70°C pendant 1 min
 Gradient de température: 70→270°C à 30°C/min
 270°C pendant 12 min
 270→300°C à 10°C/min
 300°C pendant 3 min
 Température finale:
 Temps d'analyse: 25.67 min
 Temps d'équilibrage de la colonne: 0.5 min
 Pression constante: Ajuster le SI à 10.7 min (+/-0.5min)
 Température de la ligne de transfert 300°C

CONFIDENTIAL

LNDD 0664

THE GC/C/IRMS SOP:

LNDD	MODE OPÉRATOIRE	Codification : M-AN -41 Version : B Date : 28/10/2005 1 / 2
MODE OPERATOIRE D'ANALYSE POUR LA CONFIRMATION DE L'ORIGINE DES METABOLITES DE LA TESTOSTERONE PAR CPG/C/SMRI		

CONDITIONS GC

Température initiale: 70°C pendant 1 min
 Gradient de température: 70→271°C à 30°C/min
 271°C→281°C à 0.6°C/min
 281°C pendant 3 min
 281→300°C à 5°C/min
 300°C pendant 5 min
 Temps d'analyse: 45 min
 Pression constante: Ajuster le SI à environ 870s

1

USADA 0329

100

When Appellant complains about the fact that the internal standard is off by almost four minutes between the two methods, he is in fact complaining that LNDD followed its standard operating procedure, which is designed to improve peak separation in the IRMS analysis.

Importantly, LNDD's IRMS methods were reviewed and approved in the ISO certification process. Accordingly, it is important to note that Appellant's arguments in this case do not simply challenge whether or not LNDD can identify the analytes in Appellant's sample,

but instead constitute an attempt by Appellant to invalidate LNDD's standard operating procedure for IRMS. Indeed, if Appellant is to be successful in convincing this Panel that the LNDD analysts were unable to properly identify 5alpha and pdiol in this case, he must, in fact, establish that LNDD's entire method is invalid. Accordingly, every IRMS report generated by LNDD over the last several years would suffer the same defect. Appellant cannot meet this burden because his arguments are based on flawed science and fail to recognize that the method employed by the analysts in this case was designed specifically in order to be able to identify the compounds of interest in this case. Appellant's request that the Panel disregard the effect of ISO accreditation and instead adopt Appellant's flawed and unsupported standards should be rejected here, as it was by the AAA Panel.

D. LNDD's Method for Identifying Peaks in IRMS is Valid

While the Panel need not look beyond the fact that ISO has already approved the laboratory's IRMS methods, further inquiry only serves to reinforce the scientific validity of the laboratory's practices with respect to peak identification in IRMS. Importantly, the AAA Panel understood exactly how LNDD identifies the compounds of interest:

[T]he lab compares the peaks and the sequence of the peaks from the GC/MS and GC/C/IRMS to identify the metabolites and the endogenous reference compounds. Specifically, to identify the substances in question, one would compare the pattern of peak heights and retention times in the GC/C/IRMS chromatograms, anchored by the internal standard with a known RT, with the pattern of peak heights and RTs in the GC/MS chromatograms obtained from the same aliquot of the sample.

AAA Panel Decision at ¶ 186 (emphasis added).

Moreover, in addition to the internal standard, which acts as a retention time marker and anchor, a second compound with a known retention time, 5beta from the Mix Cal Acetate, also provides a retention time anchor to identify the other peaks.

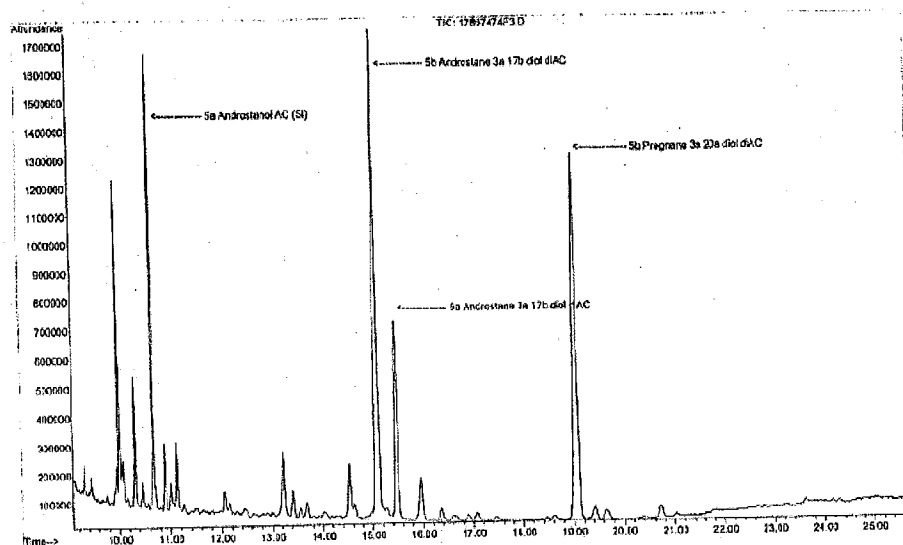
This is far from the “eyeballing” that Appellant suggests. Instead, operating under its standard operating procedure, every time that LNDD runs an IRMS analysis it adjusts the flow rate so that the internal standard elutes at approximately 870 seconds. Then, with that known anchor in place, it analyzes where the other peaks occur and knows from past experience where the other peaks of interest will appear. Indeed, the consistency of results in the subject samples supports that this is a valid scientific method.

Accordingly, as noted by the AAA Panel, based on the two retention time anchors, the LNDD method then uses peak sequence and pattern to identify the additional peaks of interest. Significantly, there is a reproducible and predictable relationship between the known anchors in the GC/C/IRMS – the internal standard and 5beta – and the retention times of the 5alpha and pdiol. There is no guess work in determining the identity of the remaining two peaks of interest. Instead, these two peaks consistently elute where they are expected to elute using LNDD’s approved IRMS method.

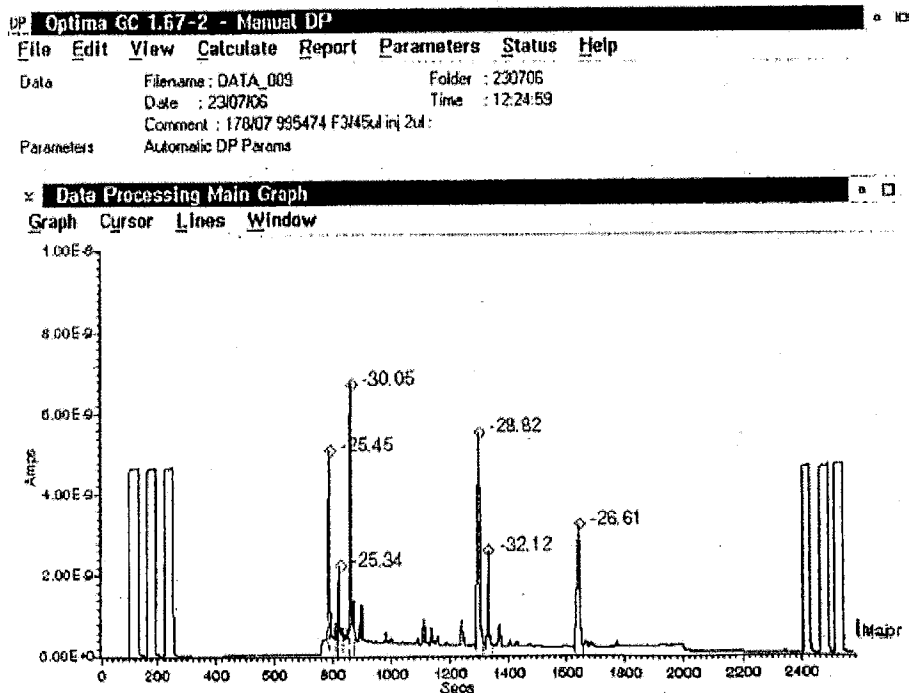
LNDD’s comparison of peak sequence and pattern between the GC/MS instrument and the GC/C/IRMS instruments is scientifically reliable. It is not disputed that LNDD correctly identified the peaks for the internal standard, 5beta, 5alpha and pdiol, on the Fraction 3 GC/MS chromatogram.²¹

²¹ In the GC/MS phase of the IRMS process, the compounds in question are run through the gas chromatograph and then the mass spectrometer to produce two pieces of information: a retention time for each analyte and a mass spectrum showing the component ions for that analyte. During the discovery process, at Appellant’s request, LNDD produced the full scan mass spectra data for all six compounds of interest in Appellant’s sample. Of particular relevance to this appeal, the full scan data show that LNDD isolated and identified 5beta, 5alpha, and pdiol in Appellant’s sample. See USADA Ex. 26 at LNDD0337-0339 (A sample); LNDD0343-0345 (B sample). The full scan data show that the analyte in question, for example, 5alpha, comes out at a certain retention time in GC/MS and that no other compounds are under the 5alpha peak. In other words, the full scan confirms that the peak labeled 5alpha is 5alpha and only 5alpha. The same can be said for the pdiol and the other relevant peaks.

File : D:\Mad22\Jul106\2307\1780747\F3.D
 Operator : 49
 Acquired : 23 Jul 2006 11:33 using AcqMethod MAN_52.M
 Instrument : MSD22
 Sample Name: 178/07 995474 F3
 Misc Info : 178/07 995474 Fraction 3 dans 400ul
 Vial Number: 3



Appellant claims, however, that LNDD cannot identify the 5alpha and pdiol peaks on the Fraction 3 GC/C/IRMS chromatogram. The AAA Panel disagreed and correctly found that all of the major peaks in Appellant's GC/MS chromatogram are identifiable in Appellant's Fraction 3 GC/C/IRMS chromatogram.



The Panel's conclusion is correct for three reasons. First, Appellant has conceded that when the same column is used in the two instruments, the peaks for all four compounds of interest will come out of the instruments and appear on the chromatograms in the same order.²² Second, the compounds identified as major peaks in Appellant's GC/MS chromatogram will also be major peaks in Appellant's GC/C/IRMS chromatogram.²³ Third, the comparison of sequence and pattern between the GC/MS chromatogram and GC/C/IRMS chromatogram is further established by the fact that the identity of two of four peaks of interest (the internal standard and 5 beta peaks in Appellant's GC/C/IRMS chromatogram) is also not contested.²⁴

1. There is a Relationship Between Peak Height in GC/MS and GC/C/IRMS in this Case

It is well-settled that when the same column is used, the peaks of interest will appear in the same order on both the GC/MS and GC/C/IRMS chromatograms. It is also not disputed that the second and third major peaks from the left on the GC/C/IRMS chromatogram are the internal standard and 5 beta. However, Appellant disputes that the next two major peaks on that

²² Appellant's citation (see Appellant's Br. at 37) to the Skogsberg article as support for the argument that different columns can change the order of elution for analytes is unpersuasive. Aside from the fact that the columns in this case are the same, the analytical methods and compounds addressed in the article are different from those at issue here, making the article readily distinguishable.

²³ It is for this reason that the AAA Panel's decision at paragraph 179 emphasized the importance of precisely identifying the compounds present in the GC/MS analysis. Because the GC/C/IRMS analysis is run from the same aliquot, the same compounds will be present and identifiable in the GC/C/IRMS analysis.

²⁴ The internal standard was added to the sample because it has a known retention time. The retention time for 5beta was confirmed in the analysis of the Mix Cal Acetate, which contains 5 beta.

chromatogram can be identified by LNDD's method as 5alpha and pdiol. He bases his argument on the fact that peak height in GC/MS and GC/C/IRMS measure different things.

Appellant is correct that the height of the peaks in his Fraction 3 GC/MS chromatogram do not measure exactly the same thing as the height of the peaks in his Fraction 3 GC/C/IRMS chromatogram. However, he is incorrect in suggesting that the peak heights for the major peaks in both chromatograms are irrelevant to determining that the same substances are eluting in the same order. For chemically similar compounds, like the compounds of interest in Appellant's Fraction 3 Sample, GC/MS peak height is largely a measure of the number of molecules of a compound detected by the instrument. The signal in the GC/C/IRMS instrument is due to CO₂ produced from combustion of the compound. The peak height in the GC/C/IRMS instrument is determined by two factors: First, the number of molecules of a compound detected (the same as GC/MS) and second, the number of carbon atoms present in each molecule of that compound.²⁵ Accordingly, where two compounds have the same number of carbon atoms and the instrument measures the same number of molecules for each compound, the peaks will be the same height. However, if one of these compounds has only half as many carbon atoms, the peak for that compound would be half as high.

In Appellant's Fraction 3 chromatogram, each molecule of the internal standard has 21 carbon atoms; each molecule of 5beta and each molecule of 5alpha have 23 carbon atoms, and each molecule of pdiol has 25 carbon atoms. In comparing Appellant's GC/MS and GC/C/IRMS chromatograms, as both 5beta and 5alpha have the same number of carbon atoms, the relative heights of the 5beta and 5alpha peaks in the chromatograms from the two instruments would be

²⁵ It is important to remember in looking at a GC/C/IRMS chromatogram that peak height and the delta value of a peak are not related.

expected to be roughly the same. In fact they are. Further, because the number of carbon atoms in all of the compounds of interest in Appellant's Fraction 3 sample are similar, one would not expect any big difference in peak heights for the compounds of interest between Appellant's GC/MS and the GC/C/IRMS chromatograms. In fact, there is none.

While there are other factors that can also have some impact on comparing peak height between the two instrument, there is no doubt in this case that the major peaks, including the 5alpha and pdiol peaks that have been positively identified on Appellant's GC/MS chromatogram, appear in the same order as big peaks on his GC/C/IRMS chromatogram, thus providing further positive identification of both the 5alpha and pdiol peaks in Appellant's GC/C/IRMS chromatogram.

2. Appellant is Wrong that a Simple Relative Retention for Calculation can be used Between Two Different Instruments

As set forth above, Appellant's analysis of the relationship between retention times in the GC/MS and GC/C/IRMS analysis is based on Dr. Meier-Augenstein's flawed testimony that relative retention times between the two instruments must match. See Meier-Augenstein Testimony, Tr. at 1056. Dr. Meier-Augenstein's opinion that you cannot identify analytes in IRMS unless you have matching relative retention times is unsupported by any evidence and underscores his lack of experience in the use of IRMS to detect exogenous testosterone. In an effort to support this incorrect testimony, Appellant in his brief attempts to over simplify the process for "adjusting" relative retention time to account for the differences between machines. See Appellant's Br. at 41-3.

While Appellant's argument is flawed in his over simplification, his argument does recognize that when the proper adjustments are made, there is a predictable and reproducible relationship between GC/MS and GC/C/IRMS retention times. However, retention time is not a

sufficiently robust calculation to fully capture and explain the relationship between the retention times in GC/MS and GC/C/IRMS. Instead, a more complicated set of calculations, which account for the numerous factors affecting retention times between the two instruments, must be used to define the predictable and repeatable relationships between the respective retention times.

VIII. APPELLANT'S RECYCLED ARGUMENTS PROVIDE NO BASIS FOR OVERTURNING THE AAA PANEL'S DECISION

The other failures alleged in Appellant's brief essentially recycle the Appellant's Proposed Findings of Fact submitted to the AAA Panel. Rather than repeat the AAA Panel's thorough analysis of each of these issues, this brief will often direct this Panel to the paragraphs of the AAA Panel Decision where each issue is discussed and, as appropriate, provide discussion for further clarification of the issue. In sum, during the prior proceedings, USADA established and the AAA Panel agreed that:

- LNDD's quality controls worked;
- LNDD's instruments were operating within linearity specifications;
- The chromatograms produced in the case are reliable;
- LNDD's manual integration was a quality control step;
- LNDD's chain of custody complies with the ISL;
- Non-forensic corrections do not affect the results in the case; and
- Appellant's results are consistent with the known science concerning testosterone.

Appellant has presented no new evidence in his brief at this stage and therefore has provided no basis to conclude that the AAA Panel reached an incorrect result.

A. Allegation that LNDD's Controls "Failed"

The AAA Panel thoroughly addressed each of Appellant's "failed" control arguments, starting at ¶ 190 of the AAA Panel Decision.

1. LNDD Has an Effective Positive Control

The first part of Appellant's argument is that although LNDD's controls met all of LNDD's acceptance criteria, LNDD should have used different controls.

LNDD used its Mix Cal IRMS control and its Mix Cal Acetate control to confirm that the IRMS instrument was measuring delta values accurately. The delta values of the steroids in these controls cover the high and low range of the delta values found in the testosterone metabolites and endogenous reference compounds in Appellant's sample. Appellant's expert Dr. Meier-Augenstein acknowledged that the Mix Cal Acetate is "a very nice way to test whether the instrument on the benign conditions operates perfectly well within specifications." See Meier-Augenstein Testimony, Tr. at 1449. He went on to argue that as an additional control, LNDD should have measured both of the endogenous reference compounds and all four of the testosterone metabolites evaluated in Appellant's sample in a urine matrix. In contrast, Dr. Ayotte testified that the Mix Cal Acetate is an adequate positive control. See Ayotte Testimony, Tr. at 809. The AAA Panel rejected Dr. Meier-Augenstein's argument at the hearing. As the AAA Panel concluded, "there is nothing to indicate that LNDD has a deficient positive control system." AAA Panel Decision at ¶ 212. Further, if a different control had been required by the ISL, then ISO would not have approved LNDD's IRMS method. Finally, LNDD did establish that it was able to consistently measure 5alpha, 5beta, andro, etio, pdiol and 11-ketoetio in a urine matrix. LNDD measured the delta values of the those six compounds together with Appellant's A and B Samples and every other time Blank Urine pool number 4 was run between June and August 2006, and the results were consistently the same.

2. Appellant's Injection Sequence Argument Fails

The second part of Appellant's argument is his claim that the injection sequence for his sample was interrupted. Appellant repeatedly points to USADA's briefs where USADA said that controls were run "immediately" before and after Appellant's samples. Appellant's complaint is that in the analysis of his A Sample, there was approximately a four and a half hour delay between the time the last fraction of Appellant's urine was injected (at Step 13) and the time the second Mix Cal Acetate was injected at Step 14. In Appellant's B Sample, there was approximately a five and a quarter hour delay between the time the Mix Cal Acetate was injected at Step 7 of the injection sequence and the time the first Blank Urine was injected at Step 8. While these two delays in no way compromised the accuracy or relevancy of the control results, Appellant claims that during these delays, LNDD analysts destroyed data or manipulated results that they did not like. That is simply not true. The acquisition time for control samples and Appellant's samples are clearly reflected in the document packages. See Exs. 24 and 25. The results obtained for the controls were within expected ranges. As such, there are no concerns that the instrument was not performing properly. Finally, the implication that LNDD was doing something improper in regard to Appellant's samples during this time is unfounded.

There is nothing in the ISL that requires LNDD to run any particular combination of controls in its IRMS method, to run a control like Mix Cal Acetate before and after a sample, to run controls in any particular sequence, or to run a sequence without interruption. There is certainly nothing in either the ISL or LNDD's standard operating procedures that requires that controls be run "immediately" either before or after an athlete's sample. Further, there is no ISL

prohibition against stopping or interrupting an injection sequence once it has been commenced.

See Ayotte Testimony, Tr. at 810:1-25, 859:1-867:25.²⁶

To support his claim, Appellant quotes Claire Frelat as saying that controls were rerun because they were not correct. See Appellant's Br. at 65. This is misleading and inaccurate. Appellant neglects to point out that in making this statement, Ms. Frelat was talking about the log files that correspond to the analysis of some of Appellant's other seven Tour samples, not the Stage 17 Samples. Even as to those other non-Stage 17 samples, she was also only talking about "controls" not Appellant's "samples." In his brief, Appellant additionally states that "Ms. Mongongu also testified that she could not remember what happened during the gap in the testing of the B Sample." Appellant's Br. at 51-52, (emphasis added). Importantly, Ms. Mongongu performed the analysis of Appellant's A Sample, but she did not perform the analysis of Appellant's B Sample.

As Ms. Frelat testified at the hearing, the explanation for the delay in Appellant's Stage 17 B Sample injection is simple. It is clear from LNDD's documentation package, Ex. 25 at USADA0360, that at approximately 12:24 p.m. when the injection of the Mix Cal Acetate at Step 7 of the sequence was completed, that the Blank Urine and Appellant samples were still undergoing preparation and were not ready for injection. The preparation process was completed at 17h00 (5:00 p.m.). See Ex. 25 at USADA0302. The Blank Urine and Appellant's Sample

²⁶ As the AAA Panel stated: "As confirmed in the testimony of Dr. Ayotte, the ISL does not require that samples be run through automatically or consecutively without delay. Nor was evidence presented to this Panel demonstrating that this gap in time would result in inaccurate results. The Respondent has not provided this Panel with any evidence indicating the requirement in either the ISL or LNDD's SOP that each step in the injection sequence be performed consecutively or without delay. **The Panel therefore accepts the submissions of the Claimant [USADA] on this point and finds that there was no failure on the part of the Lab to ensure effective quality control.**" AAA Panel Decision ¶ 229 (emphasis added).

were then injected at Step 8, which started at 17:03:53, less than four minutes after Appellant's B Sample was ready for injection. Appellant's attempt to attribute nefarious intent to this delay is entirely defeated by the fact that his expert, Dr. de Boer, was present for the B Sample analysis and raised no issue with this delay. See Ex. 25 at USADA0386.

The time gap between the last injection of Appellant's A Sample in Step 13 and second injection from the Mix Cal Acetate control vial at Step 14 occurred because the second injection from the Mix Cal Acetate vial on the auto sampler failed to inject automatically. Ms. Mongongu did not intentionally stop the injection sequence nor were there any other injections made during this time gap. It is not unusual that Ms. Mongongu would have a specific recollection on this point since this was the only IRMS confirmation which she performed on any sample from the 2006 Tour. Given the fact that the sequence was started up again at approximately 8:39 p.m., the most likely explanation for this time gap is that after the sequence stopped before completing Step 14, Ms. Mongongu started the sequence up again when she checked on the analysis before leaving work that evening. More importantly, it is not necessary that LNDD have an explanation for this time gap. As the AAA Panel noted, under the ISL, LNDD is not obliged to provide any explanation for injection time delays. "There was no explanation regarding the delay between the injection of the Mix Cal Acetate and the Respondent's Sample "A" fraction, but this does not amount to a departure from the ISL and as such the Respondent has failed to rebut the presumption." AAA Panel Decision at ¶ 230.

3. Appellant's Batch Data Processing Results Argument is Unpersuasive

Appellant claims that by looking at pages entitled, "Batch Data Processing Results," it can be determined that LNDD destroyed data from controls run together with Appellant's Stage 17 Sample. To make this point, Appellant refers to Mix Cal IRMS 003-2 in the A Sample, Mix

Cal IRMS 003-2 in the B Sample and Mix Cal IRMS 003-3 in the B Sample. Appellant notes, for example, that the delta value shown for Mix Cal IRMS 003-3 for the B Sample on the injection sequence page (Ex. 25 at USADA0331) is -31.42. However, the delta value for that same injection shown on the batch data processing results page (Ex. 25 at USADA0358) is -31.44.

There are two reasons why this discrepancy is not evidence of data destruction. First, the reason for this difference is that the delta value shown on the injection sequence page (USADA0331) is recorded automatically by the instrument before manual integration. The delta value reflected on the batch file page (USADA0358) is the final delta value after manual integration is performed. Second, when one looks at the acquisition times for the three Mix Cal IRMS injections identified by Appellant, they were all sandwiched between other recorded injections. There would have been no time for the allegedly deleted Mix Cal IRMS injections to have occurred.

4. Appellant's Delta Value and International Standard Argument Should be Rejected

Appellant's third claim that LNDD's controls failed is based on his erroneous assumption that the 5alpha AC internal standard was a control for delta value measurement. This claim by Appellant is addressed in detail by the Panel, starting at ¶ 192 of the AAA Panel Decision. As the Panel noted, LNDD (and also the Montreal laboratory) uses this internal standard as a retention time marker to establish a standard for retention time, not as a control to establish the instrument's ability to accurately measure delta values. In fact, the 5alpha AC internal standard elutes at the very beginning of the chromatogram where, both Dr. Ayotte and Dr. Schanzer testified, one would expect to have some interference with delta value measurement. See AAA Panel Decision at ¶¶ 199-200.

Because LNDD uses the 5alpha AC internal standard as a control for retention time, but not delta value measurement, LNDD has no corresponding acceptance criterion for the delta value measurement of the internal standard. The ± 0.5 delta unit figure that Appellant seeks to apply to the 5alpha AC internal standard is simply not applicable. *Id.* at ¶ 196. This contrasts with the Mix Cal Acetate and Mix Cal IRMS controls that are used as controls for the accuracy of delta value measurement. For those controls, LNDD's operating procedures provided an acceptance criterion for evaluation of those controls, which is that 3 out of the 4 steroids measured in each control must be within ± 0.5 delta units of the established value for that steroid.

5. LNDD's IRMS Instrument was Linear

Appellant's claim that LNDD's IRMS instrument was not linear and that nonlinearity somehow affected the validity of the reported delta values for Appellant's sample is thoroughly addressed in the AAA Panel's Decision, starting at ¶ 221, and ultimately rejected.

Linearity is the ability of the IRMS instrument to correctly measure the delta values of both large peaks and small peaks. The ISL does not establish any linearity requirements. Specifically, the ISL does not establish how often the linearity of an instrument should be checked nor does it require that linearity be checked both before and after the analysis of an athlete's sample.²⁷ Similarly, there is no specific linearity requirement established in any LNDD standard operating procedures, other than the statement that "[linearity checks will be performed on a monthly basis]" See Ex. 112 at LNDD0547.

²⁷ For example, it would make no difference to the validity of the result in this case under either the ISL or LNDD's standard operating procedure if the instrument were sold after Appellant's sample was analyzed and thus there was no subsequent linearity testing of that instrument.

First, Appellant's Dr. Davis claims that based on the linearity tests which were conducted by LNDD on this instrument on 26 June 2006 (Ex. 26 at LNDD 0313), 31 July 2006 (Id. at LNDD0320), and 25 September 2006 (Id. at LNDD 0327) that the instrument was non-linear. The AAA Panel correctly noted that under the linearity specification set forth in the operating manual for this instrument, that the instrument was linear. The AAA Panel rejected Dr. Davis's use of the linearity specification for a more recent model of the instrument. See AAA Panel Decision at ¶ 222.

Second, Appellant argues that the peaks for the four testosterone metabolites and two endogenous reference compounds identified in his sample were not within the linearity range checked by LNDD. Appellant's Dr. Meier-Augenstein claimed that the range of linearity should be based on peak area. Dr. Brenna countered that peak height, not area, should be used in establishing a linearity range. The AAA Panel noted that Dr. Brenna's position was expressly supported by the operating manual for the instrument. See AAA Panel Decision at ¶ 220.

Finally, Appellant contends that LNDD did not follow its own standard operating procedure by conducting a linearity test once a month. The AAA Panel agreed that LNDD had not followed its standard operating procedure. However, linearity testing was conducted within 30 days before and 30 days after the A Sample analysis on July 23, 2006. It was also conducted within 30 days before, but more than 30 days after, the B Sample analysis on August 4, 2006.

The AAA Panel concluded that LNDD's failure to conduct a linearity test in the month of August did not cause Appellant's adverse analytical finding. The AAA Panel noted in particular Dr. Brenna testified that instrument non-linearity only becomes a problem when comparing large peaks and small peaks. Where the two peaks to be compared are approximately the same height (as is the case with the 5alpha and pdiol peaks in this case), even if the instrument were non-

linear, that would not significantly affect the delta-delta value comparison between them. The AAA Panel also noted that the GC/C/IRMS instrument must have been linear at the time Appellant's A and B Samples were analyzed because otherwise the instrument would not have accurately measured the delta values in the Mix Cal Acetate control which Appellant's Dr. Meier-Augenstein acknowledged were accurate and which spread over the same peak height range as Appellant's samples. See AAA Panel Decision at ¶ 225.

B. Appellant's Stage 17 Chromatograms are Reliable

Appellant takes a two-part approach to attacking LNDD's GC/C/IRMS Stage 17 A and B Sample F3 chromatograms. First, he relies on Dr. Meier-Augenstein's opinion that these chromatograms were of poor quality. Second, he asserts that any poor quality chromatogram is a violation of ISL Article 5.4.4.2.1.

During cross examination, Appellant's counsel frequently switched back and forth between Appellant's Stage 17 chromatograms, chromatograms from Appellant's other seven Tour samples, LNDD chromatograms of samples from other athletes, and examples of good chromatograms and bad chromatograms from other laboratories.²⁸ The only IRMS chromatograms upon which the positive test in this case were based are the Stage 17 Fraction 3 chromatograms (containing both 5alpha and pdiol) for Appellant's A and B Samples.

The AAA Panel accepted the testimony of Dr. Ayotte, Dr. Schanzer, Dr. Catlin, Dr. Shackleton and Dr. Brenna, all of whom expressed the opinion that LNDD's Stage 17 Fraction 3 chromatography was good. The AAA Panel specifically pointed to Dr. Brenna's testimony explaining why the very small peak shown between the 5beta and 5alpha peaks in the

²⁸ Thus, on cross examination when Dr. Catlin gave two chromatograms grades of "C" and "C-minus," he was referring to the chromatograms from Appellant's Stages 11 and 15 samples, not Appellant's Stage 17 sample.

GC/MS chromatogram did not affect the delta value of the 5alpha peak in the GC/C/IRMS chromatogram. See AAA Panel Decision, ¶¶ 236-37.

The AAA Panel also put to rest Appellant's argument that LNDD's Stage 17 Fraction 3 chromatograms could somehow have violated Article 5.4.4.2.1 of the ISL because of "matrix interference." Article 5.4.4.2.1 is found in subsection 5.4.4.2 of the ISL, entitled "Validation of Methods," which in turn is a subsection of Article 5.4.4, "Test Methods and Method Validation." The articles in these sections address the general ability of the laboratory's methods to produce chromatograms that avoid matrix interference. These articles do not address matrix interference in any specific chromatogram. As Dr. Ayotte testified, a laboratory does not violate Article 5.4.4.2.1 anytime it produces a chromatogram that contains matrix interference. Further, as noted by the AAA Panel, the language in Article 5.4.4.2.1 provides that the "method should avoid interference" even with respect to methods (as opposed to individual chromatograms), the language is not mandatory. See AAA Panel Decision at ¶ 240.

C. IRMS Data Processing is a Quality Control

The GC/C/IRMS portions of the analysis of Appellant's Stage 17 A and B Samples were conducted on an IsoPrime instrument that uses OS2 software. The delta values reported for the relevant testosterone metabolites and endogenous reference compounds are derived from chromatograms that reflect the peak areas – that is, the area under the peaks – for those compounds as represented by the IRMS chromatograms. When analyzing urine, the instrument will generate a response to material that is not a compound of interest, which is called "background." The background is not considered (i.e., it is subtracted out) in computing the area under peaks. As such, the reported delta values for the compounds of interest are influenced by where the baseline dividing peak from background is established, and where a peak is determined to have started and stopped. On each chromatogram, the OS2 software automatically

establishes a baseline and the start and stop points of each peak. Dr. Brenna testified that the baselines and peak starts and stops that are established automatically by the OS2 software must also be checked by the analyst and manually optimized. This is a quality control step to assure that the peak starts and stops have been properly identified. See Brenna Testimony, Tr. at 277:19-23 (“And I said it once, I’ll say it a second time: I consider it a quality control step. That is to say, one’s determining whether the automatic software has chosen the limits of integration properly.”)

Appellant has sought to characterize this process as a “human, subjective interpretation” of peak starts and stops and background. However, the testimony of USADA’s witnesses, including Dr. Brenna (Tr. at 272-75), Ms. Mongongu (Tr. at 453-47), and Mr. Frelat (Tr. at 676-77), emphasized that LNDD’s analysts follow a process set out in its standard operating procedure. LNDD’s IRMS method is part of its ISO accreditation. See Ex. 112 at LNDD0603-0609.

When a chromatogram is generated, the analyst inspects the software’s automatic placement of the background and peak starts and stops. The very fact that LNDD has a standard operating procedure on this process is an indication that the software does not always automatically generate the right result. In order to determine whether the automated placement of these points is accurate, the analysts use a diagnostic tool called the “2/1” (two-over-one) trace (sometimes called a 45/44 trace). This tool is essentially a different way of depicting information gathered during the analysis of the samples. Rather than reporting the data as a chromatogram, the 2/1 trace shows, in graph form, the ratio of ^{13}C to ^{12}C . Where more ^{13}C is present, the signal plots above the “x” axis. As more ^{12}C is detected, the signal moves below the “x” axis. When the signal has gone up, then down across the “x” axis, and then up again to the

“x” axis, a peak is defined. See also Brenna Testimony, Tr. at 262:1-263:2. Using the 2/1 trace, the analyst optimizes placement of the background and peak start and stop points to ensure that the peak area calculations are being made on peaks, rather than a combination of peaks and background. Sometimes this process requires multiple attempts by the analyst to correctly optimize the background or a peak start or a peak stop.

After baseline has been accurately established and the peak start-stops have been assigned based on inspection of the beginning of the rise of the peak in the 2/1 trace plot, the analyst clicks on the “calculate” prompt on the instrument and the instrument software performs the calculation to determine the peak area (this is what is meant by “integrating” the peak) after subtracting the background based on the peak start and stop points assigned by the analyst.²⁹

1. No Violation of the ISL Occurred

Despite Appellant’s repeated claims, the AAA Panel found that LNDD’s procedures for optimizing background and peak calculations do not violate the ISL. This conclusion was supported not only by the testimony of USADA’s witnesses, but also by the report of the AAA Panel’s independent expert, Dr. Botrè. Ex. 114.

Appellant argues that Article 5.4.4.4 of the ISL required LNDD to document any respect in which manual integration changed the background or peak start-stops established automatically by the OS2 software. However, as explained by Dr. Ayotte, who was a member of WADA Laboratory Committee that was involved with the review and approval of the ISL, ISL

²⁹ Appellant’s Brief also re-hashes the argument that the manner of “manual integration” at LNDD was hidden during the discovery process. However, contrary to Appellant’s claims, LNDD’s responses are consistent with the lab’s procedures. After the analyst sets the peak start-stops, the background subtraction and delta values are calculated automatically by the software.

Articles 5.4.4.4.1.3 and 5.4.4.4.1.4 do not require any such documentation. See Ayotte Testimony, Tr. at 803-805.

Dr. Brenna's testimony that manual integration is both appropriate and necessary as a quality control measure to ensure reliable results was supported by Dr. Ayotte (Tr. at 802-803. 807-808)³⁰, Dr. Catlin (Tr. at 1236), Dr. Buisson (Tr. at 931-32), and Ms. Mongongu (Tr. at 453-57).

Appellant further claims that it was an ISL violation for LNDD not to better document its manual optimization process. Article 5.4.4.4.1.4, which is a subsection of Article 5.4.4.4.1, entitled "Data and Computer Security" provides:

5.4.4.4.1.4 All data entry, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, the information that was changed, and the individual performing the task.

As Dr. Ayotte testified, this provision applies to changes to **reported** data, whether in paper or electronic format. See Ayotte Testimony, Tr. at 805:15-806:16.

And what 5.4.4.4.1.4 deals with is the integrity of the files that are in your computer and that has created or served to create the results. ... So it's – my opinion has to do when we are acquiring the data, when we are getting the information and the response from an instrument, we are creating the data. We are not altering records and reports into the computer system.

Tr. at 805:24-806:15. Ms. Mongongu gave similar testimony. Tr. at 527:24-528:8. When the technicians at LNDD or Montreal manually refine the baselines and peak start-stops on

³⁰ Indeed, Dr. Ayotte confirmed in her testimony that technicians in her lab use manual integration, as well: "The analysts are instructed to perform manual intervention on background, to establish background subtraction or peak, to determine peak as much as the field. It is necessary to ensure accuracy of results." Tr. at 802:23-803:3.

chromatograms, that is part of the data analysis process; it is not a change to already reported data, which requires a forensic correction audit trail.³¹

Appellant's witness Dr. Davis argued that documenting the steps taken to optimize the background and peak parameters could have been accomplished by the LNDD technicians clicking on the "save parameters" prompt the first time manual refinement was performed on a chromatogram. However, if manual optimization was performed by LNDD multiple times on the same chromatogram, as Dr. Davis observed to be the case, the OS2 software would only save a single change. See Davis Testimony, Tr. at 1838.

While it might have been possible for the LNDD analysts to have electronically preserved some part of the baselines and peak start-stops established by manual optimization, they would not have had any reason to believe that such a preservation effort would serve any useful function in the future. As far as the parties are aware, this is the first time that electronic data files have ever been produced in a doping case. The argument that all electronic data files (including those which would show manual refinement of chromatograms) are required by the ISL fails because it is far beyond the scope of the documentation that a laboratory is required to produce under WADA TD2003LDOC regarding Laboratory Documentation Packages. Indeed, Appellant's witness Dr. Goldberger testified that in the more than 125 court cases in which he

³¹ This process was described by Dr. Ayotte, who testified that: "if you want to improve the manual integration that has been done by an instrument, it's better to blow up, and have the zoom in so that you can see exactly what you are trying to do and to achieve.

Q (by Mr. Young): And would it be typical for the analyst to make a copy every time they zoom in or zoom out?

A: I'd say that in reviewing most of the documentation package from the other lab, I have not seen tails of manual integrations. We see the final results. Ayotte Testimony, Tr. at 807:20-808:6 (emphasis added).

has testified, electronic data files had never been requested. See Goldberger Testimony, Tr. at 1037, 1094.

2. Dr. Botrè Concluded that LNDD's Process is Scientifically Sound and Aimed to Improve the Quality of the Signal

It is of particular note that the AAA Panel's independent scientific expert, Dr. Botrè, addressed Appellant's arguments in his report following the reprocessing of the electronic data files. Dr. Botrè stated:

- 7.11 The above data also show that the manual subtraction of the background performed by the Paris laboratory, apart from being covered by their internal Standard Operating Procedures, appears to be a scientifically sound process, aimed to improve the quality of the signal and, therefore, the reliability of the obtained results, and not to alter the results of the analysis. This is particularly evident if one considers that the totally automatic reprocessing of the EDFs on the old instrument gave rise to a value of the difference between pregnanediol and 5-alpha-diol greater than 3 also for the negative reference urine, both on the occasion of the "A" and the "B" sample analysis.
- 7.12 Apart from the numeric data, the appropriateness of the manual subtraction of the background is also evident from the comparison, between the manual and the automatic subtraction of the background, of the baseline of the upper part of the plots reported on the graphical page of the relevant, reprocessed outputs.
- 7.13 Finally, there was nothing in the data obtained by reprocessing the EDFs related to the stability and to the linearity runs that could invalid[ate] the results of the analysis of the "A" and the "B" sample.

Ex. 114 (emphasis added). Both parties had the opportunity to question the Panel's independent expert about these conclusions; however, neither party elected to do so.

For all these reasons, it is clear that the AAA Panel was correct in finding that LNDD's manual processing did not constitute an ISL violation.

D. Reprocessing the Electronic Data Files

As described in the AAA Panel opinion at ¶¶ 135-36, Appellant repeatedly argued that LNDD's IRMS results for his Stage 17 Sample were unreliable in part because they were

produced using allegedly outdated OS2 software. See, e.g., Appellant's Br. at 16. At Appellant's insistence, the EDFs from the original instrument were obtained by the Panel's independent expert, Dr. Botrè. "The files were then run in different modes of the original equipment and on the new GC/C/IRMS instrument using MassLynx software. In addition to reprocessing the data on the MassLynx software, the data was reprocessed three different ways using the original software." AAA Panel Opinion at ¶ 136.

Despite having specifically demanded the opportunity to reprocess the EDFs, Appellant devotes little space to the results in his brief. The reason for this is readily apparent. Prior to the reprocessing taking place, Appellant apparently hoped that, when the EDFs from his Stage 17 Sample were re-run on the newer MassLynx software, the resulting delta values would be negative. However, the MassLynx results were even more positive than the original results. Appellant also hoped to get a negative result by asking that the EDFs be reprocessed three different ways on the original instrument using the OS2 software. Again Appellant's sample was positive no matter how the EDFs were reprocessed. In fact, since the reprocessing established that Appellant's sample was positive by such a wide margin, it showed that the manual optimization employed by the analysts was not necessary in order to determine that the sample was clearly positive.

The following is a chart of the EDF reprocessing results produced by Appellant at the hearing (GDC01350). The EDFs were reprocessed four different ways:

995474	Original Result	Auto	Manual	Zero	Masslynx
A Sample					
E-11K	-2.58	-1.72	-2.32	-1.76	-2.18
A-11K	-3.99	-3.14	-3.65	-2.94	-3.78
5B-P	-2.15	-1.70	-2.65	-2.08	-2.63
5A-P	-6.14	-5.65	-6.95	-5.55	-7.22
B Sample					
E-11K	-2.02	-0.32	-0.35	-1.66	-2.39
A-11K	-3.51	-1.67	-1.61	-2.81	-4.01
5B-P	-2.65	-3.37	-3.05	-2.33	-2.80
5A-P	-6.39	-7.61	-7.19	-5.58	-7.03

Blanks	Original Result	Auto	Manual	Zero	Masslynx
A Sample					
E-11K	-0.87	-0.51	-0.56	-0.06	0.09
A-11K	-0.48	-0.48	-0.53	-0.02	-0.59
5B-P	-0.55	-0.92	-0.27	-0.47	-1.00
5A-P	-1.59	-3.65	-1.87	-1.46	-2.45
B Sample					
E-11K	-1.08	-1.11	-0.94	-0.25	-0.51
A-11K	-0.08	0.03	0.17	0.83	0.55
5B-P	-0.67	-1.33	-0.69	-0.54	-1.52
5A-P	-1.60	-3.45	-1.89	-1.24	-3.66

The delta-delta value difference between the 5alpha testosterone metabolite and the pdiol endogenous reference compound have been highlighted. The column headings are explained below.

- **“Original Result”** – the original values reported for Sample 995474 using manual optimization.
- **“Auto”** – reprocessing with the OS2 software using the automatic integration feature with no manual optimization.
- **“Manual”** – reprocessing with the OS2 software using LNDD’s manual optimization process.
- **“Zero”** – reprocessing with the OS2 with the automatic baseline subtraction feature turned off and no manual optimization.

- “**MassLynx**” – reprocessing the data using MassLynx software.³²

This chart establishes that Appellant’s sample was positive no matter how Appellant asked for it to be processed. The AAA Panel noted this consistency in its Decision. See AAA Panel Decision at ¶ 251. In fact, as the Panel noted, some results “were even more consistent with exogenous use of testosterone than the original ones.” Id.

The fact that Appellant’s Stage 17 Sample was positive when analyzed on the MassLynx software is of particular note, because reprocessing using the MassLynx software did not involve any manual optimization.³³

Based on the evidence and the AAA Panel’s conclusions regarding the reprocessed data, it is clear that the reprocessing provides two pieces of information relevant to rebutting Appellant’s various claims. First, the reprocessed data corroborates the conclusion that the procedure by which the LNDD analysts manually optimize the background points and peak starts and stops is a quality control feature. Dr. Botrè also remarked on this aspect of the reprocessed results in his report See Ex. 114 at § 7.11; see also AAA Panel Decision at ¶ 140.

Second, the reprocessed results provide additional corroboration that LNDD was correct in reporting Appellant’s Stage 17 Sample as positive for exogenous testosterone.

³² As described by the testimony of Dr. Brenna, the least reliable evidence in the charts above are the results obtained from either the “Zero” reprocessing or the “Auto” reprocessing. Each of these processes were requested by Appellant but, as established through testimony at the hearing, and in Dr. Botrè’s report, those processes are flawed methodologies. See, e.g., Brenna Testimony, Tr. at 285-26. Accordingly, one would expect differences between the results produced by those methods and the original LNDD method, with LNDD’s original results being the more accurate reflection of the samples ¹³C/¹²C composition.

³³ With respect to the MassLynx results, Dr. Brenna testified that the representatives of the parties agreed that the -3.66 value for the B Sample blank urine 5A-P in the above table should be disregarded because the software crashed when processing that file. See Brenna Testimony, Tr. at 288.

Appellant attempts to mitigate the corroborating effect of the reprocessing results by arguing that the reprocessed results were not identical to the original results. This argument is unpersuasive. In essence, the different methods of processing the data give the instrument different instructions on how to calculate background and where to set peak start and stop points. As these points govern the calculation of peak area, it is nonsensical to suggest that the results of such calculations should be the same.³⁴

When the delta values from the original analysis are compared to the manual reprocessing by Ms. Mongongu and Ms. Frelat there are no significant differences with one exception. The delta value differences for andro-11keto and etio-11keto were considerably smaller in reprocessing the B Sample than they were in the original analysis. This occurred because the value reported for 11-keto in Fraction 2 of the B Sample reprocessing was considerably lower than the 11-keto value reported originally. This lower value for 11-keto caused the delta differences for both andro-11-keto and etio-11-keto to be much smaller. (This was explained in the testimony of Dr. Ayotte, Tr. at 897-900). This discrepancy does not involve Fraction 3 of Appellant's sample which contained the metabolite (5alpha) and endogenous reference compound (pdinol) upon which LNDD's Adverse Analytical Finding was based. The original B Sample Fraction 2 manual integration results are consistent with the MassLynx result; it is only the manually reprocessed B Sample Fraction 2 result that is out of line.

Appellant's Brief implies that in reprocessing the EDFs, Ms. Mongongu and Ms. Frelat were attempting to reproduce their original results rather than to honestly conduct the reprocessing analysis. However, Appellant's expert Dr. Davis testified that he did not believe

³⁴ Appellant's citation to Dr. Brenna's testimony that he would be concerned by these changes is taken out of context.

that the analysts were trying to achieve a specific result. See Davis Testimony, Tr. at 1843 (“they [Ms. Mongongu and Ms. Frelat] were genuinely just looking at the baseline and trying to fit – trying to fit the lines and fit the piece the best way they could.”).

As discussed above and noted by both the AAA Panel and Dr. Botrè in his report, the results for 5alpha are consistently positive, and when run on the MassLynx software that Appellant put so much stock in, the results were actually more positive than his original results. The Panel correctly found that the additional information obtained from the reprocessing of the electronic data files is reliable. Moreover, it is “consistent with the determination that the [Appellant] was doping” during Stage 17 of the Tour. See AAA Panel Decision at ¶ 253.

E. Chain of Custody

Appellant has raised no chain of custody issue with his sample before it arrived at LNDD. Appellant has also raised no issue with aliquot chain of custody. The only chain of custody issue Appellant has raised involves the chain of custody for the A and B Sample bottles.

USADA agrees with Appellant that the purpose of bottle chain of custody is “to ensure that the urine tested suffered no contamination, tampering, or mislabeling.” Appellant’s Br. at 69. It is also beyond dispute that under UCI Rules, the only chain of custody requirements applicable in this case are those found in the ISL and the accompanying WADA Technical Document TD2003LCOC.

Appellant’s chain of custody argument rests on the assumption that the ISL requires that the individuals on both sides of every transaction be reflected on a contemporaneous chain of custody document (e.g., A to B, B to C, C to D). In fact, the ISL and the Technical Document only require that separate chain of custody documents exist which identify each person who had custody of the sample bottle (e.g., A, B, C, D). Moreover, Appellant totally ignores the provision of the Technical Document that provides that a sample bottle need not be in an

individual's possession when it is in a "controlled zone" within the laboratory. After bottle opening, both Appellant's A and B bottles were within the controlled zone in the LNDD laboratory at all times.

Appellant claims that LNDD should be required to use the "Z" form chain of custody document used by the UCLA laboratory which he claims documents all transfers between individuals on a single page.³⁵ That type of documentation is not required by the ISL. Rather, as noted by Dr. Ayotte it is common for other WADA-accredited laboratories, like LNDD, to document chain of custody through a series of individual documents identifying the individuals who had custody of the bottle. ISO raised no issue with LNDD's approach to chain of custody documentation in LNDD's accreditation audit. Rather, the ISO audit report, with reference to the ISL and the WADA chain of custody Technical Document, states that LNDD's sample management was very satisfactory. Ex. 26 at USADA0392, 0396-0397.

The applicable ISL standard for laboratory bottle chain of custody is set forth in Article 5.2.2.2 of the ISL.

ISL Article 5.2.2.2 provides:

5.2.2.2 The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for *Samples* from receipt through final disposition of the *Samples*. The

³⁵ In response to the argument at pages 69-70 of Appellant's Brief, Appellant argues that a Z form must be required because otherwise how would one know whether an undocumented transfer of the bottle took place? The Z form, which Appellant argues must be required, provides no greater assurance against unrecorded transfers than the LNDD documentation. For example, if the Z form showed that Person A completed a task with the bottle at 9:00 and then transferred the bottle to Person B at 11:00, if one assumes the possibility of an unrecorded transfer, it is equally possible that A transferred to C and got the bottle back again before A then transferred to B as reflected on the chain of custody form.

procedures must incorporate the concepts presented³⁶ in the *WADA Technical Document for Laboratory Internal Chain of Custody* (Annex C) (*emphasis added*).

Ex. 8. The WADA Technical Document for laboratory internal chain of custody is TD2003LCOC (Ex. 102), which provides:

The Laboratory Internal Chain of Custody is documentation (worksheets, logbooks, forms, etc.)³⁷ that records the movement of *Samples* and *Sample Aliquots* during analysis. A Laboratory Internal Chain of Custody does not require a separate form.³⁸ Within the Laboratory, the Laboratory Internal Chain of Custody shall be a continuous record of individuals in possession³⁸ of the samples or *Sample Aliquots*. When not in an individual's possession, it should be documented that the *Sample* or *Aliquot* is within a controlled zone (Ref *International Standard for Laboratories* 5.4.3.2). The *Sample* or *Aliquot* must be in an individual's possession when in an uncontrolled or unsecured area of the laboratory.³⁹ The entry into the Laboratory Internal Chain of Custody should be completed at the time that any change of possession occurs. The Laboratory Internal Chain of Custody must contain the name or initials of the individual, date of transfer, and the purpose of the transfer of possession.⁴⁰ The individual's complete signature/name should appear in the documentation at least once.

A chain of custody is required for both 'A' and 'B' *Sample* bottles and every *Aliquot* prepared for a testing procedure. In the case of *Samples*, the Laboratory Internal Chain of Custody should record

³⁶ As noted by the AAA Panel, compliance with concepts, not literal compliance, is all that is required. See AAA Panel Decision at ¶¶ 276-278.

³⁷ The fact that LNDD's bottle chain of custody is based on separate forms, each identifying an individual who was in possession of the bottle, is clearly acceptable.

³⁸ The Technical Document only requires that the "individual" (singular) in possession be identified on a chain of custody document, not additionally the person who transferred the bottle to him.

³⁹ When the bottle is in a controlled zone, chain of custody documentation showing that it is in an individual's possession is not required. Not surprisingly, when Appellant quotes this section of the Technical Document in his appeal brief, he deletes the portion that refers to controlled zones. See Appellant's Br. at 68.

⁴⁰ There is no requirement, as Appellant suggests, that the chain of custody documentation must account for everything that happened to the bottle for the entire time period that it was in an individual's possession or within a controlled area.

all movement from receipt in the Laboratory through storage and sampling to disposal ...

Any forensic corrections that need to be made to the document should be done with a single line through and the change should be initialed and dated by the individual making the change. No white out or erasure that obliterates the original entry is acceptable.

The chain of custody, along with relevant testimony⁴¹ from individuals documented on the chain of custody documents, should provide a complete record of the *Sample* or Aliquot location.

Ex. 102, TD2003COC (footnotes not in original).

The chain of custody arguments raised by Appellant are virtually identical to the arguments presented by Appellant to the AAA Panel in his Proposed Findings of Fact. The AAA Panel goes into considerable detail addressing each of Appellant's arguments, starting at ¶ 260 of the AAA Panel Decision.

The AAA Panel observed that many of Appellant's chain of custody arguments are based on a summary document found at Ex. 24 in USADA0253-0254. The AAA Panel correctly noted that this summary document is not the original chain of custody documentation described in TD2003LCOC, and that it might be better described as a Table of Contents. See AAA Panel Decision at ¶ 264. Instead of relying on this Table of Contents, the AAA Panel did as directed by TD2003LCOC and traced bottle chain of custody through the original LNDD documents. After doing so, the AAA Panel and its expert concluded that they were "satisfied that the sample and aliquots can be accounted for at all times when the original documents are examined." Id. at ¶ 264. For this Panel's assistance, attached as Exhibit 144 is a diagram of the LNDD laboratory, which shows the controlled zone within the laboratory. Superimposed upon that diagram are the 15 steps of bottle movement for the A Sample bottle and the 7 steps of bottle movement for the

⁴¹ The Technical Document clearly contemplates that testimony can be used to fill in gaps in the chain of custody documentation.

B Sample bottle. The AAA Panel also took particular note of the fact that Appellant's chain of custody complaints pertain to times when the bottles were in controlled zones within the LNDD laboratory and therefore, under TD2003LCOC, do not need to be in the possession of a particular individual. See AAA Panel Decision at ¶ 267.

Finally, the AAA Panel notes that Appellant's expert, Dr. de Boer, who attended the B Sample opening and analysis, did not conclude that LNDD's chain of custody documentation was "fatally flawed" when he opined that "LNDD worked in a transparent and professional way and according to transparent and professional procedures." AAA Panel Decision at ¶¶ 269, 270; Ex. 25 at USADA0368. Dr. de Boer should have been paying attention to B Sample bottle chain of custody when he attended the B bottle opening and analysis on behalf of Appellant. The B bottle was removed from the positive freezer at 9:12 a.m. and was thereafter opened in front of a group of witnesses, including Dr. de Boer and Appellant's lawyers. The B bottle chain of custody process ended when all of the urine in the bottle was used up in aliquotting for T/E confirmation, which took place at 11:05 a.m. During this two-hour period, Dr. de Boer had the opportunity to personally watch each transfer and step in the B bottle chain of custody process.

F. Non-Forensic Corrections

Appellant points to a number of instances where LNDD personnel made transcription errors or non-forensic corrections when filling in summary reports based on accurate instrument-generated data.

It is unfortunate that some transcription mistakes were made, and USADA is aware of no good reason why those individuals preparing summary reports did not use proper forensic correction methodology. However, none of this undermines the reliability of LNDD's analytical results. In every case where there was a transcription mistake or a non-forensic correction was made, the correct data entry can be traced back to an original document contained in the LNDD

documentation package. There is no question that the analytical results reported by LNDD pertain to Appellant.⁴² There is no question that the data upon which LNDD's adverse analytical finding was based was data that can be traced directly back to the analytical reports coming from the analytical instruments.

The AAA Panel correctly concluded that none of these transcription mistakes or non-forensic corrections caused Appellant's positive test. See AAA Panel Decision at ¶ 289.

G. Appellant Claims that LNDD's Analytical Results are Inconsistent with Known Science

Appellant claims that LNDD's IRMS results show a breakdown of testosterone that is inconsistent with both the peer-reviewed literature and the science of testosterone metabolism. Appellant is wrong on both counts.

Specifically, Appellant claims that when the four testosterone metabolites are influenced by the administration of exogenous testosterone, their values should rise and fall together. Appellant's Br. at. 56. In other words, Appellant claims that because there is so much difference in the delta values of 5alpha (-27.72), 5beta (-23.73), andro (-25.05), and etio (-23.63), the measured delta values must be the result of laboratory error.

What is known about the metabolism of testosterone is that: a) different individuals can metabolize testosterone in very different ways; b) the way that testosterone is administered (e.g., transdermal gel, patch, oral tablet, or injection) significantly influences how that testosterone is metabolized in the body; and c) dosage and time of administration of any exogenous testosterone can significantly affect results obtained from any subsequent IRMS analysis.

⁴² Indeed, in closing, counsel for Appellant conceded that Appellant was not challenging that this was his sample. See Tr. at 2054:11-13.

As explained at length by Dr. Shackleton in his testimony in the AAA Hearing, some individuals have an innate tendency to metabolize testosterone along pathways that favor the production of 5alpha, other individuals have an innate tendency to metabolize testosterone along pathways that favor the production of 5beta. Thus, if three individuals take exogenous testosterone, one individual may metabolize more of that exogenous testosterone into 5alpha, another may metabolize more of that exogenous testosterone into 5beta, and the third individual may metabolize the exogenous testosterone into equal amounts of 5alpha and 5beta.⁴³

In addition to the metabolic preferences of different individuals, the method by which exogenous testosterone is administered makes a tremendous difference in the resulting metabolic pathway of that exogenous testosterone. Testosterone administered transdermally, either by gel or patch, would be influenced by the 5alpha reductase enzymes in the skin and would favor the production of 5alpha more than the production of 5beta. See Ex. 152 at 141. Conversely, testosterone taken orally would be more affected by enzymes in the liver which would favor the production of 5beta over 5alpha.

The studies which use IRMS to look at the metabolism of exogenous testosterone support the conclusions that there are significant differences in the innate metabolic preferences between individuals favoring either the 5alpha or 5beta pathways. They also establish that the metabolism of exogenous testosterone favoring either the 5alpha or 5beta pathway will be greatly influenced by the form of testosterone of administration. In addition, the studies show

⁴³ The testosterone metabolites measured by IRMS will always be a mixture of the metabolites of exogenous testosterone and some naturally produced testosterone. 5 alpha diol and 5beta are usually the more sensitive metabolites to look at in detecting exogenous testosterone administration because the andro and etio produced from the metabolism of exogenous testosterone are more likely to be diluted by natural testosterone and other steroids produced from a number of other metabolic pathways. See Ex. 154.

that after the administration of exogenous testosterone 5alpha and 5beta as measured in urine do not always go down or come back up together at the same rate or in concordance. Thus, the difference between a measured delta value for 5alpha and a measured delta value for 5beta could vary, depending on how much time had passed since the exogenous testosterone administration.

Five studies measuring 5alpha and 5beta after exogenous testosterone administration were discussed in the AAA Hearing. Those studies were:

- a) Schanzer (Cologne laboratory) Cologne Workshop Presentation 2007. Two individuals—testosterone gel. Ex. 34a.
- b) Schanzer (Cologne laboratory) Cologne Workshop Paper. One individual—testosterone gel. Ex. 34.
- c) Maître (Lausanne laboratory). One individual—oral testosterone. Ex. 145.
- d) Shackleton 1997. Five individuals--testosterone injection. Ex. 40 at 88-96.
- e) Aguilera (UCLA Laboratory) 1999. Ten individuals--testosterone injection. Ex. 40 at 45-52.
- f) Aguilera (UCLA Laboratory) 2001. Two individuals--route of administration not discussed, but given the year of the study, probably testosterone injection. Ex. 40 at 72-80.

The studies confirm that how the exogenous testosterone is applied influences whether that exogenous testosterone will metabolize into more 5alpha or more 5beta. As would be expected, for both of the individuals in the Schanzer study who received transdermal application of testosterone gel, the 5alpha delta value was much more influenced by the transdermal testosterone than the 5beta delta value. See Ex. 34. In contrast, in the Maître study where the

subject was administered oral testosterone, the impact on the 5beta metabolite was more pronounced. See Ex. 145.

These studies support the conclusion that the metabolic pathways of exogenous testosterone can differ widely between individuals. The studies do not support Appellant's contention that 5alpha and 5beta values should always rise and fall together after the administration of exogenous testosterone. What the studies show is that often 5alpha and 5beta values fall together, but sometimes they don't; and often 5alpha and 5beta values rise together, but in some individuals they don't.

Appellant's contention that the difference of 3.99 delta units between the 5alpha and 5beta in his Stage 17 Sample is not supported by science is simply incorrect. For example, looking at the 1999 Aguilera study where ten subjects were injected with testosterone, in nine of the ten subjects, the metabolism of the exogenous testosterone into 5alpha and 5beta were relatively similar. See Ex. 145. However, in the tenth subject (Subject A), the effect of the exogenous testosterone administration on the two metabolites was not at all equal. See id. For Subject A, the measured difference between 5alpha and 5beta was more than 4.5 delta units. See id. Similarly, looking at the two subjects in the Schanzer study, for individual P3, the difference between the measured delta values of the 5alpha metabolite and the 5beta metabolite ranged from 1 to 2.5 delta units. See Ex. 34. For individual P9, the difference between 5alpha and 5beta ranged, depending on the time of measurement, between 1.6 and 3.3 delta units. See id. The Shackleton study (where the largest difference between 5alpha and 5beta was about 2.5 delta units) illustrates the importance of how long after administration a sample is taken. In two of the five individuals studied, there were times for each individual during the post-injection period that

the 5alpha metabolite was more influenced by the exogenous administration, and other times when the 5beta metabolite was more influenced by the exogenous administration.⁴⁴ See Ex. 40.

Testosterone administered by injection has a relatively long clearance period, several days to a month depending on dosage. On the other hand, as demonstrated in a seven-subject study by Baume (Ex. 43 at 367) delta values after oral administration are typically back to normal within 24 hours and sometimes in as little as eight hours.

All of these studies involved volunteers who were administered testosterone under laboratory conditions by a single route of administration. Even if these studies supported Appellant's theory (which they do not), they would be of dubious application to the case of an athlete who is trying to avoid detection and who has the opportunity to switch between routes of administration (e.g., transdermal gel, patch, or oral testosterone), or to use a combination of these application methods simultaneously, to switch dosages, or to switch times of administration.

Neither USADA nor LNDD knows what testosterone product or combination of testosterone products Appellant used, nor is it USADA's burden to prove the route of administration. As previously explained, the pattern of delta values in Appellant's eight Tour samples could be significantly affected by what type of testosterone or combinations of types of testosterone Appellant used, the dosage used, and the time between administration and sample collection in the afternoon of the various stages after which Appellant was tested.

⁴⁴ Appellant's brief claims that in the 2001 Aguilera study "the greatest difference between 5 alpha and 5beta for control subjects was -1.39 per mil." First, the -1.39 figure isn't reported in the study. Second, the "control subjects" Appellant refers to were not believed to have used exogenous testosterone. One of the two known exogenous testosterone users (#2) in the study had differences between 5 alpha and 5beta of up to -3.1 per mil. Subject #3, a suspected, undeclared user, had differences of up to -2.8 per mil. Since the issue here is what differences in 5 alpha and 5beta can be expected for exogenous testosterone users, these are in the two relevant subjects from that study.

There is nothing in the T/E ratios of Appellant's eight Tour samples that undermines the IRMS delta values reported for these samples. It is beyond argument that athletes can dope with testosterone and still avoid having a T/E ratio greater than 4:1. This is further illustrated in the Schanzer presentation where during testosterone administration, five of the 18 subjects (subject numbers P1, P11, P16, P17 and P18) never recorded a T/E value greater than 4:1 during transdermal testosterone gel administration. Ex. 34 at Appendix 1. Outside of the laboratory setting, as in this case, where Appellant could have been attempting to manipulate his T/E ratio by using epitestosterone, not much can be gained by trying to compare the small fluctuations in T/E ratio within the normal range (other than the large spike in the Stage 17 Sample) with the fluctuations in IRMS results. For example, Patrik Sinkewitz had a T/E ratio of only 1.6 to 1 when he was using testosterone during the 2007 Tour de Suisse. Ex. 150 (T/E results provided to USADA by UCI). Even in the laboratory context, T/E ratios and IRMS results do not necessarily rise and fall together. For example, in the Baume study, after the administration of oral testosterone, IRMS delta values for one subject (S1) dropped significantly, while the T/E ratio showed no change at all. Ex. 43 at 367. Similarly, in the Schanzer study, in one subject (P16), the continuous application of testosterone gel over six weeks had no effect on his T/E ratio. Ex. 34 at Appendix 1.

Finally, Appellant states at page 58 of his brief, "the IRMS test results are also inconsistent with known science because, as explained by Dr. Amory, Appellant's luteinizing hormone ("LH") values, as shown before and after July 23 (Stage 20), are inconsistent with the chronic use of testosterone. See Tr. at 1550:1-1552:13; see also Ex. GDC00620. Appellant's Brief states that "Dr. Amory's testimony with respect to LH has never been contested." In fact, nowhere in the cited portion of Dr. Amory's testimony or anywhere else in his testimony did

Dr. Amory say anything about what Appellant's LH values were before or after July 23 or express any opinion as to what significance could be drawn from them. Dr. Amory did not give any specific testimony regarding Appellant's LH levels. As Appellant has failed to reference any evidence supporting this argument, it should be disregarded.

H. IRMS Analysis of Appellant's Other Samples Corroborate the Stage 17 Findings

In addition to the Stage 17 Sample, seven other urine samples were collected from Appellant during the Tour. No IRMS Analysis was performed on these samples during the original testing because none of these samples had a T/E ratio greater than 4:1, which under the WADA Prohibited List would have triggered IRMS analysis.

In December 2006, USADA proposed to conduct IRMS analysis on Appellant's other seven Tour B Samples. (There was no remaining A Sample left for six of the seven samples.) Appellant engaged in a vigorous campaign of opposition to that proposal and the matter was ultimately briefed and argued before the AAA Panel. It is USADA's position that Appellant fought to suppress the further analysis because he knew that additional samples would show his use of exogenous testosterone. The AAA Panel's Order of March 17, 2007, found no basis for Appellant's objections and provided that USADA could go forward with the further IRMS analysis testing. (For the Panel's convenience, this order is Ex. 147.)

The IRMS analysis of Appellant's other seven Tour samples took place at LNDD from April 16-23, 2007. Representatives of both Appellant and USADA were present. Appellant subsequently raised a complaint alleging that his representatives were denied information and access during the further analysis process. That complaint was rejected by the Panel in the Order of May 8, 2007. See Ex.148.

The IRMS analysis of Appellant's other seven Tour samples was performed by LNDD on an IsoPrime2 instrument using MassLynx software. During the further analysis process, Appellant's samples were "blinded" by the addition of three samples from the UCLA Laboratory, which were provided by USADA's observer Dr. Rodrigo Aguilera, and by the masking of all ten sample bottles. During the further analysis, only the parties' representatives knew whether a particular sample was from Appellant or had been provided by Dr. Aguilera. See e.g., Mongongu Testimony, Tr. at 463-64.

The result of the further analysis was that exogenous testosterone was detected in four of Appellant's other seven Tour samples. Accord AAA Panel Decision at ¶ 134 (referring to the table below). The following table sets forth the results of the further analysis together with the A and B Sample analytical results from Appellant's July 20, 2006, Stage 17 Sample:

Collection Date	Blind Sample #	UCI Sample #	5alpha pdiol	5beta pdiol	Andro-11 Keto	Etio-11 Keto	LNDD Page #
7/3/2006	993865	995462	—	-1.04	0.22	-0.95	LNDD1488
7/11/2006	993856	994203	-2.91	-1.05	-0.25	-1.29	LNDD1391
7/13/2006	993855	994277	-4.62	-4.09	-1.99	-2.32	LNDD1106
7/14/2006	825425	994276	-1.01	-0.70	-1.70	-1.04	LNDD1297
7/18/2006	825428	994075	-5.06	-3.56	-1.22	-1.89	LNDD0915
7/20/2006	*****	995474A	-6.14	-2.15	-3.99	-2.58	USADA0186
7/20/2006	*****	995474B	-6.39	-2.65	-3.51	-2.02	USADA0352
7/22/2006	825429	994080	-4.80	-1.67	-1.36	-1.68	LNDD1012
7/23/2006	825424	994171	-4.96	-1.45	-0.64	-1.43	LNDD0725
Aguilera	825427	**NL1**	-1.31	-0.95	0.00	-0.94	LNDD1582
Aguilera	825426	**NL2**	-0.77	-0.88	0.32	-0.74	LNDD0820
Aguilera	825423	**NL3**	-1.21	-0.79	0.09	-0.91	LNDD1203

The UCI Rules, which are consistent with the World Code, provide that a doping violation for the “presence” of a prohibited substance (Article 15.1) is only established when a Prohibited Substance is detected in both the athlete’s A and B specimens or the analysis of the B specimen is waived. However, Article 15.2 of the UCI Rules, also prohibits the “use” of a Prohibited Substance, and Article 17 provides that doping can be proved by any reliable means.

This case was brought by USADA against Appellant in September 2006 based on the Stage 17 Adverse Analytical Finding. When the results of the further analysis became available in April 2007, USADA did not seek, at that late stage in this proceeding, to amend its charge against Appellant to include separate anti-doping rule violations based on use. Rather, USADA’s position in this case has been that the further analysis results strongly corroborate the Stage 17 Adverse Analytical Finding.

Importantly, Appellant had previously rested his defense in part on the claim that it made no sense to use testosterone during only one stage of the Tour. While this defense would not be sufficient in any event to overcome the Stage 17 Adverse Analytical Finding, it is also completely undermined by the further analysis results which show that Appellant was using exogenous testosterone several times during the Tour.

Moreover, the further analysis results also corroborate the Stage 17 Adverse Analytical Finding by undermining Appellant’s argument that the Stage 17 Adverse Analytical Finding was the product of laboratory error. Appellant is now asking the Panel to believe that laboratory error occurred in the analysis of five samples, not just one. USADA submits that this is reliable corroborative evidence of Appellant’s anti-doping rule violation.⁴⁵

⁴⁵ In an effort to mitigate the damaging effect of this evidence, Appellant challenges the validity of LNDD’s analytical results for his other seven Tour samples. During the analysis of the other seven Tour samples, there were a number of occasions where a problem arose which

Importantly, Appellant had previously rested his defense in part on the claim that it made no sense to use testosterone during only one stage of the Tour. While this defense would not be sufficient in any event to overcome the Stage 17 Adverse Analytical Finding, it is also completely undermined by the further analysis results which show that Appellant was using exogenous testosterone at numerous times during the Tour.

Moreover, the further analysis results also corroborate the Stage 17 Adverse Analytical Finding by undermining Appellant's argument that the Stage 17 Adverse Analytical Finding was the product of laboratory error. Appellant is now asking the Panel to believe that laboratory error occurred in the analysis of five samples, not just one. The AAA Panel noted this evidence, but did not rely on this additional corroborative evidence in finding that Appellant had committed a doping violation.

IX. OTHER MATTERS

A. Appellant's Racing After Declaring He Would Not Compete Should Alter His Suspension Start Date

UCI Rule 275 provides that an athlete's suspension for a doping violation begins on the date of the hearing decision unless fairness requires otherwise. In this case, the AAA Panel used

caused either Ms. Mongongu or Ms. Frelat to interrupt the injection sequence and re-inject a control, which overrode the previous file. (There is no evidence that any of the three fractions of Appellant's sample were re-run.) Appellant claims first that Ms. Mongongu and Ms. Frelat re-injected controls to fraudulently manufacture positive findings and second that by overriding files, LNDD violated the ISL. Neither argument was persuasive to the AAA Panel. Dr. Ayotte testified during both direct and cross examination that it is not unusual and is perfectly acceptable during sample analysis for a laboratory to rerun control samples and overwrite the previous files. See Ayotte Testimony, Tr. at 859-867; 906-908. Dr. Ayotte also testified that there is no issue running control samples out of sequence. Id. at 810. The AAA Panel's Decision roundly rejects Appellant's contentions regarding deletion of data. See AAA Panel Decision at ¶¶ 254-57. In particular, the Panel determined that "the theory of a Lab conspiracy was without foundation and facts to come to such a conclusion." Id. at ¶ 257.

its discretion to institute an earlier ineligibility date because Appellant filed a voluntary declaration of non-competition as of January 30, 2007. See AAA Decision at ¶ 320.6. Appellant then chose to participate in a USA Cycling-sanctioned race, the Leadville Trail 100 Mountain Bike Race, on August 11, 2007, where he placed second. See Ex. 146. Appellant violated his self-imposed ineligibility period well after the AAA Hearing. Appellant's should not be given the benefit of his self-imposed non-competition declaration as he failed to honor it. The World Code defines status during ineligibility as follows:

Article 10.9 Status During Ineligibility. No Person who has been declared ineligible may, during the period of ineligibility, participate in any capacity in a Competition or activity (other than authorized anti-doping education or rehabilitation programs) authorized or organized by any Signatory or Signatory's member organization.

Ex. 4 at 22.

Appellant's participation in the Leadville competition negates the justification for the AAA Panel's decision to set an earlier ineligibility date.

Because Appellant did not honor his voluntary ineligible status, his period of ineligibility should commence on the date of the AAA Panel's decision as provided in the UCI Rule and run for a period of two years.

B. Witness Designations

Respondent's witness designations are transmitted herewith, and specifically incorporated herein by reference.

C. Objections

Respondent objects to several witnesses designated by Appellant. Specifically, Respondent objects to the designation of LNDD witnesses (Dr. de Ceaurriz, Ms Cerpolini, and Mr. Barlagne) whom Appellant had the opportunity to examine in person at the AAA Hearing

and elected not to do so. Second, Respondent objects to Appellant's designation of Daniel Dunn, a partner at Holme Roberts & Owen, as a witness. Mr. Dunn, an attorney representing Respondent in this case, was not called to give testimony at the AAA Hearing, and there is no reason to expect he will need to be called as part of the shorter proceedings on appeal. With regard to Appellant's designation of Timothy Brockwell as an adverse witness, Respondent does not plan to call him and has no power to require him to appear.

D. Supplements to the Record

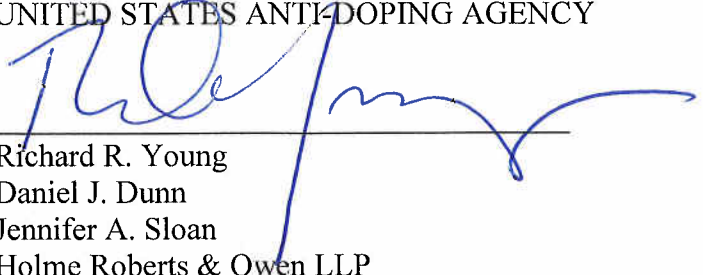
USADA is also enclosing its Supplements to the Record prepared by Appellant. Two documents were omitted: USADA's Proposed Findings of Fact and Conclusions of Law, and USADA's opening slides from the AAA Hearing. In addition, USADA is supplying a corrected version of Ex. 130 (Simon Davis curriculum vitae). It appears that the wrong document was originally included. USADA respectfully requests that the record be supplemented accordingly.

X. CONCLUSION

For all of the foregoing reasons, Respondent respectfully submits that the evidence in this case establishes that the presence of exogenous testosterone in Appellant's Stage 17 Sample constitutes an Anti-Doping Rules Violation and that the consequences imposed by the AAA Panel should be upheld, with the exception of the start date of Appellant's suspension, which should commence on the date of the AAA Panel Decision and run for two years. Further, Respondent requests that the Panel award costs and fees in a manner consistent with CAS Rules and precedent, based on the evidence submitted and arguments presented in this proceeding.

Respectfully submitted this 31st day of January, 2008.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 31st day of January, 2008, true and correct copies of the foregoing **UNITED STATES ANTI-DOPING AGENCY'S RESPONSE BRIEF** was served by electronic mail and facsimile, with copies to follow by FedEx, as follows:

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TABLE OF CONTENTS

I.	Introduction.....	1
II.	Statement of Facts.....	5
	A. The 2006 Tour de France.....	5
	B. Summary of Prior Proceedings	7
III.	Applicable Law and Burden of Proof.....	12
IV.	Issues on Appeal	13
	A. Questions Before the Panel.....	13
	B. The Role Of The ISL And ISO	14
V.	Use and Detection of Exogenous Testosterone	16
	A. Doping With Testosterone	16
	B. Use of IRMS to Detect Testosterone	17
	C. The Science of IRMS.....	18
	D. WADA Positivity Criteria.....	21
	E. CAS Panels Have Repeatedly Found Doping Based on IRMS	23
VI.	Appellant's Sample Contained Exogenous Testosterone	24
	A. LNDD's IRMS Method	25
	B. IRMS Analysis of Appellant's Stage 17 Sample Establishes Doping.....	27
	C. IRMS Results.....	27
	1. LNDD's Methods are Accredited by ISO.....	28
	2. Quality Controls Establish that the GC/C/IRMS Instrument was Working Properly.....	29

3.	Stability Check.....	31
4.	Mix Cal IRMS Control	31
5.	Mix Cal Acetate Control.....	32
6.	Blank Urine Control.....	33
VII.	Appellant's Attack on LNDD's Peak Identification in IRMS Does Not Establish an ISL Violation	35
A.	Appellant's Interpretation of WADA TD2003IDCR is Fatally Flawed.....	35
1.	TD2003IDCR Does Not Apply to Relative Retention Times Between GC/MS and GC/C/IRMS	37
2.	Appellant's Incorrect Interpretation of the Technical Document is not Supported by the Evidence	40
B.	LNDD Used the Same Column Type in the GC/MS and GC/C/IRMS Instruments	43
C.	The Differences Between the Method Files for GC/MS and GC/C/IRMS are Intentional and Acceptable	46
D.	LNDD's Method for Identifying Peaks in IRMS is Valid.....	50
1.	There is a Relationship Between Peak Height in GC/MS and GC/C/IRMS in this Case.....	53
2.	Appellant is Wrong that a Simple Relative Retention for Calculation can be used Between Two Different Instruments.....	55
VIII.	Appellant's Recycled Arguments Provide No Basis for Overturning the AAA Panel's Decision	56
A.	Allegation that LNDD's Controls "Failed"	56
1.	LNDD Has an Effective Positive Control.....	57
2.	Appellant's Injection Sequence Argument Fails	58
3.	Appellant's Batch Data Processing Results Argument is Unpersuasive ..	60
4.	Appellant's Delta Value and International Standard Argument Should be Rejected.....	61
5.	LNDD's IRMS Instrument was Linear	62

B.	Appellant's Stage 17 Chromatograms are Reliable	64
C.	IRMS Data Processing is a Quality Control	65
1.	No Violation of the ISL Occurred	67
2.	Dr. Botrè Concluded that LNDD's Process is Scientifically Sound and Aimed to Improve the Quality of the Signal.....	70
D.	Reprocessing the Electronic Data Files	70
E.	Chain of Custody	75
F.	Non-Forensic Corrections	79
G.	Appellant Claims that LNDD's Analytical Results are Inconsistent with Known Science	80
H.	IRMS Analysis of Appellant's Other Samples Corroborate the Stage 17 Findings	86
IX.	Other Matters	89
A.	Appellant's Racing After Declaring He Would Not Compete Should Alter His Suspension Start Date	89
B.	Witness Designations.....	90
C.	Objections	90
D.	Supplements to the Record	91
X.	Conclusion	91