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**IN THE COURT OF ARBITRATION FOR SPORT**

IN THE MATTER OF FLOYD LANDIS,

CAS 2007/A/1394

FLOYD LANDIS V. UNITED STATES ANTI-DOPING AGENCY

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**DECLARATION OF SIMON DAVIS, PhD**

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I, Simon Davis, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the following facts and, if called as a witness, could and would competently testify to them.

2. I am an expert in the field of carbon isotope ratio test processes and instrumentation generally. Further, I am an expert in the Isoprime carbon isotope ratio testing instrument used by the Laboratoire National de Dépistage et Dopage ("LNDD") and its related software and instrumentation and test processes.

3. I received a Bachelor of Science with Honours in Environmental Biology from Oxford Brookes University in 1991. I received a Ph.D. in Stable Isotope Mass Spectrometry from Liverpool JMU, in association with Cambridge University, in 1996. Prior to obtaining my Ph.D., I worked as a field scientist for the Food and Agricultural Organization (FAO) of the United Nations (UN) in Sierra Leone.

4. My first job after obtaining my Ph.D. was as a Laboratory Manager, Liverpool JMU, from 1995 to 1997. In that capacity, I was responsible for the day to day management of laboratory, which performed Carbon Isotope Ratio testing. The laboratory performed tests in the areas of sports physiology and ecology. In that capacity, I managed laboratory processes and reviewed test results, performed quality control management and developed and implemented testing methodologies.

5. I then worked as a Stable Isotope Systems Engineer for Micromass UK Ltd. from May 1997 to July 1998. In that capacity, I was responsible for ensuring that the end user received a fully tested and properly manufactured carbon isotope ratio instrument. I installed instruments and trained end-users. At Micromass, I worked on the Isoprime instrument

exclusively. In fact, I worked on the first ever IsoPrime instrument. I have tested and installed approximately 20 to 30 IsoPrime instruments.

6. I then worked at the Lawrence Berkeley National Laboratory, University of California, at Berkeley from July 1998 to June 2000. I began that position as a post-doc fellow, however, during my time at the laboratory, I became a staff scientist at the laboratory. In that capacity, I worked with the IsoPrime instrument and also performed contract work for Micromass. I worked on the development of stable isotope testing, and the effects of groundwater pollution. I performed all of this work using an IsoPrime instrument.

7. I then became a Development Project Leader at Micromass UK LTD from June 2000 to March 2003. There, I was in charge of developing the IsoPrime instrument, and specifically as it related to its use as an anti-doping instrument. Further, I also helped write the software used on the newer IsoPrime instrument, known as Masslynx.

8. I then became a Research Officer at Queens University from March 2003 to March 2005. I ran a stable isotope laboratory and was primarily responsible for writing grant proposals and performing research and publishing papers. While there, I checked to ensure that instruments were properly maintained and that laboratory procedures were properly performed.

9. I am currently the Technical Director and part owner of MassSpecSolutions. I build our own stable isotope mass spectrometer – a carbon isotope ratio instrument. I manage the development of the engineers, the software and the carbon isotope ratio instrument itself. I have sold one of these instruments to the Portugese anti-doping laboratory in Lisbon, Spain.

10. I have previously testified as both a defense witness and a witness against an athlete in anti-doping cases. In particular, I conducted the anti-doping control for the World's Strongest Man Competition in 2003.

11. I have been involved with this case as a consulting expert and a testifying expert in the AAA proceeding below. As part of that, I have reviewed the document package in this case and related documents, transcript of the hearing of *United States Anti-Doping Agency v. Floyd Landis*, held on May 13 – 23, 2007 and the resulting Award of the Majority and the Dissent, the exhibits in that case and the pleadings and briefs in this appeal and the underlying case. I was also present for, testified at, and observed much of the AAA proceeding below. Further, I have personally participated, on behalf of Appellant, in observing the reprocessing of the Stage 17 test results at LNDD and the retesting of the other stages (aside from Stage 17) that USADA claims corroborates the Stage 17 test results.

12. I have not yet submitted a bill to Appellant for participating in this appeal and the preparation associated with it. I am participating in this appeal because I believe that to upholding an anti-doping sanction on the evidence in this case is a moral and ethical wrong.

13. After a review of the files and records and laboratory documents in this case, I have concluded that the CIR test results allegedly supporting an adverse analytic finding against Floyd Landis in the above-captioned case, including the CIR results for Stage 17 and other stages from the 2006 Tour de France, are inaccurate, unreliable and of no scientific worth.

14. Further, I conclude that LNDD has performed improper laboratory procedures and done other things to cover up its many errors for the purpose of establishing an anti-doping violation in this case when the scientific evidence does not support it.

#### **BACKGROUND OF THE ISOPRIME INSTRUMENT**

15. The Isoprime is an instrument built and designed by Micromass.

16. The Isoprime manufactured two versions of the Isoprime, the JA series and the JB series.

17. LNDD has two Isoprime instruments, a JA series instrument and a JB series instrument. Throughout my declaration, I will reference the older, JA series instrument at LNDD as the Isoprime1. Similarly, I will reference the newer, JB series instrument at LNDD as the Isoprime2.

18. The JA series instrument preceded the JB series instrument. I helped build the very first JA series machine in 1997. The JA series instrument, was in essence, a temporary version of the Isoprime instrument. It was used as a platform for the transition for the instrument's use from OS2 to Windows software. Only a few instruments were actually built, and most of those were later converted to JB instruments. I have personally viewed the Isoprime1 at LNDD, and it bears the marking JA-10, which is one of the ways that I know it is one of the very few nonconverted JA instruments currently in existence.

19. I also helped develop the improvements to the JB series machine. Specifically, I helped design the combustion interface for the JB series instrument, which takes the sample and converts it into CO<sub>2</sub>. The JB series had an improved head amplifier, different resistors, fundamental way in which the signal is measured. The better the resistor, the better the results. The JA uses glass valves. The JB uses a solid state resistors.

20. Based upon my experience building and designing Isoprime instruments, I am intimately familiar with all aspects of the operation of the JA instrument and the JB instrument.

21. The JB series is a more accurate instrument than the JA series instrument because the JB series can acquire smaller pieces of data more accurately, and therefore can display the chromatographic information with greater resolution. For example, a baseline in a chromatogram shown in the JA series will appear with less detail and less resolution than a baseline in a chromatogram show in the JB series. By this comment, I must emphasize that the

test results acquired by LNDD's Isoprime2 are not accurate and reliable, for the reasons set forth below. The JB series is a more accurate instrument if the data acquired is more accurate. However, in this case, due to poor data acquisition, the isotope ratios and chromatograms calculated by the Isoprime2 are unreliable and of no evidentiary value.

22. The Isoprime instrument and the Finnegan instrument GC/C/IRMS are very different instruments in terms of quality. The Finnegan instrument used by Dr. Brenna in his laboratory per his testimony is substantially more expensive than the Isoprime instruments and is better built and engineered.

### **BACKGROUND OF THE TESTING IN THIS CASE**

#### **The Testing of Sample 995474**

23. The samples at issue in this case are all from the 2006 Tour de France (the "Tour"). Sample 995474 is from Stage 17 of the Tour.

24. Sample 995474 was provided by Appellant on July 20, 2006.

25. Sample 995474 was one of eight samples Appellant provided during the Tour.

26. Sample 995474 was tested at the Laboratoire National de Dépistage et du Dopage ("LNDD").

#### **The Retesting Procedure**

27. The seven samples Appellant provided during the Tour (in addition to Sample 995474) were provided at the end of the following stages: Stage 2 (Sample 995642 on July 3), Stage 9 (Sample 994203 on July 11), Stage 11 (Sample 994277 on July 13), Stage 12 (Sample 994276 on July 14), Stage 15 (Sample 994075 on July 18), Stage 19 (Sample 994080 on July 22), and Stage 20 (Sample 994171 on July 23). *See* Ex. 41, USADA0412, 0419, 0426, 0433, 0440, 0447, 0458, 0465.

28. Each of these seven other samples was tested at LNDD. *See* Ex. 41, USADA0415, 0422, 0429, 0436, 0443, 0461, 0468.

29. None of these seven other samples displayed an AAF in the test of the A Sample. As such, during the Tour: (1) Appellant was not notified of any issue related to anti-doping control and (2) no further testing of the B Samples was conducted.

30. Following extensive briefing and a ruling from this Panel, USADA commenced the retesting of the B Samples from each of the other seven stages.

31. The retesting began at LNDD on April 16, 2007.

32. I was present at the retesting process from April 16 to 20, 2007 to serve as an observer on behalf of Appellant. I am aware that Paul Scott stayed on to continue the observation for a few extra days.

33. The retesting was not done on the same instrument as the IRMS tests for Sample 995474. Sample 995474 was tested on the Isoprime1. The retesting was done on LNDD's Isoprime2. I do not know why the retesting was done on the Isoprime2, instead of the Isoprime1. Likewise, I do not know why LNDD chose to use the older JA instrument to test the Appellant.

34. The results of the retesting are summarized at Exhibit GDC01363.

#### **The Reprocessing of the Electronic Data Files**

35. I am aware that the Panel ruled, following the exchange of motions between Appellant and Appellee, that Appellant had the ability to examine the Electronic Data Files ("EDF") for Sample 995474 in preparation for trial. Following this order, the Electronic Data Files ("EDFs") of Sample 995474 were extracted and analyzed at LNDD subject to the limitation that Appellant was not allowed direct access to the EDFs.

36. The EDFs are the raw data files, in electronic form, of the results of the IRMS tests conducted on Sample 995474.

37. The extraction and analysis of the EDFs was observed by representatives for Appellant (me and my colleague Dr. Will Price) and for USADA (Dr. Larry Bowers and Dr. Jeanine Jumeau), as well as by the Panel's expert, Dr. Francesco Botrè.

38. On April 26, 2007, Dr. Botrè and representatives for both parties arrived at LNDD. They were told that: (1) the EDFs from the IsoPrime1 (the instrument used to test Sample 995474) had already been copied to an archive CD and (2) the original information on the IsoPrime1 hard-drive had been erased. Furthermore, the actual time and date stamps related to the creation of each of the EDFs was destroyed in the copying process, so that it was impossible to tell when those EDFs were created.

39. Also on April 26, 2007, the log files from the IsoPrime2 were copied onto a separate CD. These log files are a record of the testing procedures performed in conjunction with the retesting of the other samples taken from Appellant during the Tour -- Stage 2 (Sample 995642 on July 3), Stage 9 (Sample 994203 on July 11), Stage 11 (Sample 994277 on July 13 ), Stage 12 (Sample 994276 on July 14), Stage 15 (Sample 994075 on July 18), Stage 19 (Sample 994080 on July 22), and Stage 20 (Sample 994171 on July 23). The log files are Exhibits GDC01056-01075.

40. On May 4, 2007, Dr. Botrè and representatives for both USADA and Appellant arrived at LNDD. LNDD technicians then performed a series of operations on the EDFs, some of which were at my direction. Claire Frelat performed these operations on the Sample B for Sample 995474 and Cynthia Mongongu performed these operations on Sample A for Sample 995474.



41. Because the LNDD technicians did not know how to transfer data from the CD onto the computer operating the IsoPrime1, I performed this part of the procedure.

42. The first operation occurred at Dr. Botrè's direction. This operation involved LNDD's attempt to reproduce the original test results using the same processes used to determine those results. In producing both the original and reprocessed test results, LNDD CIR test technicians used a manual processing technique, which included both: (1) manual adjustments to the background of the chromatograph, and (2) manual integration of peaks. Manually adjusting the background involves adding and deleting defined background points. Tr. of R. at 1763:1-10. Manual integration of the peaks involves manually defining the start and end point of each peak. In attempting to reproduce the original CIR test results from Sample 995474, LNDD CIR technicians again used a manual processing technique. However, despite twenty-two attempts to do so, LNDD technicians were unable to reproduce the original test results. The chart showing the number of reprocessing attempts is Exhibit GDC01365. The chart showing the results of the reprocessing is Exhibit GDC01350.

43. In addition, three other sets of values were obtained using three distinct processes: (1) delta-delta values were calculated using the automatic background subtraction embedded within the software program, (2) delta-delta values were calculated with the automatic background subtraction disabled and (3) delta-delta values were calculated using the Masslynx software loaded onto the IsoPrime2. The delta-delta value equals the delta value of the target compound minus the delta value of the endogenous reference compound. The delta-delta value is the value used to determine an AAF and is expressed as the "per mil" value. The chart showing the results of this reprocessing is Exhibit GDC01350.

44. LNDD IRMS technicians did not know how to convert the EDFs into data readable by Masslynx. Therefore, I performed this part of the operation. Tr. of Proceedings at 1764:4-10.

**MY TESTIMONY BELOW**

45. I have read my direct examination and cross-examination from the AAA proceeding below, and adopt it in its entirety. I would like to make one additional clarification of that testimony, and it is as follows.

46. During my cross-examination, I testified about linearity specification as it related to the Isoprime1. For reference, I had obtained an Isoprime specification sheet off the manufacturer's website. I testified that this Isoprime specification sheet provided data that would be useful in analyzing the lack of linearity of the Isoprime1. In AAA Award, the majority panel criticized me for using an instrument specification from the manufacturer "for a different version of the instrument." AAA Award, paragraph 222, *see also* Tr. of Proceedings 1995: 1 – 9. Contrary to the majority panel suggestion, this specification was for all versions of the Isoprime. The Panel may have been confused because the graphic on the web depicted a new Isoprime – as one might well expect in a promotional document – but to be very clear, the specifications for all Isoprime machines are the same.

47. The data in the Isoprime specification sheet that I referenced during the AAA panel is entirely correct, and there are two sources that show that the specification applies to the Isoprime1. The first is the Engineer's Handbook for the JA series instrument, which shows that the specification is exactly the same as the specifications referenced to the AAA panel below. The second is a pamphlet from the manufacturer stating, again that the specification is exactly the same as the specifications referenced to the AAA panel below.

## THE DECLARATION OF KEITH GOODMAN

48. I have reviewed the declaration of Keith Goodman in its entirety and agree with all of the statements contained his declaration (except for the personal background info), with the modifications set forth below. Indeed, I would be perfectly comfortable in adopting those paragraphs as part of my declaration, but in order to prevent this declaration from being unnecessarily lengthy, I felt it was better to simply adopt the relevant paragraphs contained above. The modifications are as follows:

49. Wherever Dr. Goodman's declaration references "As a director of a laboratory" I would replace it with "As a designer and builder of carbon isotope ratio instruments." I also note that on the quality control issue, my familiarity with the Isoprime leads me to believe that appropriately-conducted quality controls are especially important with for the Isoprime instrument used by LNDD to test Sample 995474. I reference the fact that LNDD was operating this instrument with older software, the Optima GC 1.67-2 software, that was not the Isoprime IRMS instrument. This software is now 10 years old and can be identified by its code number 1.67-2.

50. I have also read the discussion regarding the use of two different columns by LNDD in the GC/MS phase and the GC/C/IRMS phase. I have also read the sections in the Appellee Brief that indicate that USADA intends to call a witness who will say that he put in the same column, but simply failed to properly note the method file to reflect that he put in the same column. As a laboratory scientist, it is simply unreasonable to believe that a laboratory technician would not have noticed that the method file had an improper entry noting that different columns were present, and remained uncorrected. On the other hand, if it were true that the method file had an improper entry and went uncorrected, it shows that the laboratory

technicians were not competent to perform the basic maintenance and operation of the instrument, a conclusion that I am able to reach because of the points below.

### **ADDITIONAL POINTS**

#### **LINEARITY**

51. One of the instrument checks supposedly performed by LNDD was monthly linearity tests. Linearity is the ability of a GC/C/IRMS instrument to accurately quantify the isotopic ratio of each testosterone metabolite and endogenous reference compound regardless of their concentration in the sample. In other words, linearity is the ability of the instrument to accurately measure isotopic ratios of the target analytes whether there is a large or small amount of the analyte in the sample. Therefore, to test the linearity of the instrument, the instrument manual instructs the laboratory to run a method file that comes with the instrument. *See* GDC 522, Page 32 of the Checking the System Prior to Running a Sample Section. The method file causes the CO<sub>2</sub> reference gas to be injected into the isotope ratio mass spectrometer. This injection is repeated nine more times within a set period in between each injection. While the method file is being run, the operator is instructed to vary the pressure of the CO<sub>2</sub> reference gas such that each injection is at a different concentration, with each change varying randomly, such that the entire response range is from 1 to 10 nanoamps. Finally, instrument specifications from the manufacturer indicated that the difference over the entire range of the run should be no more than 0.3%.

52. LNDD's SOP regarding linearity requires that the linearity runs be performed once each month. (Ex. 26, LNDD0547). The document package indicates that they were not. In the first instance, I believe that running a linearity test only once per month is remarkably insufficient to ensure that the instrument is nonlinear. In fact, the manual of the IsoPrime

instructs that laboratory to perform a linearity check before each run. Because the failure of the instrument to be linear has a substantial effect on the test results, generally accepted scientific principles and methodology also require that linearity tests should be performed before each run similar to that of other quality controls. Especially when the test results are going to be used in a disciplinary hearing. Further, performing a linearity test before each run on the IsoPrime instrument is necessary because the IsoPrime JA and JB series instruments have a well known problem with drifting in and out of linearity. Therefore, establishing that the instrument was linear several days to weeks earlier or later, does not provide any confidence that the instrument was linear when Mr. Landis' Stage 17 sample was analyzed.

53. Nonetheless, regardless of whether LNDD's SOP is scientifically valid, pursuant to the information in the document package, LNDD failed to follow its own SOP. Per the document package, LNDD's linearity testing dates were: (1) June 26, 2006, roughly one month before the Stage 17 A Sample was tested (Ex. 26, LNDD0313, 0315, 0317), (2) July 31, 2006, roughly one week after Mr. Landis' A Sample was tested (Ex. 26, LNDD0320, 0322, 0324) and (3) September 25, 2006, roughly a month-and-a-half after Mr. Landis' B Sample was tested (Ex. 26, LNDD0327, 0329, 0331). The July 31, 2006, linearity run was performed more than a month after the June 26, 2006 linearity check. Further, LNDD did not perform any linearity test in August 2006. I am aware that on February 27, 2008, counsel for USADA produced a linearity test that is purported to be the linearity test performed on August 21, 2006. I find that this recent production of the linearity test is rather convenient in light of the AAA panel's decision finding that LNDD failed to follow its own SOP during the appealed case.

54. USADA asserts that LNDD's SOPs establish "no specific linearity requirements" other than that the test is to be performed monthly, which as I note above (pursuant to its own

documents), it did not follow. Appellee's Brief at 62. This is incorrect. LNDD's SOP sets forth the specific method in which the linearity test is to be performed and the acceptance criteria for this test. However the method and acceptance criteria are not in compliance with the specifications in the instrument manual. First, the SOP does not require that the test be performed over the full range of 1 nanoamp to 10 nanoamp as required by the operating manual. The SOP allows the operator to vary the range from 2 nanoamps to 9.5 nanoamps. The SOP also contradicts the manual by instructing the operator to vary the reference gas pressure every other injection, instead of on every injection. By only varying the pressure every other injection, the amount of available data points is effectively reduced by half. This reduction of available data makes it more likely that a nonlinear instrument would pass LNDD's linearity test. The last deviation between the instrument manual and the LNDD SOP is that instead of graphing the results and measuring the slope of the line, LNDD simply requires that the difference between the greatest isotopic value and the smallest isotopic value be less than 0.7‰. The acceptance criteria is radically more lenient than that found in the manual. In fact, given that LNDD's measurement of uncertainty in single samples is 0.5‰, it is remarkable that the acceptance criteria is so lenient. Further, the 0.7‰ is contrary to the linearity criteria set forth in the paper co-authored by Dr. Jacques de Ceaurriz in which the linearity acceptance criteria at LNDD is listed as 0.3‰. *See* Ex. 26, LNDD0210.

55. The deviations between LNDD's testing procedure and acceptance criteria from that described by the instrument manual permits a nonlinear instrument to easily pass as linear under LNDD's SOP. LNDD's failure to follow the strict instrument manufacture's specifications with respect to linearity is not surprising given the extraordinarily relaxed quality

control standards and acceptance criteria discussed in Keith Goodman's declaration, which I concur with.

56. Even based on the limited data that LNDD's linearity test obtains, the instrument is not linear by the instrument manufactures specifications.

57. I have reviewed all IsoPrime1 linearity results provided by LNDD, including the suspicious newly-produced linearity runs from August 21, 2006, and in five of the twelve runs, the IsoPrime1 was not within the manufacturer's specifications.

58. The runs not within specification are found at LNDD0313, LNDD0315, LNDD2020, LNDD2021 and LNDD0329.

59. Based on the calculations above, the IsoPrime 1 used by LNDD is not linear.

60. USADA claims that the "AAA Panel correctly noted that under the linearity specification set forth in the operating manual for this instrument, that the instrument was linear." Appellee's Brief at 63. This is simply not true. The AAA panel, in fact, said nothing about the operating manual. Instead, the AAA panel simply accepted LNDD's SOP as being a valid means of measuring the Isoprime's linearity. For all the reasons I have stated above, the conclusion of the AAA panel was a mistake. But irrespective of that mistake, the AAA panel certainly never drew any conclusions about the linearity of the Isoprime under the manufacture's specifications. Using the manufacturer's specifications, LNDD's Isoprime is not linear under any of LNDD's test.

61. Additionally, USADA argues that "the ISL does not establish any linearity requirements" and that for this reason, LNDD's failings with respect to linearity are immaterial. Appellee's Brief at 63. That the ISL does not include a section requiring a laboratory to perform linearity checks is evidence that the ISL is not an exhaustive document and that compliance with

the ISL alone does not guarantee reliable and accurate results. A linear instrument is essential in obtaining accurate and reliable test results. USADA's own expert, Dr. Brenna, has testified as to the importance of using a linear instrument. Tr. of Proceeding at 323:11-15. Accordingly, whether or not linearity is required by the ISL should have no bearing on this case, ensuring that the instrument is linear is required by generally accepted scientific principles and methods.

62. I have reviewed Dr. Brenna's testimony in the previous proceeding regarding linearity and his testimony is not relevant or applicable to whether the IsoPrime 1 was linear at the time Mr. Landis' Stage 17 sample was analyzed. Dr. Brenna opined that based on his experience with CIR testing, "it's rare the machine is not linear." Tr. of Proceeding at 322-328. This testimony is immaterial because Dr. Brenna's laboratory does not use the IsoPrime instrument and his testimony has not indicated that he has any experience using an IsoPrime instrument either. The instrument that Dr. Brenna's laboratory uses, the Thermo-Finnegan, measures linearity using entirely different methods, parameters, and criteria. Further, unlike the IsoPrime JA and JB series, the Thermo-Finnegan isotope instruments have no history or well-known problems maintaining linearity. With the instrumentation used by Dr. Brenna, it is no surprising that Dr. Brenna does not have "experience" with linearity problems when performing the CIR test. His "experience," however, does nothing to alter the fact that the IsoPrime in fact does have a tendency to drift in and out of linearity. And critically, Dr. Brenna's "experience" does not change the fact that LNDD's linearity data for the IsoPrime does not meet the manufacture's specifications.



**LNDD GC/IRMS STAFF WAS NOT COMPETENT TO PERFORM THE CIR ANALYSIS**

63. My conclusions about the CIR test results being inaccurate, unreliable and of no evidentiary value is supported by the lack of competence of the LNDD staff who performed the CIR test.

64. I have managed a laboratory, and am intimately familiar with the necessity of properly performing the tests on the Isoprime instrument. In my opinion, laboratory staff must be competent to perform the CIR test and quality controls associated with the CIR test. I recognize that maintaining good training protocol and laboratory standards is critical to achieving good laboratory test results.

65. In my personal observations of LNDD staff and the record in this case, I have seen substantial and persuasive evidence concerning: (1) various other errors committed by LNDD technicians, (2) the failure of LNDD technicians to understand critical hardware and software and (3) other indicators that LNDD technicians lack of competence in the IRMS equipment and in its operation.

66. In my opinion these observations and errors should give this Panel no assurance in the accuracy or reliability of LNDD's test results. These observations are as follows:

67. LNDD had no training program for the operation of the two GC/C/IRMS instruments in its possession. In the AAA proceeding below, Dr. Claire Buisson testified on cross-examination that: (1) she was the supervisor of CIR testing at LNDD. *See* Tr. of Proceedings at 927:10-12; and (2) she did not directly train Claire Frelat and Cynthia Mongongu, the only technicians who performed CIR testing in this case. *See* Tr. of Proceedings. at 929:19-930:1.

68. The effect of the lack of a training program was made clear when Claire Frelat testified in the AAA proceeding below that she defined a significant difference in the final per mil values in the CIR testing process as between 1.5 and 1.6. When asked where the SOP defines a significant difference as 1.5 or 1.6 per mil, she stated that it was "not written anywhere – my answer was really concerning myself." *See* Tr. of Proceedings at 729:9-11.

69. In the AAA proceeding below, Claire Frelat, who was the LNDD technician who performed the CIR analysis of Appellant's Sample B of Sample 995474, testified that she had only started working on the Isoprime independently four months prior to analyzing Appellant's B Sample and that her training consisted only of supervised running of blanks for approximately one week. She conceded that she never attended a class or seminar or had other formal training. Tr. of Proceedings 681 – 683.

70. As described above, I attended both the retesting and reprocessing process described above. On both occasions, I had the opportunity to observe and speak with the LNDD technicians about the IRMS test process. I conclude that IRMS technicians Claire Frelat and Cynthia Mongongu were not competent to run the IsoPrime1 and IsoPrime2 instruments unsupervised nor seemed to know how the software worked. *See* Tr. of Proceedings at 1845:5-12. They regularly sought help from others. The following evidence corroborates my conclusion.

71. I also note that LNDD did not have the manual for its Isoprime instrument, as admitted by LNDD in its discovery responses. Ex. B to USADA's Response to Respondent's Second Request for Production of Documents ¶ 4 at 9. I emphasize that the Isoprime instrument is a complex instrument and that it is essential to have an operating manual when using the instrument.

72. A good example of what can happen when the a laboratory does not have the user manual is shown by LNDD's operation of the IsoPrime1 at a Penning pressure in excess of the maximum allowable pressure. When it conducted the CIR analysis of Sample 995474, LNDD operated the IsoPrime1 at a Penning pressure of  $5.2 \times 10^{-6}$  millibars. *See* Ex. 24, USADA0176.

73. The IsoPrime manual specifies that:

Wait until the pressure shown on the Penning gauge falls below  $5E-6$  mbar. If there are no major leaks along the inlet capillaries the pressure will fall quickly and settle to the operating pressure between 2 and  $4E-6$  mbar. Failure to reach the operating pressure indicates major leaks. These must be cured before proceeding any further.

Caution: Ensure that the Penning gauge reading is less than  $5E-6$  mbar.

74. *See* Ex. GDC00522.

75. Operating the GC/C/IRMS instrument at pressures of  $5E-6$  millibars or above can result in reduced sensitivity and precision of the reported results and in increased variance values. I testified to this fact during the AAA proceeding. *See* Tr. of Proceedings at 1800:7-1802:15.

76. In addition, the fact that USADA and LNDD had no understanding of the indicator light on the control unit for the pump on the GC/C/IRMS instrument should give the CAS Panel no assurance in LNDD's ability to operate its GC/C/IRMS instrument properly.

77. USADA has asserted in its briefs that the GC/C/IRMS instrument has a light that indicates when the operating pressure is too high, and that "the light turns yellows as a warning

followed by red and instrument shutdown." USADA's Pre-Hearing Brief ¶ 106. This assertion was accompanied by a picture of the light.

78. This is completely untrue. The light that USADA is referring to is on the control unit for the pump, and is lit when the pump is operating at a satisfactory speed. The light does not change color and there is no warning. If there is a huge leak (low pressure) the light will go out. *See* Tr. of Proceedings at 1788:10-1789:6.

79. LNDD's lack of familiarity with its own instrument indicates that LNDD has no ability to operate its IRMS instrument properly.

80. Lastly, LNDD did not understand that it had to remove the lifting rings on its IsoPrime2 instrument before operation. This shows that LNDD does not fundamentally understand its machine or how it operates.

81. The lifting rings are large metal rings, as shown in Exhibit GDC00734, which are designed to be used solely to install the GC/C/IRMS instrument. *See* Tr. of R. at 1784:3-13. They must be removed prior to operating the instrument. *Id.* at 1786:12-17. I took the picture that is GDC 00734 when I was in LNDD.

82. The GC/C/IRMS instrument uses a large magnet to produce accurate CIR results. The presence of so much metal so close to the magnet interferes with the accuracy of the results. *See* Tr. of R. at 1785:6-12. LNDD's lack of familiarity with its own instrument should give the CAS Panel no assurance in LNDD's ability to operate the GC/C/IRMS instrument properly.

83. Based upon the foregoing, I conclude that the LNDD staff was not competent or experienced enough to (1) perform the manual integration described by USADA as a "quality control" method, (2) perform the judgments necessary to perform any non-automatic

manipulation of data and (3) perform generally the CIR test in this case to achieve accurate or reliable test results.

### **DATA DELETION**

84. As described below, I have seen numerous instances of data deletion in both the testing of Sample 995474 and the analysis of the other stages of the Tour de France. Because Sample 995474 was tested on the Isoprime1, I can only see examples of data deletions from the document package. However, with respect to the testing of Stage 2 (Sample 995642 on July 3), Stage 9 (Sample 994203 on July 11), Stage 11 (Sample 994277 on July 13 ), Stage 12 (Sample 994276 on July 14), Stage 15 (Sample 994075 on July 18), Stage 19 (Sample 994080 on July 22), and Stage 20 (Sample 994171 on July 23), I was able to view instances of data deletion from the log files because these stages were tested on the Isoprime2. The Isoprime2 has a log file that is retained and can be examined. The log file is a history of all the operations on a particular sample, including instances of deletion. These instances of deletion are shown by the fact that a run is resaved with the same file name such that the original file is not saved to the hard drive. Thus, the original file is overwritten and lost forever. As described more fully below, there were multiple instances of data deletion in both the testing of Sample 995474 (using Isoprime1) as well as the testing of other stages (using Isoprime2).

85. As an engineer intimately familiar with the Isoprime instrument, I conclude the numerous instances in which LNDD deleted data in this case constitutes violations of the ISL and a deviation from good laboratory practices such that it forms an independent ground upon which to question both the competence of LNDD staff and the laboratory test .

86. Specifically, I believe that (1) LNDD failed to comply with ISL 5.4.4.4.1.4, which requires that data entry be recorded with an audit trail, when its technicians deleted data during

the testing of Sample 995474 and during the retesting process, (2) LNDD failed to comply with ISL 5.2.6.1, which requires that the laboratory have documented procedures to ensure a coordinated record related to each analyzed sample, when its technicians deleted data during the testing of Sample 995474 and during the retesting process.

87. The destruction of data in this case is consistent with LNDD's inability to properly conduct testing procedures, to achieve consistency in its testing processes or to produce accurate and reliable test results.

88. The fact that the destruction and deletion of data involved quality control measures supports my lack of confidence in the accuracy or reliability of the test results in this case.

89. Not all instances of destruction of data constitutes an ISL violation. For example, there might not be a violation if sequence files were deleted, but the sequence was rerun in its entirety and the deletion was properly recorded. That is not the situation in this case. Here, LNDD manipulated the destruction and deletion of data, such that the total picture presented by LNDD made the testing and IRMS sequences look as if they were uninterrupted.

1.1. Before I describe the data deletion in detail, let me explain the possible reasons for data deletion in the IRMS test. These reasons include an attempt to hide the fact the instrument was not operating properly. Specifically, these data deletions would cover up instances in which quality controls and other tests fall outside of expected or anticipated results. Rerunning the samples and deleting the inconsistent results allows LNDD to make the test processes appear to be consistent with known quality controls or expected results. The other possibility is that the LNDD staff simply do not understand that rerunning quality control standards until they achieve expected result is wrong. Indeed, there is some evidence to this effect, when Cynthia Mongongu

testified that controls were re-run because the results were "not correct." *See* Tr. of Proceedings at 595:14-22.

90. The first example of data destruction occurred in Sample 995474. For both the A and B Samples, there was a summary page entitled "Batch Data Processing Results." This summary page contained values reflecting the individual test results from each of the tests conducted in the Sample A and Sample B sequences. For Sample A, the summary page is Ex 24, USADA0155. For Sample B, the summary page is Ex 25, USADA0359. In both the Sample A and the Sample B sequences, it is clear that LNDD cherry-picked the results that appear on the "Batch Data Processing Results" page. LNDD's manipulation is clear because the individual test results on the "Batch Data Processing Results" page do not match the results on the individual test pages that were included in the document package.

91. For Sample A, the results of the Mix Cal IRMS 003-2, Exhibit 24, USADA0179, do not match the results shown on the "Batch Data Processing Results" page. Ex. 24, USADA0155.

92. For Sample B, the results of the Mix Cal IRMS 003-3, Exhibit 25, USADA0359, do not match the results shown on the "Batch Data Processing Results" page. Ex. 25, USADA0331.

93. Also for Sample B, the results of the Mix Cal IRMS 003-2, Exhibit 25, USADA0358, do not match the results shown on the "Batch Data Processing Results" page. Ex. 25, USADA0331.

94. There is no record in the document package of all the test results from the summary "Batch Data Processing Results" page for either Sample A or Sample B. The Panel

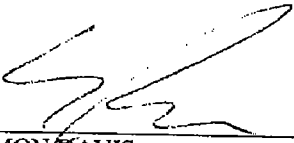
finds that this evidence shows cherry-picking of data and deletion or destruction of the original data.

95. The second example of data destruction also occurred in conjunction with the testing of Sample 995474. For the Sample A and Sample B sequences, there are time gaps: 5 hours and 14 minutes and 4 hours and 40 minutes, respectively. I note that in the record, on cross-examination, Claire Frelat testified that controls were re-run because the results were "not correct." See Tr. of Proceedings at 595:14-22.

96. The third example of data destruction occurred in conjunction with the retesting process, during which the B Samples taken on July 3 (Sample 995642), July 11 (Sample 994203), July 13 (Sample 994277), July 14 (Sample 994276), July 18 (Sample 994075), July 22 (Sample 994080) and July 23 (Sample 994171) were tested.

97. The IRMS testing of these samples was conducted on LNDD's IsoPrime2 instrument. The IsoPrime2 is able to retrieve a record of all operations performed in connection with the testing of a particular sample. These files, called "log files," were recovered for Sample 995642, Sample 994203, Sample 994277, Sample 994276, Sample 994075, Sample 994080 and Sample 994171. See Exs. GDC01056-01075.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. This declaration was executed on March 7, 2008 in Holmes Chapel, U.K.

  
SIMON DAVIS