



Tribunal Arbitral du Sport
Court of Arbitration for Sport

CAS 2010/A/2162 Doping Control Centre, Universiti Sains Malaysia v. WADA

ARBITRAL AWARD

delivered by the

THE COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President: The Hon. Michael **Beloff** Q.C. Barrister, London, England

Arbitrators: Prof. Richard H. **McLaren**, Barrister, London, Canada
Mr Romano **Subiotto** Q.C. Barrister, Brussels, Belgium

in the arbitration between

Doping Control Centre University Sains Malaysia, Malaysia
represented by Mr Mark Gay, Attorney-at-law in London, England

Appellant

and

World Anti-Doping Agency, Switzerland
represented by Richard Young, Attorney-at-law in Colorado Springs, United States of
America

Respondent

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1. INTRODUCTION

- 1.1 This is an appeal by *Doping Control Centre University Sains Malaysia* (“the Centre”) v *World Anti-Doping Authority* (“WADA”) against a decision of WADA dated 17th June 2010 to revoke the WADA accreditation of the Centre (“the Decision”) for, *inter alia*, breaches of the International Standard for Laboratories (“ISL”).
- 1.2 This is the first time that WADA has taken such a step, and the appeal engages the important issue of when and in what circumstances it is appropriate for it to do so. This matter was forcefully argued on both sides by experienced advocates.

2. PARTIES

- 2.1 The Centre was, until the revocation complained of, the only WADA accredited Centre in South East Asia.
- 2.2 WADA is a Swiss private law foundation whose headquarters are in Montreal, Canada, but whose seat is in Lausanne, Switzerland. It is a global regulator whose self-proclaimed mission is
- “To promote, co-ordinate and monitor the fight against doping in sport in all its forms”.*

3. BACKGROUND FACTS

- 3.1 The circumstances set out below are a summary of the main background facts as established on the basis of the written submissions of the parties and the evidence examined in the course of the proceedings.
- 3.2 On 28th May 2004, WADA published technical document TD2004NA. It provided so far as material:

“WADA Technical Document - TD2004NA

<i>Document</i>	<i>TD2004NA</i>	<i>Version Number:</i>	<i>1.0</i>
<i>Written by:</i>	<i>WADA Laboratory</i>	<i>Approved by:</i>	<i>WADA Executive</i>
<i>Date:</i>	<i>28 May, 2004</i>	<i>Effective Date:</i>	<i>13 August, 2004</i>

REPORTING NORANDROSTERONE FINDINGS

1. Introduction:

This document has been established to harmonize analysis and reporting of norandrosterone Adverse Analytical Findings by Laboratories.

The administration of 19-norsteroids such as 19-nortestosterone (nandrolone), 19-norandrostene-3,17-dione and 19-norandrostene-3,17-diol (delta-4 and -5 isomers) has been shown to lead mainly to the excretion of 19-norandrosterone (NA), 19-noretiocholanolone (NE) and 19-norepiandrosterone (NEA). The latter is found exclusively as its sulfoconjugate while the others are usually excreted as their glucuronide derivative. The sulfate derivatives, generally persistent, may be prevalent at the end of the excretion period.

After the i.m. administration of the long-lasting preparations of nandrolone, the metabolites may be detected for months, but metabolites formed after the oral ingestion are excreted massively in the first hours and remain detectable for only a few days. The excretion of 19-norandrosterone generally predominates that of the 5 β -isomer but inversed proportions have been reported in some individuals after oral administration either at the end of the excretion period or when Δ^5 -isomers of related norsteroids were taken (1). Norandrosterone is excreted during pregnancy and as a minor metabolite of norethisterone (2).

Special procedures such as more sensitive instrumentation, larger volumes of urine and more extensive sample clean-up were needed to detect, identify and quantify endogenous 19-norandrosterone (with limits of detection needing to be ten times lower than routine testing i.e. around 0.01 ng/mL). Under tightly controlled conditions, when 19-norandrosterone was detected in male specimens, it was found at mean values of less than 0,1 ng/mL which is well below the limit for reporting Adverse Analytical Findings (3). The physiological levels of 19-norandrosterone measured in samples collected from females are lower than 1 ng/mL, a maximum value of 0.8 ng/mL having been recorded during ovulation and correlates apparently with high levels of estrogens (4).

It appears that exercise does not increase physiological levels of 19-norandrosterone significantly and certainly not sufficiently to approach the threshold (5). A few urine specimens collected from sportsmen after the competition were reported to contain 19-norandrosterone in an amount approaching 1 to 2 ng/mL. However, these observations were made without adequate controls to exclude possible administration of norsteroids (6).

Although highly improbable, the intake of a substantial amount of non-castrated pig offal, in which the presence of norsteroids such as 19-nortestosterone has been demonstrated, could result in the excretion of 19-norandrosterone in an amount above the threshold during a few hours after ingestion (7).

Finally, the administration of some nutritional "supplements" can be the source of the presence of 19-norandrosterone in human urine samples (8).

2. Reporting requirements

The following requirements shall be applied by all Laboratories in their routine practice.

The Laboratory is to report as an Adverse Analytical Finding, any urine Sample from either a male or a female containing 19-norandrosterone (19-NA) at a concentration greater than 2 ng/mL. The specific gravity of the Sample is to be equal to or lower than 1.020 (measured in the Laboratory using an appropriate instrument). For urine Samples with a specific gravity above 1.020 a correction to the threshold is to be made. The correction of the threshold to take into account the specific gravity of the Sample will be calculated using the following formula:

Threshold 1.020 ng/mL = (Specific gravity of the sample - 1 / (1.020 - 1)) • 2 ng/mL

In addition to meeting the identification criteria (TD2003IDCR) the Laboratory must demonstrate that the concentration of 19-NA is above the threshold. The concentration of 19-norandrosterone must also be determined when it is lower than 10 ng/mL. The estimated expanded uncertainty must be considered for reporting.

More than one metabolite of administered norsteroids may be detected, but only the identification and quantification of 19-NA and its glucuronide (calculated as the total following hydrolysis of the glucuronide) is sufficient to report an Adverse Analytical Finding.

Before reporting an Adverse Analytical Finding in the urine Sample of a female, the Laboratory must take steps to ascertain that the presence of low levels of 19-norandrosterone is not due to pregnancy or to the intake of a birth control preparation or progestogen medication containing norethisterone. The Laboratory must document the absence of hCG i.e. less than 5 mIU/mL of immunoreactive hCG to exclude the possibility that an Adverse Analytical Finding had arisen because of pregnancy. The Laboratory will determine whether it is reasonable that the 19-norandrosterone was excreted in the amount measured consequent to the intake of

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norethisterone, by verifying that the major isomer of glucuroconjugated tetrahydronorethisterone is present. The Laboratory will in such a case add the following phrase to the report "could be compatible with a norethisterone treatment".

The official text of the technical document on the Reporting Norandrosterone Findings shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail."

3.3 In the fourth quarter of 2004, the Centre incorrectly reported a WADA quality assessment sample as containing the steroid DHEA ("the historic samples").

3.4 The WADA Centre Committee described this result as a "*potentially false positive*."

3.5 In May 2005, WADA assessed the Centre in a visit and noted that:

"The DHEA issue from 2004 PTO4 was especially of concern as it suggested a lack of understanding of the Technical Document on this endogenous steroid and possibly related compounds...

It was evident from the corrective actions presented to WADA that they had never seen a DHEA administration and had no idea of how to confirm its use... Suggest that they organize IRMS for any suspects before reporting a positive result."

3.6 Between 2004 and 2008, no concerns of WADA about the Centre were drawn to the Panel's attention,

3.7 In May 2005, WADA published an Explanatory Technical Note entitled "*Stability of 19 Norandrosterone Findings in Urine*" ("the Note"). It provided, so far as material, as follows:

"

MAY 13, 2005

EXPLANATORY TECHNICAL NOTE

Stability of 19-norandrosterone findings in urine

In 2004, D. Thieme et al.¹ reported the formation of 19-noretiocholanolone (19-NE) and 19-norandrosterone (19-NA) in some athletes' urine samples following incubation. Other groups recently confirmed this finding. This new phenomenon is extremely rare and appears to occur in particular conditions. At present, ongoing scientific investigations have not determined

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the origin of this phenomenon and therefore extra precautions have been taken to ensure that all evaluation criteria mentioned hereunder encompass a sufficient safety margin. Such level may be reduced in the coming months with the knowledge gathered from research which is presently being conducted.

The formation of 19-NE and 19-NA is observed under particular -conditions and in extremely rare urine samples-exhibiting as common features, the presence of low and comparable levels of 19-NA and 19-NE where $19\text{-NA}/19\text{-NE} < A/E$, and turbidity. Also, as an additional indication, in most cases, the specific gravity is high ($> 1,020^2$). To be 'extremely cautious we consider that it is possible that this phenomenon may be observed for sample where the 19-NA concentration is lower than 10 ng/mL. However, the low levels of 19-NA observed in such unstable urines are ranging from 0.1 to only a maximum of 5.4 ng/mL³ (corrected for a specific gravity of 1.020). The 19-demethylation of etiocholanolone (E) and androsterone (A) is observed after incubation of those specimens. The reaction, favouring the 5 β -over the 5 α -isomer, has been shown to depend on the temperature e.g., incubations at 37°C producing higher yields, and on the concentration of substrate.

When all the common features of "unstable" urine described are not observed and in any case when the level of 19-NA is above 10 ng/mL, adverse analytical findings shall be reported according to TD2004NA.

Urine samples below 10 ng/mL of 19-NA and exhibiting all of the common features described above shall be submitted to a stability test before reporting an adverse analytical finding."

- 3.8 On 22nd January 2009, disciplinary proceedings were instituted against the Centre. The attached case summary said:

"Issue: The Malaysian Centre in Penang reported a False Negative result for the 2008 WADA Double Blind PT Sample (details below). Incorporating 10 points for a false negative result (as noted in the ISL version 5.0 Annex A section 3.5), the Centre has accumulated a PT score of 32 points which is greater than the 30 point total threshold in the past 12 month period. Therefore, the Centre is considered non-compliant to the

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requirements of the WADA PT program and suspension of accreditation is to be determined”.

This was described in the Decision as “*non-compliance with the ISL, inter alia, the reporting of several unsatisfactory z-scores and two false negatives in the context of the External Quality Assessment Scheme (“EQAS”) conducted by WADA in 2008 and elaborated in the evidence of Thierry Boghosian, WADA’s laboratory accreditation manager, who said:*

“In the “blind” EQUAS, the laboratory reported an unsatisfactory z-score for a stimulant threshold substance (quantitative analysis) and failed to identify and report a beta-blocker (false negative in a qualitative analysis). In the double blind EQUAS the laboratory failed to identify and report an anabolic androgenic steroid, then a false negative.”

3.9 On 9th March 2009, the Disciplinary Committee of WADA recommended that the Chairman of the WADA Executive Committee “*render a decision based on the following terms:*

1. *That the WADA-accreditation of the Doping Control Centre Penang (DCCP) be suspended for a period of 2 months for any anti-doping activities.*
2. *That the suspension be effective immediately and be notified to all relevant national public authorities, national accreditation bodies, national anti-doping organizations, national Olympic committees, international federations and the International Olympic Committee, as stipulated in the ISL.*
3. *That during the period of suspension DCCP takes and documents corrective action(s) and that delay in submitting the proper corrective action(s) may lead to an extension of the period of suspension.*
4. *That during the period of suspension, an expertise based on an onsite visit be provided by an expert to be appointed by WADA and that all costs relating to such expertise be borne by DCCP.”*

3.10 On 20th March 2009, the Chairman of the Executive Committee, acting under delegated powers, incorporated the recommendation into a decision suspending the Centre for 2 months, effective immediately.

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3.11 On 6-7th May 2009, a site visit by WADA to the Centre took place. The report on the visit concluded:

“The WADA representatives were pleased to note that the Centre has been active during their suspension period to address these issues as well as maintain competence. As noted above, some work remains to be done and it is considered that the Centre personnel clearly understand the various issues and have the desire and the will to obtain and maintain the highest degree of quality. It is also noted that the authorities, including the university, NADO and Malaysian government have voiced their support for the Centre.

However, it is noted that many of the Centre corrective actions previously submitted lacked sufficient detail in the investigation for root cause as well as the preventive action. Therefore, a number of deficiencies have been detailed above for which remedial actions are to be continued and completed. It is further recommended that the Centre suspension be extended until such time that these issues are properly addressed and appropriate corrective actions have been completed.

Based on the Centre's acceptance and progress on many of the identified issues, the candid interactions with and the keen interest demonstrated by the Centre staff, it is the shared opinion of Dr. J Miller and T Boghosian that the Centre has taken the noted deficiencies into consideration and is willing and capable to appropriately address the issues identified”.

3.12 On 10th June 2009, the Centre's suspension was lifted. In the letter to Dr Latiff informing her of this action, the Committee recommended that the Centre undertake a fundamental change in the quality management approach, and expressed concern as to whether Dr Latiff's numerous responsibilities allowed her to give her sufficient support to senior staff.

3.13 On 1st October 2009, WADA circulated its technical document TD 2009 NA. It stated, *inter alia*:

“WADA Technical Document - TD2009NA

<i>Document</i>	<i>TD2009NA</i>	<i>Version</i>	<i>1.0</i>
<i>Written by:</i>	<i>WADA Laboratory</i>	<i>Approved by:</i>	<i>WADA Executive</i>
<i>Date:</i>	<i>September 15, 2009</i>	<i>Effective Date:</i>	<i>Jan 01, 2010</i>

HARMONIZATION OF ANALYSIS AND REPORTING OF 19-NORSTEROIDS RELATED TO NANDROLONE***1.0 Introduction***

This document has been established to harmonize the analysis and reporting of 19-norsteroids related to nandrolone as Adverse Analytical Findings by Laboratories.

The detection of the use of nandrolone and other 19-norsteroids is based primarily upon the identification of the main urinary metabolite, 19-norandrosterone (19-NA) in an amount greater than 2 ng/mL. More than one metabolite (e.g., 19-noretiocholanolone (19-NE)) of administered norsteroids may be detected and reported but the identification and quantification of the 19-NA metabolite only (derived from hydrolysis with β -glucuronidase) is sufficient to report an Adverse Analytical Finding.

2.0 Analysis***2.1 Identification and Quantification***

In addition to meeting the identification criteria described in the IDCR Technical Document, the Laboratory shall demonstrate that the concentration of 19-NA is above the threshold as set out in the MRPL Technical Document.

The quantification method used to calculate the concentration of 19-NA shall include or have the following characteristics:

- a deuterated internal standard (d_4 -19-NA-glucuronide is the preferred internal standard since it corrects for both the hydrolysis and other analytical steps);*
- a calibration curve at an appropriate range bracketing the estimated concentration of the analyte;*
- the use of appropriate quality control samples. For example, a negative control (without the presence of 19-NA or at a concentration < 1 ng/mL of 19-NA) and a positive control in the range of 3 to 5 ng/mL of 19-NA may be used. Alternatively, a freeze-dried urine reference material with approximately 2 ng/mL of 19-NA may be used (e.g., NMI Reference number MX002).*
- the expanded measurement uncertainty established by the Laboratory shall be less than ± 0.4 ng/mL at the threshold.*

2.2 Additional mandatory tests

The Laboratory shall also perform methods to test for pregnancy (e.g. hCG) and detection of tetrahydronorethisterone in urine Samples from female Athletes that have 19-NA concentrations greater than the threshold.

In extremely rare circumstances, 19-NE, and to a lesser extent 19-NA, can be formed by 19-demethylation of abundant endogenous steroids. These "unstable" Samples show the presence of low and comparable levels of 19-NA and 19-NE where the ratio of 19-NA/19-NE is less than the ratio of A/E (androsterone /etiocholanolone).

When concentrations less than 10 ng/mL of 19-NA are measured and the Sample shows the above feature of instability, the Laboratory shall perform a stability test. The stability test, which incorporates deuterated androsterone and etiocholanolone, has been described by Grosse et al [1]

- *If the stability test is positive (ie, Sample is "unstable"), the 19-NA result shall not be reported*
- *If the stability test is negative, the Sample shall have a GC/C/IRMS analysis performed on the 19-NA [2]. The criterion for an unstable urine by GC/C/IRMS shall be a difference of less than 3‰¹ between the measured δ values ($\Delta\delta = \delta_{\text{Androsterone}} - \delta_{19\text{-NA}}$) of 19-NA and androsterone. The GC/C/IRMS analysis should include the confirmation of the 19-NA peak identity (for example by GC/MS analysis).*
- *If the stability test is negative and the GC/C/IRMS test shows that the 19-NA is endogenous, the 19-NA result shall not be reported.*
- *If the stability test is negative and GC/C/IRMS test shows that the 19-NA is exogenous, the result shall be reported as an Adverse Analytical Finding.*

3.0 Reporting

(...)

3.1 Adjusted Thresholds

Only in the case of urine Samples measured with a specific gravity above 1.020 (in the Laboratory), an adjustment to the threshold shall be made to take into account the specific gravity of the Sample (since higher 19-NA concentrations have been associated with higher specific gravities (e.g. [3])), using the following formula:

$$\text{Threshold}_{\text{adjusted}} = [(\text{Specific gravity of the Sample} - 1) / (1.020 - 1)] \times 2\text{ng/mL}$$

3.2 Decision limit for 19-NA

A decision limit (DL)³ shall be established by adding the expanded measurement uncertainty determined from inter-laboratory WADA External Quality Assessment Scheme (EQAS) test results to the adjusted threshold. For the DL, $k_{0.95} = 1.645$ (one sided) shall be used. Based on this determination, a guard band of 0.4 ng/mL ⁴ shall be added to the adjusted threshold to determine the DL for an individual 19-NA test result⁵. The DL (after adjustment of the threshold for specific gravity) shall be included on the Laboratory test report. The DL shall be used to determine whether an Adverse Analytical Finding is reported for the Sample.

The result from a Sample shall be reported as an Adverse Analytical Finding if the measured mean concentration is greater than the DL unless a Sample meets one of the conditions discussed in sections 3.3 and 3.4 below. If the Sample does meet one of the conditions discussed in 3.3 and 3.4 below, then it shall be reported as an Atypical Finding and both the Testing Authority and WADA shall be notified of the results as a comment in the test report.

3.3 Female Athlete's Samples

When 19-NA exceeds the DL in the urine Sample of a female Athlete, the Laboratory shall include in the test report the results of tests to determine whether the 19-NA is due to pregnancy or to the intake of a medication containing norethisterone.

3.3.1 If hCG is present at a concentration less than 1000 IU/L, a comment or opinion shall be added to the test report indicating that the test was performed and that the 19-NA result was not consistent with pregnancy. An example would be:

"The Sample was analyzed for hCG and the concentration was less than 1000 mIU/mL; indicating that the 19-NA finding is not the result of pregnancy."

3.3.2 If another compound, such as pregnanediol, is used to detect pregnancy, a comment or opinion shall be added to the test report indicating that the test was performed and that the result was not consistent with pregnancy,

3.3.3 If tetrahydronorethisterone (metabolite of norethisterone contraceptive) is not detected in the urine Sample, a comment or opinion shall be added to the test report indicating that the test was performed and that norethisterone was not

present. An example would be:

"The Sample was found not to contain tetrahydronorethisterone by GC/MS analysis; indicating that the finding is not the result of an administration of a norethisterone contraceptive."

3.4 19-demethylation

In the rare event that a Sample is found to meet the common features of an "unstable" urine and therefore tested as in Section 2.2 above, the Laboratory shall include the results of the stability test(s) in the test report for the 19-NA Adverse Analytical Finding. Therefore, a comment shall be on the test report indicating that the stability test was performed and that the Sample is stable. In addition, the results of the GC/C/IRMS analysis, including the δ values for 19-NA and androsterone and the $\Delta\delta$ value shall be included in the test report."

3.14 From 1st January 2010, TD2009NA was in effect, but it was not until 22 March 2010 that the Centre became aware of this.

3.15 On 18th January 2010, the Scientific Project Manager of WADA wrote to the Centre stating that:

"[b]ased on the results, the performance of your Centre is in conformity with the WADA 2009 EQAS-04 expected results, and, therefore, no particular measures need to be taken at this time.

We also wish to advise you that the overall performance of the WADA-accredited laboratories in 2009 was reviewed by the WADA Centre Committee during its meeting on December 9-11, 2009. We are pleased to inform you that your Centre's good performance in the WADA External Quality Assessment Scheme over the period of the last twelve (12) months (from January to December 2009) has been noted by the Committee".

3.16 In the early part of 2010, the Centre had dealt with samples of two athletes, a footballer, Hassan Ghaly ("Ghaly"), and an unnamed female athlete ("the trigger samples") in a manner which raised concerns in WADA.

3.17 On 22nd March 2010, as already noted, the Centre became aware of TD2009NA.

3.18 In April 2010, the Centre Committee of WADA investigated the trigger samples.

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3.19 On 16th April 2010, before WADA's awareness of concerns over the trigger samples, but after the 2009 suspension, WADA Scientific Project Manager wrote to the Centre that:

"[b]ased on the results, the performance of your Centre is in conformity with the WADA 2010 EQAS-01 expected results, and, therefore, no particular measures need to be taken at this time".

3.20 On 21st April 2010, Dr Rabin, WADA Science Director, wrote to the Centre raising questions about sample 982747, the Ghaly sample.

3.21 On 22nd April 2010, the Centre replied to Dr Rabin.

3.22 On 29th April 2010, WADA informed the Centre that disciplinary proceedings had been instigated by reference to the trigger samples on ground of:

- *"Presumption of non-compliance with the ISL;*
- *Presumption of use of inappropriate methodology leading to reporting of false positive."*

It enclosed the Laboratory Committees Decision and Recommendations which read as follows:

"In consideration of these two cases, the WADA Centre Committee has recommended the following actions:

1. *Immediate Suspension of the Penang Centre for the analysis and reporting of Threshold Anabolic Androgenic Steroids.*
2. *A full on-site audit of the Centre's analytical and reporting procedures be conducted during the suspension period preferentially in conjunction with the Centre's ISO 17025 Accrediting Body.*
3. *Following the on-site audit, an assessment to be conducted by the WADA Centre Committee and recommendations provided to a Disciplinary Panel to consider re-instatement or revocation of accreditation".*

3.23 On 10th May 2010, the Centre submitted its answer. It said:

"[p]lease be informed that the issues raised in the case summary have been addressed in our response to Dr Rabin's letter dated 21 April 2010. With regards to this case please be informed that:

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1. *A CAR (Corrective Action Request) has been lodged on the 5 Jan 2010 in response to the case for the IAAF.*
2. *Following the B sample analysis on the 21 March 2010, a worksheet for the analysis and reporting of nandrolone was created based on the Technical Document TD2009NA; this procedural change is reflected in the subsequent analysis of two 19-NA suspects in April 2010 and included as part of the RCA activity.*
3. *The Centre has conducted a Root Cause Analysis (RCA) on the non compliances, from which the report may be reviewed during the site audit.*
4. *Communication issues as part of the RCA has resulted in the creation of another email address (usmdcc@gmail.com) for the Centre; this has been communicated to Mr Thierry Boghosian for inclusion as one of the official email addresses for all WADA communications to the Centre.*

Further to your request, please be informed that there is already a scheduled NATA audit planned in late June of 2010 with two technical assessors expected during that audit, one of whom will be auditing the sports section. We would also welcome a WADA site audit before the NATA audit if this is deemed possible”.

3.24 On 21st May 2010, the Disciplinary Committee recommended revocation of the Centre’s accreditation. It stated:

- “1. *Pursuant to article 4.4.11.3, WADA Executive Committee shall revoke the accreditation of a Centre if it determines that the revocation is necessary to ensure the full reliability and accuracy of doping tests.*
2. *According to the Disciplinary Committee Procedural Rules, any such decision is to be rendered on the basis of the recommendation made by the Disciplinary Committee.*
3. *Having carefully and thoroughly reviewed the full case file, including the answer submitted by the Malaysian Doping Control Center in Penang and the recommendation from the Centre Committee, the Disciplinary Committee is of the unanimous view that the Malaysian Doping Control Center in Penang seriously and repeatedly violated the ISL and relevant technical documents.*

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4. *In particular, the Malaysian Doping Control Center in Penang has:*
 - *Reported a false positive, which is a clear violation under ISL Annex A, provisions 3.4.2 and 3.4.5;*
 - *Did not proceed with the B sample confirmation in accordance with ISL 5.2.4.3.2.4;*
 - *Did not follow its own SOP during the confirmation procedure;*
 - *Violated the TD2009NA Version 1.0, which allows only reporting of atypical finding in condition indicative of pregnancy;*
 - *Violated the TD2009NA Section 3.2, which requires the determination of a decision limit.*
 - *Demonstrated serious issues in its management system which included a lack of appropriate internal control and inability to operate under the rules which were in force at the time.*
5. *The Centre Committee has recommended:*
 - a. *An immediate suspension of the Malaysian Doping Control Center in Penang for the analysis and reporting of threshold anabolic androgenic steroids.*
 - b. *A full onsite audit of the Centre's analytical and reporting procedures to be conducted during the suspension period, preferentially in conjunction ISO 17025 accrediting body.*
 - c. *Following the onsite audit, an assessment to be conducted by the WADA Centre Committee, and recommendation provided to a disciplinary panel to consider reinstatement or revocation of accreditation.*
6. *The Disciplinary Committee is, however, of the view that it is essential to the fight against doping that the highest degree of confidence be placed in the work of the accredited laboratories.*
7. *It considers furthermore that the false positive reported by the Malaysian Doping Control Center in Penang is not the result of a single mistake, but rather of an accumulation of a number of mistakes which demonstrates a serious lack of competence on the part of the Centre.*

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8. *The Panel is also concerned by the fact that none of these mistakes had been identified by the Centre while it was reviewing the documentation, and considers that this also demonstrates a clear lack of internal control.*
9. *The Disciplinary Committee notes, in addition, that the Malaysian Doping Control Center in Penang was suspended 12 months ago, and that despite such suspension, it has not improved its level of performance to the expected level.*
10. *On that basis, the Disciplinary Committee is of the view that a number of the conditions spelled out under provision 4.4.11.3 of the ISL are clearly met, and in particular, that the Malaysian Doping Control Center in Penang has seriously and repeatedly violated the ISL and relevant technical documents.*
11. *The Disciplinary Committee therefore recommends, in application of Article 4.4.11.3 that WADA Executive Committee to revoke the accreditation of the Malaysian Doping Control Center in Penang.*
12. *The Disciplinary Committee respectfully differs from the recommendation of the Centre Committee on the grounds that a suspension was already given to this Centre 12 months ago, with insufficient results, as noted above. It appears to the Disciplinary Committee that stronger measures be taken in the circumstances in order to ensure full reliability and accuracy of drug tests and the accurate reporting of test results in accordance with the requirements of the ISL.*
13. *The Disciplinary Committee draws the attention of the Executive Committee to the fact that under provision 4.4.11.3, that Committee will have the opportunity to determine what steps need to be followed by the Malaysian Doping Control Center in Penang prior to the possible granting of a new accreditation.*

On these grounds, the Disciplinary Committee unanimously recommends to the Chairman of the WADA Executive Committee:

1. ***The Malaysian Doping Control Center in Penang be immediately suspended.***
On these grounds, the Disciplinary Committee unanimously recommends to the WADA Executive Committee:
2. ***The accreditation of the Malaysian Doping Control Center in Penang be revoked."***

3.25 On 25th May 2010, the Chairman of the Executive Committee suspended the Centre's accreditation with immediate effect.

3.26 On 4th June 2010, the Director of the Centre wrote to WADA that it accepted having *“made a number of errors that warrant a suspension of accreditation until I can convince WADA that our performance meets, and will continue to meet, the high standards appropriately set by WADA in its important task of protecting the health of the athlete and the integrity of sport. However, I believe that to revoke the accreditation of my Centre is not proportionate with the shortcomings in performance. I hereby request the WADA Executive Committee to permit me to file a response to the allegations indicated in the Disciplinary decision before a final decision regarding the future of my Centre is made”*.

3.27 On 4th June 2010, the WADA Director of legal affairs replied:

“(…)

2. As per our procedure, you were given the opportunity to provide a full explanation prior to the Disciplinary Committee rendering its recommendation. You used that opportunity, and your correspondence was forwarded to the Disciplinary Committee, together with the entire file, prior to their meeting. The Disciplinary Committee has therefore taken its decision following a careful review of all the available facts.

3. The WADA Executive Committee has now been informed of the Disciplinary Committee's recommendation and will make a decision on such recommendation in accordance with the rules. Should the WADA Executive Committee decide to follow the Disciplinary Committee's recommendation, the accreditation of your Centre will be revoked. You will then have the right to appeal such decision, should you wish, to the Court of Arbitration for Sport within 21 days of notification”.

3.28 On 17th June 2010, the Chairman of the Executive Committee revoked the Centre's accreditation in the following terms:

“1. That the WADA accreditation of the Doping Control Center Penang (DCCP) be revoked for any anti-doping activities.

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2. *That the revocation of DCCP accreditation will enter into force within 30 days from notification of this decision. In the meantime, the suspension remains applicable and DCCP is therefore ineligible to perform analysis of doping control samples for any testing authority.*
3. *That WADA immediately notify all relevant national public authorities, national accreditation bodies, national anti-doping organizations, national Olympic committees, international federations and the International Olympic Committee, as stipulated in the ISL.*
4. *In accordance with article 13.6 of the World Anti-Doping Code, this decision may be appealed by DCCP before the Court of Arbitration for Sport (CAS) within 21 days of its notification”.*

3.29 On 30th July 2010, the WADA Scientific Project Manager wrote to the Centre:

“Based on the results, the performance of your laboratory is in conformity with the WADA 2010 EQAS-02 expected results, and, therefore, no particular measures need to be taken at this time.

The Document Package for the WADA 2010 EQAS-02 clenbuterol sample prepared by your laboratory has been found satisfactory by the WADA Laboratory Committee”.

3.30 Since the date of the decision, two further cases ("the subsequent samples") have caused WADA concern, and were relied on by them in their opposition to this Appeal.

3.31 As a result of disclosure in the course of the Appeal, yet further cases were drawn to WADA's attention and relied upon by them ("the disclosure samples").

3.32 The history of all trigger samples, the subsequent samples and the disclosure samples is set out in section 4.

4. **THE SAMPLES**

The trigger samples

(1) **Hossam Ghaly: Sample 982747**

4.1 Hossam Ghaly is a Saudi football player.

4.2 On 18th February 2010, the sample was received at the Centre.

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- 4.3 On 5th March 2010, the Centre issued its A sample Certificate of Analysis reporting Mr Ghaly's sample as an AAF for 19-NA i.e above the threshold 2 ng/mL at the level of 5.8 ng/mL.
- 4.4 On 25th March 2010, the Centre issued a Certificate of Analysis for Mr Ghaly's B sample reporting it as an Atypical Finding ("ATF") for 19-NA at a level of 5.1 ng/mL.
- 4.5 In March 2010, Mr Ghaly was provisionally suspended by the Saudi Arabian Anti-Doping Committee.
- 4.6 During the analysis of his B sample on 22nd March 2010, Mr Ghaly requested that his sample be sent to the Cologne Centre for IRMS analysis.
- 4.7 On 12th April 2010, the Cologne Centre reported Mr Ghaly's sample as negative.
- 4.8 On 14th April 2010, the Centre issued a new Certificate of Analysis reporting Mr Ghaly's sample as: IRMS negative "*does not indicate an application of nandrolone or nandrolone pro hormones*".
- 4.9 On 7th May 2010, the Saudi Arabian Anti-Doping Committee proceedings against Mr Ghaly were terminated.

(2) **Female Track and Field Athlete: Sample 2366001**

- 4.10 The unnamed Female track and field athlete is a US marathon runner.
- 4.11 On 9th December 2009, the female athlete's sample was received at the Centre.
- 4.12 On 29th December 2009, the Centre issued a Certificate of Analysis reporting her sample as an AAF containing 19-NA at a quantity of 2.5 ng/mL and stating an opinion "*The findings above could be compatible with a non-testosterone ingestion*".
- 4.13 On 29 December 2009, the sample Certificate of Analysis was forwarded by the Centre to the Singapore Athletic Association with a letter advising that the Centre would be conducting the B specimen analysis of this sample within 7 days.
- 4.14 On 29 December 2009, the Singapore Athletic Association forwarded the Certificate of Analysis to both IAAF and USADA.
- 4.15 On 5th January 2010, both the IAAF and USADA raised questions about the Centre's A sample Certificate of Analysis.
- 4.16 As a result, the Centre did not proceed with the B sample analysis.
- 4.17 In further response to the questions raised by the IAAF and USADA, the Centre both initiated a Corrective Action Request ("CAR") and sent the athlete's sample to the Cologne Laboratory for IRMS analysis.

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- 4.18 On 17th March 2010, the Cologne Laboratory issued an IRMS report which indicated the application of norandrosterone or an exogenous nandrolone prohormone.
- 4.19 On 25th March 2010, the Centre issued a new A sample Certificate of Analysis reflecting that it had reviewed the case and checked for pregnancy and the use of birth control pills and that the IRMS result was consistent with exogenous norandrosterone administration.

- 4.20 The opinion states:

"RESULTS:

The sample was found to contain 19-Norandrosterone at 2.5 ng/mL \pm 0.2 ng/mL (k=2) greater than the threshold of 2 ng/mL.

OPINION:

The sample was also analysed for the following:

- i) hCG, the 19-Norandrosterone finding is not due to pregnancy.*
 - ii) Tetrahydronorethisterone, the 19-Norandrosterone finding is not due to administration of a norethisterone contraceptive.*
 - iii) IRMS, the 19-Norandrosterone finding is consistent with exogenous administration."*
- 4.21 Because of issues with the Centre's analysis, including the fact that the concentration of 19-NA was not greater than the threshold, and the perceived real possibility that the exogenous IRMS result was caused by the athlete's use of birth control pills, the IAAF and USADA decided not to take the case further.

The subsequent samples

- (3) **Samir Ibrahim Ali Hassan: Sample 2409825**

- 4.22 Mr Hassan is a football player in the United Arab Emirates.
- 4.23 On 27th October 2009, Mr Hassan's sample was received at the Centre.
- 4.24 On 3rd December 2009, the Centre issued an A sample Certificate of Analysis that declared the sample as an AAF, finding 19-NA at 6.0 ng/mL.
- 4.25 On 30th December 2009, a Certificate of Analysis for Mr Hassan's B sample also found an AAF for 19-NA (no concentration was given).
- 4.26 On 3rd January 2010, the United Arab Emirates Disciplinary Committee ("UAEDC") issued its first decision finding that Mr Hassan committed an anti-doping rule violation

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and imposing a period of ineligibility of two years (of which Mr Hassan served eight months).

4.27 On 23rd January 2010, Mr Hassan filed an appeal with CAS.

4.28 On 2nd August 2010, Mr Hassan requested that his sample be sent to the Cologne Laboratory for IRMS analysis.

4.29 On 30th August 2010, the Cologne Laboratory's analytical report found that the IRMS analysis of Mr Hassan's sample was "*negative*."

4.30 On 1st September 2010, UAEDC issued a second decision, cancelling the prior decision and reinstating Mr Hassan's eligibility.

4.31 On 5th October 2010, the sole CAS arbitrator rendered an award in Mr Hassan's favor overturning the first decision of the UAEDC and awarding Mr Hassan CHF 10,000 in costs against the UAE Anti-Doping Committee.

(4) **Hassan Tir: Sample 2409887**

4.32 Mr Tir is a football player from the United Arab Emirates.

4.33 On 15th December 2009, Mr Tir's sample was received at the Centre.

4.34 On or about 2nd February 2010 based on the Centre's Report of an AAF to WADA, it appears that the Centre issued a Certificate of Analysis for his B sample.

4.35 The B sample Certificate of Analysis reported the sample as an AAF for 19-NA at a concentration of 3.5 ng/mL.

4.36 On 16th February 2010 the UAEDC issued its first decision imposing a period of two years ineligibility was imposed on Mr Tir, commencing 31st December 2009 (of which he served 9 months).

4.37 On 6th March 2010, Mr Tir appealed to CAS.

4.38 On 5th April 2010, a CAR noted that there had been a failure to perform the Urine Stability test prior to reporting of Nandrolone for, *inter alia*, Mr Tir's sample. A month later, Mr Tir requested that his sample be sent to the Cologne Laboratory for IRMS analysis.

4.39 On 30th August 2010, the Cologne Laboratory reported Mr Tir's sample as IRMS negative.

4.40 On 1st September 2010, the UAEDC issued a second decision terminating proceedings against Mr Tir and restoring his eligibility.

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(5) **Al Kowaibki: Sample 2316189**

4.41 Al Kowaibki was a Saudi Arabian footballer.

4.42 On 19th January 2010, Al Kowaibki's sample was received at the Centre.

4.43 On 2nd February 2010, Al Kowaibki's sample was reported as an AAF.

4.44 On 22nd March 2010, the Centre (belatedly) became aware of TD2009NA.

4.45 On 25th November 2010, WADA requested a document package.

4.46 On 1st December 2010, the Centre carried out an assessment of the sample's stability feature and found that it was unstable.

(6) **Female Track and Field Athlete 2367331**

4.47 The unnamed Female Track and Field Athlete is not further identified.

4.48 On 12th October 2010, the female athlete's sample was received at the Centre.

4.49 On 26th October 2009, the sample was reported to IAAF as an AAF. The sample was found to contain 19-Norandrosterone at 23.86 ng (mL of 0.62 g/mL (k=2) greater than the threshold of 2ng/mL.

4.50 On 5th April 2010, a CAR was made acknowledging non-compliance with WADA TD 2009 NA version 1.0) for failure to perform an hcg analysis.

5. PROCEEDINGS BEFORE THE COURT OF ARBITRATION FOR SPORT

Appeal

5.1 On 8th July 2010, the Centre filed a Statement of Appeal with the Court of Arbitration for Sport ("CAS") against the Decision and submitting the following request for relief:
"The Centre requests that the decision of WADA to revoke the Accreditation of the Centre be declared illegal and unenforceable."

5.2 On 4th November 2010, the Centre filed its Appeal Brief. This document contains a statement of the facts and legal arguments accompanied by supporting documents.

5.3 The Centre's case was epitomised by its conclusion and claim for relief:

“First, it is submitted that the breaches of the rules of natural justice identified above are so serious that the decision of the Executive Committee and the Disciplinary Committee must be quashed. WADA has thoroughly violated the right of the Centre to be treated fairly. (“the Procedural Complaint”)

Second, it is submitted that the Disciplinary Committee’s consideration of the “errors” made by the Centre is so flawed that it should be set aside. Some of the errors were not errors; and those that could be identified as possible errors breached were minor or trivial. None of them singularly or taken together justified revocation of the Centre’s accreditation. (“The Substantive Complaint”)

Finally, the Centre has been the victim of regulatory oppression by being subjected to a procedure in breach of all of the principles governing hearing under the WADA Code. It has also had its reputation damaged by having its accreditation wrongly revoked. It is entitled both to damages for these breaches of its rights and to recoup in full the legal cost of vindicating its rights”.

Answer

- 5.4 On 30th November 2010, WADA submitted its Answer, with the following request for relief:

“WADA respectfully requests that: (1) This appeal be dismissed and, (2) that WADA be awarded its costs and attorneys fees incurred in the defense of this appeal.”

- 5.5 WADA's case was epitomised by its Introduction:

“A fundamental premise of the anti-doping system set forth in the World Anti-Doping Code (“the Code”) is that athletes, sporting organisations and the public can put their trust in the reliability of results reported by WADA-accredited laboratories. The Penang Centre has lost that trust. As a consequence of flawed Centre reports from the Penang Centre, three innocent football players (two from UAE and one from Saudi Arabia) were provisionally suspended or declared ineligible for periods ranging from one month to nine months. A fourth athlete, a U.S. runner, would have been provisionally suspended based on a flawed A Sample Adverse Analytical Finding (“AAF”) from the Penang Centre, but for the fact that

the IAAF and USADA were sophisticated enough to question the Centre's report. Only two of these cases (the Saudi football player and American runner) were considered by the WADA Disciplinary Committee. In the two other cases, the Isotope Ratio Mass Spectrometry ("IRMS") analysis by the Cologne Centre which exonerated the athletes was not performed until months after the Disciplinary Committee's decision and was only performed as a result of the player or the ADO having heard of the WADA revocation of the Penang Centre accreditation."

6. CONSTITUTION OF THE PANEL

- 6.1 On 8th November 2010, the CAS Court Office informed the parties that the Panel to hear the appeal had been constituted as follows: The Hon. Michael J. Beloff Q.C., President of the Panel; Prof. Richard H. McLaren, arbitrator designated by the Appellant; and Mr David W. Rivkin, arbitrator nominated by WADA.
- 6.2 On 17th January 2011, following the resignation of Mr David W. Rivkin, and pursuant to Article R36 of the Code of Sports-related Arbitration ("the Code"), Mr David W. Rivkin was replaced by Mr Romano Subiotto Q.C. as arbitrator nominated by WADA.

7. PRE-HEARING MATTERS

- 7.1 On 16th November 2010, pursuant to Article R37 of the Code, the Centre filed a request for provisional and conservatory measures, seeking, *inter alia*, an order that WADA discloses certain documents relating to the decision-making process and applying for an early hearing.
- 7.2 On 29th November 2010, WADA responded to the Centre's requests. By reason of the answer, no specific order on provisional and conservatory measures was needed at that time.
- 7.3 On 7th December 2010, following WADA's Answer of 1st December 2010, the Centre made further procedural requests, in particular for determination of the procedural complaint as a preliminary issue.
- 7.4 On 14th December 2010, WADA answered the Centre's requests of 7th December 2010.

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7.5 On 21st December 2010, the Panel, through the CAS Secretariat, issued several procedural directions to the parties following the Centre's requests of 7th December 2010 in the following terms:

"Witness statements: Both parties shall submit, on or before 14 January 2011, their witness statements (to stand as evidence in chief unless cogent reasons are given at the hearing for elaboration).

Historic Samples: The Panel considers that the Historic Samples (as described by Centres Counsel in his correspondence of 7 December 2010) was evidence that was available at the time of the original decision and which was, for whatever reason, not put forward to the first instance panel. The Panel considers that while article R57 of the Code of Sports-related Arbitration ("the Code") grants the Panel the right to rule de novo, the starting point ought to be the evidence adduced before the first instance Panel and not evidence that could have been adduced but was not. Therefore, Historic Samples will be excluded and will not be taken into consideration by the Panel.

Subsequent Samples: The Panel considers that the Subsequent Samples (as described by Appellant's counsel in his correspondence of 7 December 2010) were not available at the time of the original hearing and thus ex hypothesis could not have been consciously rejected as evidence at that hearing. In light of the above, the Panel has decided to permit the Subsequent Samples to be filed as further evidence now available and legitimately adduced in a de novo hearing.

Additional disclosure calendar: The parties are invited to exchange any requests for additional disclosure on or before 3 January 2011. A deadline of 5 January 2011 is fixed for submission by the parties to the Panel for resolution of any disclosure issues that they cannot resolve between themselves. The Panel will rule on any objections to disclosure by 7 January 2011 and all documents agreed or ruled as disclosable shall be produced by the parties by the 14 January 2011 (close of business)."

7.6 On 28th December 2010, the parties signed the Order of Procedure.

7.7 On 3rd January 2011, WADA filed a further request for production of documents.

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- 7.8 On 5th January 2011, the Centre indicated it would provide the requested documents to WADA by 14th January 2011.
- 7.9 On 4th January 2011, the Centre also made a request for additional disclosure of documents said to relate to the consistency of WADA's treatment of the Centre as compared to its treatment of other accredited laboratories.
- 7.10 On 6th January 2011, WADA requested the Panel refuse to the Centre's request of 4th January 2011.
- 7.11 On 7th January 2011, the Centre made further clarifications and limited the scope of the disclosure sought to be provided from WADA.
- 7.12 On 10th January 2011, the Panel rejected the Centre's latest requests for disclosure.
- 7.13 On 14th January 2011, WADA filed its witness statements.
- 7.14 On 17th January 2011, WADA filed supplemental witness statements.
- 7.15 On 18th January 2011, WADA filed further supplemental witness statements.
- 7.16 On 18th January 2011, WADA filed additional submissions and exhibits.
- 7.17 On 27th January 2011, the Panel granted the Centre leave to file a supplementary statement on the matters arising out of WADA's written submissions of 18th January 2011.
- 7.18 On 28th January 2011, the Centre filed its Supplementary Statement.

8. **HEARING**

- 8.1 On 31st January 2011, a hearing was held at the offices of Debevoise & Plimpton LLP in London, United Kingdom. The parties raised no objection as to the constitution and composition of the Panel.
- 8.2 The following persons attended the hearing:
- For the Centre, Prof. Aishah Latiff, director, and its counsel, Mr Mark Gay, assisted by Ms Sally Barnes.
 - For WADA, Mr Olivier Niggli, CFO and Legal director, and its counsel, Mr Richard Young.
- 8.3 The Panel heard evidence from the following witnesses:
- Prof. David Cowan, Head of the WADA accredited laboratories in Kings College, London, United Kingdom.

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- Prof. Francesco Botrè, Scientific Director of WADA accredited laboratories in Rome, Italy.
 - Prof. Christine Ayotte, Head of the WADA accredited laboratory in Montréal, Canada, and a member of the Laboratory Committee.
 - Dr Larry Bowers, Chief Science Officer of USADA and a member of the Laboratory Committee.
 - Dr John Miller, former Head of Laboratory Department, European Directorate for the Quality of Medicines, Council of Europe in 2009.
 - Mr Thierry Boghosian, WADA Manager of Laboratory Accreditation.
- 8.4 Dr Ray Kazlauskas, former Director of the WADA accredited body in Australia, and Mr Richard Pound Q.C., first President of WADA at the time of the dispute and a member of the Disciplinary Committee were not present at the hearing: by agreement their written statements were read by the Panel.
- 8.5 Each witness was invited by the President of the Panel to tell the truth subject to the consequences provided by the law. Each witness was examined and cross-examined by the parties and questioned by the Panel.
- 8.6 The Panel closed the hearing after hearing the parties' witnesses and invited the parties to file written closing statements by 28th February 2011. All parties accepted that their rights before the Panel had been fully respected. The Panel reserved its award, which takes account of all the arguments and material admitted before it including, but not restricted to that which is summarized herein.

9. CLOSING SUBMISSIONS

- 9.1 On 28th February 2011, WADA filed its closing statement.
- 9.2 On 1st March 2011, the Centre filed its closing statement.
- 9.3 On 9th March 2011 the Centre filed a reply to WADA's closing statement.
- 9.4 On 16th March 2011 WADA filed a reply to the Centre's reply.

10. CAS JURISDICTION

- 10.1 WADA Code ("WADC") Article 13.6 provides:

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“Decisions by WADA to suspend or revoke a laboratory's WADA accreditation may be appealed only by that laboratory with the appeal being exclusively to CAS.”

- 10.2 CAS's jurisdiction is confirmed by the signature of both parties to the Order of Procedure dated 28th December 2010.

11. ADMISSIBILITY

- 11.1 The Statement of Appeal was filed within 21 days of the receipt of the Decision.
11.2 The Appeal is therefore admissible pursuant to Article R49 of the Code.

12. APPLICABLE LAW

- 12.1 Article R58 of the Code provide so far as material:

“The Panel shall decide the dispute according to the applicable regulations and the rules of law chosen by the parties, or, in the absence of such a choice according to the law of the country in which the sports related body which has issued the challenged decision is domiciled...”

- 12.2 The parties not having chosen any particular system of law, the WADC and ISL are the applicable regulations: given WADA's domicile, Swiss law applies complementarily.

(1) WADC

WADC provides so far as material:

“ARTICLE 6.4 Laboratories shall analyse Doping Control Samples and report results in conformity with the International Standard for Laboratories.

ARTICLE 7 Each Anti-Doping Organisation conducting results management shall establish a process for the pre-hearing administration of potential anti-doping rule violations that respects the following principles:

7.1 Initial Review Regarding Adverse Analytical Findings

Upon receipt of an A Sample Adverse Analytical Finding, the Anti-Doping Organisation responsible for results management shall conduct a review to determine whether: (a) an applicable therapeutic use exemption has been granted or will be granted as provided for in the International Standard for Therapeutic Use Exemptions, or (b) there is any apparent departure from the International Standard

for Testing or International Standard for Laboratories that caused the Adverse Analytical Finding."

7.2 Notification After Initial Review Regarding Adverse Analytical Findings

If the initial review of an Adverse Analytical Finding under Article 7.1 does not reveal an applicable therapeutic use exemption or entitled to a therapeutic use exemption as provided in the International Standard for Therapeutic Use Exemptions, or departure that caused the Adverse Analytical Finding, the Anti-Doping Organisation shall promptly notify the Athlete, in the manner set out in its rules, of: (a) the Adverse Analytical Finding; (b) the anti-doping rule violation; (c) the Athlete's right to promptly request the analysis of the B Sample, or failing such request, that the B Sample analysis may be deemed waived; (d) the scheduled date, time and place for the B Sample analysis if the Athlete or Anti-Doping Organisation chooses to request an analysis of the B Sample; (e) the opportunity for the Athlete and/or the Athlete's representative to attend the B Sample opening and analysis within the time period specified in the International Standard for Laboratories if such analysis is requested, and (f) the Athlete's right to request copies of the A and B Sample Centre documentation package which includes information as required by the International Standard for Laboratories..."

(2) THE INTERNATIONAL STANDARD FOR LABORATORIES (ISL)

The ISL is available at the following web address: http://www.wada-ama.org/Documents/World_Anti-Doping_Program/WADP-IS-Laboratories/WADA_Int.Standard_Laboratories_2009_EN.pdf.

(3) WADA'S PROCEDURES

According to the witness statement of Richard Pound Q.C.:

"The Laboratory Committee is comprised in significant part of laboratory directors and others involved with WADA-accredited laboratories. In setting up the system in which a disciplinary committee reviews the recommendations of the laboratory committee, it was anticipated that there might be some natural sentiment of collegiality expressed by members of the laboratory committee towards one of their colleagues. The structure of a disciplinary committee was created to provide a

broader view of the consequences of a laboratory's failure on the anti-doping system as a whole, which is what the Disciplinary Committee did in this case."

The Panel accepts this explanation for the two committee structure.

13. **THE PROCEDURAL COMPLAINT**

13.1 The Panel intends no disrespect to the Centre in dealing briefly with the Centre's procedural complaint. The very purpose of CAS hearings being *de novo* is to render the fairness or otherwise of the procedure before the body of first instance immaterial in terms of the ultimate result. The Panel rejects the Centre's submission that the reference in the Code to the power to review the facts and law "*refers to the facts and law that were before the body producing the original decision*". The facts and law referred to are rather those which bear on the issues in the appeal; CAS is restricted only by the subjective and objective limits of the case remitted to it (see e.g., case CAS 2008/A/1618 *Marco Cedroni v. CONI*). Any more limited interpretation would be inconsistent with an unbroken line of CAS jurisprudence. As was said in *N.J.W.Y. v FINA* TAS 98/208:

"the virtue of an appeal system which allows for a full rehearing is that issues of the fairness or otherwise of the hearing before the Tribunal of first instance fade to the periphery" (para 5.3).

13.2 Moreover, such limited interpretation would have the potential to create unfairness for both parties, by disabling an Appellant as well as a Respondent from adducing fresh relevant material before CAS. It would also place an obstacle in the path of sensible and speedy resolution of a dispute which is particularly desirable in the world of sport, as the present case illustrates. The orthodox remedy provided by an appellate body in respect of a first instance decision infected by procedural impropriety is to remit the case to the first instance body for a proper hearing. Contrary to the Centre's submission, CAS would, if it made the choice to remit, not simply reinstate the Laboratory Committee's decision; it would require the Disciplinary Committee to revisit its own decision. Moreover, for CAS to quash definitively a decision to remove accreditation on procedural grounds when the evidence and arguments before it

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persuaded it that the removal was justified on substantive grounds would be manifestly contrary to the public interest.

13.3 The Centre has expressly, and properly, made this concession:

"it is not suggested for one moment by the Centre that this Panel's powers are in any way circumscribed such that it is unable to afford as full a hearing as that potentially available before the Disciplinary Committee. Nor is it suggested that by affording the parties a proper hearing (which the Centre fully acknowledges it has received in this case) that this Panel's determination is incapable of curing the procedural infelicities that occurred below".

That being so, and even assuming that the principles adumbrated in the common law case of *Calvin v Carr* 1980 AC 574 reflect the *lex ludica*, there will, in the phraseology of the Privy Council, *"at the end of the day"* have been *"a fair result reached by fair methods"* such that the Centre *"should fairly be taken to have accepted"* when becoming a WADA accredited Centre. Adapting again what was said in TAS 98/208, the Centre's entitlement *"was to a system which allowed any defects in the hearing before the (Disciplinary Committee) to be cured by the hearing before CAS"* (para 5.3).

13.4 The Panel would, however, stress that the fact that a first instance body's decision may be cured by the appeal to CAS does not have as its corollary an absence of requirement for such first instance body to act fairly. The Panel accepts that Article 8 of WADC has no direct application to removal of a Centre's accreditation. On its face, it provides safeguards only *"for any person who is asserted to have committed an anti-doping violation"*. *Non sequitur* that an organ of WADA contemplating the severe sanction of removal of accreditation is not obliged to obey the two basic rules of natural justice *audi alteram partem* and *nemo judex in causa sua* ie to let the Laboratory under threat of such removal to know the case against it and to give it an opportunity to respond; and to have the issue determined by a body that both is and is seen to be impartial and independent. The disadvantages of failure to comply with these fundamental principles are threefold. Such non-compliance may incite the recipient of an adverse decision to appeal when it might not otherwise have done so. It deprives the decision (and its reasoning) of such utility it might otherwise have by way

of guidance for the CAS Panel in its appellate capacity. It risks undermining the stature of the first instance body itself.

- 13.5 That said, the Panel refrains from considering further the details of the Centre's procedural complaints, and should not be taken, accordingly, to have expressed a view on them one way or the other, save that to observe that in principle someone who has participated in formulation of the recommendation of the Centre Committee should not sit on a Disciplinary Committee reconsidering such recommendation. If he or she does so, justice may have been done, but will not be seen to have been done.

14. THE SUBSTANTIVE COMPLAINT

- 14.1 The structures of 4.4.11.2 (suspension of accreditation) and 4.4.11.3 (revocation of accreditation) of the ISL are distinct. The former provides that WADA '*may*' suspend accreditation in certain circumstances; the latter that WADA '*shall*' suspend accreditation in certain circumstances. It follows that WADA has a duty, not merely a power to revoke accreditation if the condition for such revocation is satisfied. The condition is that '*it determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of tests results*' ('the specified purpose'). Non-exhaustive examples are then provided of circumstances which may lead to the conclusion that revocation is necessary for the specified purposes.
- 14.2 The Disciplinary Committee considered that a number of those examples featured in the case of the Centre, in particular that it had '*seriously and repeatedly violated the ISL and relevant technical documents*' (para 29); and that "*stronger measures*", which it later identified as revocation, were necessary for the specified purpose (para 31). It is accordingly for the Panel, considering the case *de novo*, to determine in the light of the material before it, whether the specified purpose can only be fulfilled by revocation, or whether only some lesser sanction satisfies the principle of proportionality.
- 14.3 The Disciplinary Committee based its decision essentially on the matters which led to the 2009 suspension and the two trigger samples. It also, as noted already, sought before the Panel to introduce material relating to 2004, (i.e. "*the historic samples*" and to four cases subsequent to its own decision, (i.e. "*the subsequent samples and the*

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disclosure samples”). The Panel permitted it to rely on the latter but not on the former material (see its Direction of 20th December 2010)). It is not for the Panel to speculate on why the Disciplinary Committee did not itself make use of the 2004 material, which *prima facie* might have been thought relevant, in its assessment; the fact is that it did not. If the Disciplinary Committee with its expertise did not consider that the 2004 material added any weight to the case against the Centre, it is not for the Panel to be, in the hallowed metaphor, more royalist than the king. Nor, in any event, would it be fair to require the Centre to confront at the appellate level, an issue that it was entitled to think was no longer live by reason of its omission from the case made against it before the Disciplinary Committee. The Panel cannot, however, be required to submit itself to a form of self-imposed amnesia. It must take account at least of the fact that in 2004, issues (on the merits of which the Panel cannot adjudicate) were raised with the Centre and should have made the Centre more sensitive of its obligations.

14.4 The subsequent and disclosure samples stood, in the Panel’s view, on a different footing. They were not available to the Disciplinary Committee since those samples postdated the Disciplinary Committee’s deliberations. The samples were clearly relevant to the issue of the Centre’s future. It is, of course, true, as the Centre pointed out, that they had not passed through the WADA internal filters of the Laboratory or the Disciplinary Committee but since the Panel is conducting a *de novo* assessment and the Centre had a full opportunity, duly taken, to deal with both cases, there was no unfairness in permitting WADA to rely on them. It would indeed have been perverse to ignore them. CAS cases allowing for the adduction of evidence not considered by the decision-making body below include *Susin v FINA* (CAS: 2000/A/274), *French v Australian Sports Commission* (CAS: 2004/A/651) *Berger v WADA* (CAS: 2009/A/1948). To allow WADA to rely on those samples is accordingly conventional, not heretical.

14.5 Civilized legal systems have long operated on the basis that it is preferable that a hundred guilty men go free than that a single innocent man is convicted. Whether that equation can be transposed in its amplitude to the context of doping violations does not itself fall for decision; what is certain is that it is unacceptable that those who participate in sport should have their careers put in jeopardy because of a laboratory’s error, and suffer not only the stigma of being classified as doping offenders, but forfeit

the rewards, financial or reputational, attendant upon their chosen activity. In the same way as they should not be at risk of obscurely drafted rules [see *Quigley v UIT CAS*: 94/29 23rd May 1995], so they should not be put at risk by incompetent analysis. Not only the participants in, but the followers of sport, have to be confident that only those who merit it are inculpated of doping offences. Doubt in this context undermines the entire anti-doping system.

15. THE PARTIES' CASES

15.1 WADA's case against the Centre rests essentially on these foundations:

- (i) It is guilty of not solitary, but serial errors by way of imperfect sample analysis in breach both of ISL and of its own Standard Operating Procedures ("SOP").
- (ii) Errors continued after a period of suspension in 2009 - itself a warning shot across the Centre's bows.
- (iii) Errors indeed occurred within a short time after the suspension had ended.
- (iv) The errors were similar in nature suggesting chronic internal malaise.
- (v) The errors stemmed from, *inter alia*, a failure to have regard to well publicized technical documents i.e. the Note and TD2009 NA.
- (vi) The excuse for lack of awareness of the latter document ie problems with reception of electronic communications aggravated rather than mitigated the failure since those problems were admittedly known; in any event the document was available on the WADA website.
- (vii) But for the initiatives of the victims of the errors, and the investigations by other laboratories, the errors would not have been unmasked, and the athletes' careers interrupted, if not terminated.
- (viii) The internal documentation of the Centre was corrupted by retrospective amendments.
- (ix) The Director had herself admitted errors.
- (x) The same persons, from the Director, Professor Latiff downwards, Normaliza Hj. Abd. Manaf, Certifying Analyst and Noor Saerah Idris, Equality Manager, who bore actual or constructive responsibility for the errors, remained in place.

[See Centre's Response to WADA Director for Legal Affairs 20th August 2010].

15.2 The case for the Centre rests essentially on these foundations:

- (i) The degree of error had been exaggerated; there was a distinction overlooked by WADA- to be drawn between falling short of best practice and acting in breach of minimum standards.
- (ii) The errors all fell within a narrow compass ie in respect of NA 19 and were insufficient to justify revocation of accreditation, as distinct from a more focused and limited sanction.
- (iii) The Centre's customers should themselves have detailed any departure by the Centre from the ISL.
- (iv) The Centre had EQUAS endorsements in 2010.
- (v) The Centre retained its ISO725 certification.
- (vi) The Laboratory Committee composed of technical experts was better able to evaluate what sanction was required than the Disciplinary Committee, a majority of whom were lawyers and lacked such expertise.
- (vii) Suspension on conditions, as recommended by the Laboratory Committee would be a proportionate response to the errors
- (viii) The process of reaccreditation, theoretically available to the Centre, was in practical terms not available; Government funding would be withdrawn if the removal of accreditation stood; such removal would be a death sentence without prospect of resurrection.

16. STANDARD OF PROOF

- 16.1 In a novel situation, the Panel has to determine precisely what standard it should apply in reaching its decision. The case does not concern a usual disciplinary case of a doping offence engaging the established test of "comfortable satisfaction."
- 16.2 WADA's object is to establish a system of WADA-accredited laboratories which can be relied upon to deliver as faultless assessments, as is humanly possible, of doping samples, which ensure and are seen to ensure, full reliability and accuracy of drug tests and the accurate reporting of results. Its paramount interest is to ensure the provision of as many laboratories as possible of the highest standard to perform this vital task.

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It has no motive to suspend or revoke a previously accredited laboratory other than in circumstances where this is justified by the overall objective it seeks to achieve, which is why the Centre's assault on its *bona fides* seems to the Panel to be ill-judged.

16.3 This prompts then the question, at what stage should a view be formed that a laboratory is unable to ensure full reliability and accuracy of all drug tests and the accurate reporting of results? Is it after it has failed to do so once, twice, three times or more? Even a single error can mean that an innocent athlete has been, or could potentially have been, suspended for two years or more.

16.4 The Panel does not consider that it is appropriate to assess whether a laboratory deserves revocation of accreditation in purely quantitative terms. The assessment must also be a qualitative one. It can articulate it no better than by saying that it is for the Panel to decide on the balance of probabilities that the decision to revoke was wrong: WADA's judgment must itself be accorded due deference, but the Panel must nonetheless be persuaded that in all the circumstances, revocation is necessary to ensure the full reliability and accuracy of testing and the reporting of the same.

17. **THE EVIDENCE**

17.1 The experts called by both sides to testify about the Centre's merits or defects as a laboratory operating in the field of testing for doping violations were all experienced and well-known figures in the small community who specialize in that area.

17.2 The Centre fairly points out that those called by WADA had previous involvement in the case which meant that they were backing their own established stance but not of course that such stance was itself *ipso facto* either wrong or partial. WADA said with no less force that Dr Kazlauskas was himself *parti pris* because he had himself been responsible for the Centre's accreditation, and Professor Cowan had also in the past given the Centre advice as to its procedures.

17.3 The Centre further drew the Panel's attention to the fact that three of WADA's experts, Dr Ayotte; Dr Miller; and Professor Bowers, called to support a case for revocation, had themselves been members of the Laboratory Committee which had proposed a lesser sanction, albeit with more limited material than was available to them when they came to give evidence in the appeal.

17.4 However, in the Panel's view, whereas evaluation of the Centre's analytical performance was a matter for scientific expertise, evaluation of the appropriate sanction called into play considerations that were not scientific. The Panel recognizes, as Richard Pound Q.C. suggested, that a natural and indeed commendable desire on the part of experts in the same field not to be seen to be too harsh towards their fellow professionals itself justifies the existence of a Disciplinary Committee unaffected by such emotions.

17.5 Where the technical experts disagree about what are appropriate practices or techniques (as distinct from their implementation in particular cases) where such are not prescribed, the Panel is not inclined to inculcate the Centre, if the views of each expert side are reasonable. The Panel has been astute to differentiate between what are maximum and what are minimum standards and to focus on what constitutes breaches of the ISL or other technical documents or rather than merely departures from best practice. But where the evidence is to the effect that the Centre's procedures or techniques were in breach of relevant regulation or guidance, or simply that mistakes have been made, then the Panel must form its own view as to the gravity of breach, or mistake and the proportionate response to it, whilst, it repeats, giving weight to a body with the pedigree and authority of the Disciplinary Committee.

18. THE ERRORS: PARTICULAR FINDINGS

Introduction

18.1 It is therefore necessary for the Panel, to make findings as to the existence, and, where established, the gravity of the analytical errors made by the Centre in relation to the trigger and the subsequent samples.

18.2 Ten specific errors are relied upon by WADA who further identify the provisions of the ISL or SOP said to be violated as appears from the Table below.

Failure	ISL or SOP violation
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP07-v11 (p 59 & 62) LSOP03-v6.0 (p 7)
2. Failure to reject analysis for	

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unacceptable QC performance (+/-10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11 (p 62)
3. Failure to conduct stability screen before reporting AAF	2005 explanatory Note and TD2009NA
4. Lab's stability screen procedure should have triggered IRMS	2005 explanatory Note and TD2009NA Ex A 13 A5
5. Use of contaminated urine for calibration standards	ISL 5.4.4.2.2
6. Improper "correction" of sample value to LQC (value not based on calibration curve)	LSOP07v11 (p 59 & 62)/ LSOP03v6.0 (p 7)
7. Failure to properly adjust reporting threshold for specific gravity	TD2004NA and LSOP07-v11 (p63)
8. Erroneous measurement of uncertainty	TD2004NA, TD2009NA for 2010 cases (0.4 guard band) ISL 5.4.4.3.2
9. Failure to check for pregnancy (hCG) before reporting AAF	TD2004NA LSOP07v11(p 63)
10. Failure to check for BC pills (tetrahyronorethisterone) before reporting AAF	TD2004NA LSOP07v11 (p63)

18.3 The Panel's analysis of all samples initially follows the tabular form set out in para 18.2 and supplements it with comments where appropriate.

Ghaly 982747

Failure	ISL or SOP violation	Centre's comment	Panel's finding
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP07-v11 (p 59 & 62) LSOP03-v6.0 (p 7)	Accept - this is because analysts treated the detected substance as an exogenous substance. Dr Kazlauskas' evidence is that this is a matter of reasonable scientific dispute. No affect on reliability of analysis.	Centre accepts failure. WADA in its own closing submission (at pg. 26) states <i>"The fact that this violation of the ISL and SOPs was caused by yet another failure of the Laboratory's quality management system does not make the violation any less serious."</i> WADA has not, however, in the Panel's view, demonstrated how this failure affects the reliability of the analysis. Prof. Ayotte states that: <i>"unreliable methods produce similar results by</i>

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			<i>pure coincidence and it does not make them reliable.” She did not, however, demonstrate how they were unreliable, and how it was that the similar results were just coincidence.</i>
2. Failure to reject analysis for unacceptable QC performance (+/-10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11 (p 62)	<p>Disagree - accept that values do not fall within $\pm 10\%$ however standard Laboratory practice was to accept if within $\pm 20\%$ - Documentary failure only - not updating SOP to state $\pm 20\%$. Evidence of Professor Cowan that values within $\pm 20\%$ are scientifically valid. No obligation in ISL to have or comply with SOPs.</p> <p>No affect on reliability of analysis.</p>	<p>The Centre's practice did not correspond to its SOP. While it may be that values within +/- 20% are scientifically valid, the Panel has no way of knowing this. The Centre's SOP are the standards that were accepted and reviewed by WADA and the ISO accreditation. The Centre should not then take it upon itself to follow a different practice in its Laboratory without notifying WADA and the ISO.</p> <p>The QC was not within the acceptable range for this analysis. According to the Centre's own SOP this sample should not have been reported as an AAF. Dr. Botrè testified that his laboratory has a +/- 10% range and he has on occasion accepted a QC outside that range, but he indicated he only did so when he was able to determine the reason for the discrepancy. In the Panel's opinion, the Centre has not demonstrated to its satisfaction that this did not have an effect on the reliability.</p>
3. Failure to conduct stability screen before reporting AAF	2005 explanatory Note and TD2009NA	<p>Accept re TD2009NA - as was not aware of document.</p> <p>Disagree re 2005 Explanatory Note - 4 criteria under note not all met, therefore no requirement to</p>	<p>While this failure to be aware of the up-to-date publication is related to 19-NA, the Panel observes that is more than just a 19-NA failure. The Centre could have neglected to implement another TD related to an entirely different</p>

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		conduct stability test.	substance. While the Centre could not be blamed for applying a document (TD2004NA) now shown through advances in testing to be unsatisfactory, if WADA had not yet published TD2009NA, it's the Centre's failure to keep abreast of current publications excites real concerns. In any event, even by reference to the Note, the Centre should have checked whether 19-NA/19-NE A/E was present, or taken additional steps to check whether a stability test should be undertaken.
4. Lab's stability screen procedure should have triggered IRMS	2005 explanatory Note and TD2009NA Ex A 13 A5	Same point as 3 above. Accept re TD2009NA. Disagree re 2005 Explanatory Note - 4 criteria under note not all met, therefore no requirement to conduct stability test and thus no consideration of IRMS.	See above under 3
5. Use of contaminated urine for calibration standards	ISL 5.4.4.2.2	Disagree - not a "contaminated" urine. Laboratory's actions in making adjustments to take the interferent into account was acceptable and was scientifically valid.	The Panel accepts the Centre's argument that this was not a contaminated urine, but rather had an additional extraneous component. However, the Panel considers that the Centre should nonetheless have used a blank urine even if there is no basis for believing that this omission affected the reliability of the results. As stated by WADA, <i>"Whether the end result of the Laboratory's use of the contaminated urine was 'not necessarily unreliable' is not</i>

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			<i>the important question."</i>
6. Improper "correction" of sample value to LQC (value not based on calibration curve)	LSOP07v11 (p 59 & 62)/ LSOP03v6.0 (p 7)	Disagree - No obligation on Laboratory to either put in place SOPs or to comply with them. In any event, scientifically valid to verify LQC against CRM.	The Centre did not follow the method set forth in its SOP, which mandates quantification of the 19-NA in an athletes' sample based on a calibration curve. There is no further mention of a subsequent adjustment to that value based on the LQC. The Centre's ISO accreditation and evaluation is based on the SOP, and therefore if the Centre does not follow its own SOP it cannot rely on its ISO accreditation to say it is compliant and should not be sanctioned. The Panel finds an absence of satisfactory explanation for why this LQC adjustment is based on one-day measurement of a CRM and an LQC done on one day, which then becomes the standard against which all future analytical runs are adjusted.
7. Failure to properly adjust reporting threshold for specific gravity	TD2004NA and LSOP07-v11 (p 63)	N/A	N/A
8. Erroneous measurement of uncertainty	TD2004NA TD2009NA for 2010 cases (0.4 guard band) ISL 5,4,4,3,2	Accept re TD2009NA (re 0.4 guard band). Disagree re ISL - only requirement is that method of estimation is "fit-for-purpose". The way the Laboratory did it was "fit-for-purpose" and scientifically acceptable. Disagree re	A breach of TD2009NA is accepted. The Panel refers back to its findings under 3. WADA provides convincing reasons to rebut Centre's position (see pp15-16 of WADA's response to Centre's closing submissions)

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		TD2004NA - it does not stipulate how measurement should be done.	
9. Failure to check for pregnancy (hCG) before reporting AAF	TD2004NA LSOP07v11 (p 63)	N/A – Male	N/A
10. Failure to check for BC pills (tetrahydronorethi sterone) before reporting AAF	TD2004NA LSOP07v11 (p 63)	N/A – male	N/A

18.4 The Panel concludes that The Centre's analysis and reporting of Mr. Ghaly's sample 982747 was based on a number of ISL violations and other failures to follow the requirements of the ISL and Technical Documents. These include:

- i) The Centre's analyst mistakenly treating the substance as exogenous when quantifying the B sample. This was a failure to fully quantify his B sample before reporting it as an AAF. This was admitted by Professor Latiff (Statement Appeal Brief para 25) and explained by the experts Dr. Kazlauskas and Professor Cowan. While the Centre's finding was reliable, there was a failure to fully quantify the B sample as required by the ISL and the Centre's SOP. The failure here lay in not identifying the error on review of the documentation information. Had a review been performed, the Centre could have initiated a procedure to re-measure the B sample.
- (ii) Failure to consider sample stability and the ratio of 19-NA/19-NE to A/E before reporting Mr Ghaly's A sample as an AAF. This is also admitted by Professor Latiff (Statement Appeal Brief, paras 5 and 27). The failure here is caused by the fact that the TD2009NA had not been received and applied. Had this step been taken, the sample would have been sent to another laboratory for further analysis which **did** occur, but on the initiative of the athlete, not of the Centre.
- (iii) Errors in arriving at the reported 19-NA quantity of 5.8 ng/mL, including inappropriate "*correction*" of the measured value of Mr. Ghaly's sample and

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use of an unreliable measure of uncertainty. The Centre's SOP did not provide for what was done.

- (iv) Failure to reject the A sample analytical run and repeat the A analysis when quality control values were found to be outside a reasonable acceptance criteria and outside the Centre's stated measure of uncertainty. This was another failure to follow the Centre's own SOP.
- (v) Use of "*contaminated*" blank urine and calibrators which were then used to quantify the 19-NA in Mr. Ghaly's sample as an AAF, instead of simply starting over and performing the analysis with uncontaminated blank urine and calibrators. There was dispute over the connotations of the word "*contaminated*" (which, however, was the Centre's own description) but even assuming it meant only an 'extraneous' element, the Panel endorses the view that the Centre should not have used a blank that contained this additional component that required correction of the results, albeit recognising this does not necessarily make the result unreliable. All the experts agreed that the Centre should **not** have used a "contaminated" urine.
- (vi) The Centre's own Corrective Action Request ("CAR") in relation to this sample requires that pools of blank urine must be analysed first and approved by a certifying scientist before use as a blank urine or calibration standards. This was yet another failure to follow the Centre's SOP.

18.5 The Centre's explanation for why it failed fully to quantify the B specimen of Sample 982747 Ghaly (in its response to Rabin, para 3.19 above) was that:

"The Centre misinterpreted clause 5.2.4.3.2.4 and 5.2.4.3.2.5 of ISL, whereby the 'B' sample results only confirmed the 'A' sample identification of the AAF. However, before reporting the results, the Centre realized that for Nandrolone, which is the endogenous threshold substance, quantification based on calibration standards must be made. The extraction could not be repeated as the remaining sample is insufficient (less than 5 mL). Therefore, decision was made to re-run all samples using SIM method for quantification purposes, and to use the high QC sample, calculated at 4.88 ng/ml (after correction against CRM) as a replacement for the calibration samples."

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- 18.6 Three months earlier in December 2009 in the B specimen analysis of sample 2409825 [Mr Hassan], the Centre also failed to quantify fully the B sample before issuing a Certificate of Analysis signed by Professor Latiff as the certifying scientist. This must, in the Panel's view, undermine any explanation that the similar later failure in respect of the Ghaly sample March 2010 was an isolated incident perpetrated at a low level within the Centre and identified and remedied at a higher one, and casts a larger shadow over the reliability of the Centre's tests for 19NA.
- 18.7 The Centre's Root Cause Analysis (RCA) Findings on the Centre's use of a "contaminated" blank control urine and calibrators in the analysis of sample 982747, of Ghaly state that:

"Personnel

The personnel involved in the analysis were unaware of the requirements in the new version of the Technical Documents TDNA2009.

The personnel involved in the analysis failed to refer to the previous version of Technical Document TDNA2004 which is also indicated in Section 39 Annex of LSOP03 Data Evaluation.

The personnel took responsibility in dealing with the contamination problems without referring to the senior analysts in reviewing the details with the signatory conclusion.

Conclusion

The laboratory had no reference to the new Technical Document that was released early this year and therefore have followed the previous TDNA2004 document.

The personnel involved assumed responsibility in dealing with the analytical anomalies without communicating with the signatories or senior scientist within the appropriate time manner before reporting the results."

- 18.8 In her witness statement, Professor Latiff, however, declines to acknowledge the failure of Centre personnel to communicate with senior scientists:

"Of course having appreciated that there was an additional component in the blank urine, we could have gone back and recommenced the analysis. We did not do so for two reasons. First, we were entirely satisfied that the additional component was not a

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contaminant and would have no impact on the reliability of the finding. Secondly, we were under time pressure from the client to produce a result. Having to go back and reproduce the whole analysis might have taken us beyond the turn-around time with the client. On this basis, the Centre proceeded, as we considered that the detection of the additional component would have no impact on the reliability of the finding.”

The discrepancy between these two explanations is itself a cause of concern suggestive at best of uncertainty and at worst of cover up.

18.9 In any event, even accepting Professor Latiff’s as being the accurate explanation, it provides no defence to a charge of incompetence. Pressure of time cannot excuse cutting of corners, endorsed at a senior level, where so much turns on accuracy of analysis. The process of readjusting values would never be part of any Laboratory’s SOP; in any event, the Centre admits that it incorrectly readjusted the value of the QC sample. The analysis should have been rerun with uncontaminated urine and appropriate quality control samples.

18.10 The use of quality controls to establish the reliability of results measured by the analytical method, and the checking of those quality control results against established acceptance criteria, is fundamental not only to the analysis of 19-NA, but to the analysis of any sample where accurate quantification is important.

Female T & F 2366001

Failure	ISL or SOP violation	Centre’s comment	Panel’s findings
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP07-v11 (p 59 & 62) LSOP03-v6.0 (p 7)	N/A - no B done	N/A
2. Failure to reject analysis for unacceptable QC performance (+/- 10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11 (p 62)	N/A	N/A

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3. Failure to conduct stability screen before reporting AAF	2005 explanatory Note and TD2009NA	Accept re TD2009NA - as was not aware of document. Disagree re 2005 Explanatory Note - 4 criteria under note not all met, therefore no requirement to conduct stability test.	The Panel repeats, <i>mutatis mutandis</i> , its findings under 3. on the Ghaly sample
4. Lab's stability screen procedure should have triggered IRMS	2005 explanatory Note and TD2009NA Ex A 13 A5	N/A	N/A
5. Use of contaminated urine for calibration standards	ISL 5.4.4.2,2	N/A	N/A
6. Improper "correction" of sample value to LQC (value not based on calibration curve)	LSOP07v11 (p 59 & 62)/ LSOP03v6.0 (p 7)	Disagree - No obligation on Laboratory to either put in place SOPs or to comply with them. In any event, scientifically valid to verify LQC against CRM.	The Panel repeats, <i>mutatis mutandis</i> , its findings under 6. on the Ghaly sample
7. Failure to properly adjust reporting threshold for specific gravity	TD2004NA and LSOP07-v11 (p 63)	Accept - but no affect on validity of results. Concentration still above adjusted threshold.	In the Panel's view, there is no excuse for this mistake. The fact that the Centre corrected itself after someone else noticed the mistake does nothing to alleviate the Panel's concerns. Furthermore, the Panel is not inclined to accept that the fact that it did not affect validity of results disposes of those concerns. There are situations where failure to adjust for specific gravity would have an adverse

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			consequence on the reporting of a sample. Even if in this case it would have still been an AAF is immaterial.
8. Erroneous measurement of uncertainty	TD2004NA TD2009NA for 2010 cases (0.4 guard band) ISL 5.4.4.3.2	Disagree re ISL - only requirement is that method of estimation is "fit-for-purpose". The way the Laboratory did it was "fit-for-purpose" and scientifically acceptable. Disagree re TD2004NA - it does not stipulate how measurement should be done. Disagree re TD2009NA - sample collected in 2009 therefore TD2009NA does not apply.	The Panel repeats, <i>mutatis mutandis</i> , its findings under 8. on the Ghaly sample
9. Failure to check for pregnancy (hCG) before reporting AAF	TD2004NA LSOP07v11 (p 63)	Accept - but performed once requested to do so by results management authority before athlete notified of AAF. No affect on the validity of the finding.	The Centre's position in this case is unacceptable. In the Panel's view, a results management authority should not have to double check a laboratory's work.
10. Failure to check for BC pills (tetrahydronorethist erone) before reporting AAF	TD2004NA LSOP07v11 (p 63)	Disagree - see second witness statement of Professor Latiff.	The Panel is not persuaded by Professor Latiff's late recall here that the check was in fact consciously done. The Panel relies on p.6 of WADA's response to Centre's closing submissions.

Unnamed Female Athlete Errors

- 18.11 WADA complained that the Centre reported this athlete's sample as an AAF without first conducting the tests for pregnancy (admitted), and the use of birth control pills (now (but not previously) contested) [Professor Latiff's new statement enclosed with Centre's closing submissions]. The Centre alleged there was no prejudice caused, but in fact, this was simply the product of luck, not of good management. This is a significant error that ultimately left enough uncertainty about the Centre's bench work and procedures to lead to a decision to not declare an AAF where, if the check had been done, the situation may well have been different.
- 18.12 The pregnancy check has been a requirement of the WADA Technical Documents since TD 2004NA the athlete reported using birth control pills. However, the Centre performed these tests only after the IAAF and USADA asked whether the tests were performed and thus reminded the Centre that these tests were required. This is an undeniable error which could have been of significant consequence to the athlete save for the fact it was caught by external agencies.
- 18.13 Professor Bowers testified that the reason that he did not think that sample 2366001 should have been declared an adverse analytical finding was that it could not be excluded that the source of the positive result was a result of the athlete's use of the norethisterone containing birth control pill (para 16). In making this statement, Professor Bowers relied upon the athlete information provided on the doping control form that the she had taken a birth control pill. Professor Bowers further stated that the IRMS report which stated that the source of the 19-NA was nandrolone or nandrolone prohormones "*does not exclude the possibility that the exogenous source of 19-NA was a norethisterone containing birth control pill.*"
- 18.14 However, Professor Latiff demonstrated that the analytical report for sample 2366001 coupled with further analysis showed that norethisterone or its metabolites were not present in the sample, referring in particular to the chromatogram at page 101 of the analytical report.
- 18.15 Be that as it may, the real vice was:
- (i) failing to carry out appropriate tests at the appropriate time or to have sufficient laboratory documentation to know whether the test had been undertaken. This injected an element of uncertainty and lack of confidence in declaring an AAF.

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- (ii) not correcting the 2.0 ng/mL threshold for NA to 2.2 ng/mL on account of the higher than normal specific gravity measured in the A confirmation testing. As to this, Professor Ayotte says:

“In her first response to USADA, the director of the Laboratory, Pr Latiff indicated in an email dated January 12 (forwarded by the IAAF) that the hCG was negative (N.B. it was tested by the Laboratory the same date) and the stability test was not done. She added that The SG (specific gravity) was 1,022 and after correction the 19-NA was 2.7 ng/mL. This is a totally incorrect application of the Technical Documents on correction for specific gravity: the threshold at 2 ng/mL should be corrected to 2.2 ng/mL and if the value of the sample were to be corrected, it would be in the other direction, resulting in a lower not higher result.

Even according to Professor Latiff, para 45, the CAR was added only after a specimen AAF certificate analysis was issued -self-evidently a serious error,

- (iii) increasing the measured value of 19-NA in the athlete's sample from 2.25 ng/mL to 2.5 ng/mL in the Revised Certificate on Analysis based on an improper “*correction*” on account of low values obtained for a quality control
- (iv) using a measure of uncertainty that was no better than “*just an initial estimate*” instead of the decision limit of 2.6 ng/mL.

18.16 Professor Latiff seeks to explain the process by which the Centre arrived at its sample as an AAF:

“In reality what happened was that we had a finding marginally in excess of the threshold but which could have been explained by the use of a contraceptive pill. It was also unclear as to whether the source was endogenous or exogenous. We did further studies and came to the conclusion that although the presence of 19-NA could not be attributed to pregnancy or birth control pills (although the athlete claimed to take them) equally, its exogenous nature could be confirmed by IRMS analysis. Bearing in mind the concentration of the sample we would always have had to conduct IRMS of the sample.”

18.17 In fact, IRMS analysis was only done on this sample because the IAAF requested it. The Centre had already given notice that it would be proceeding with the B sample analysis in seven days: and it follows inexorably that if the recipients of this A sample

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AAF had not been as well versed in analytical chemistry as were the IAAF and USADA, the sample analysis would have gone forward as a routine matter.

18.18 The Centre's statement that "*we would always have had to do IRMS analysis*" correctly identifies its responsibility, but ignored the fact that it was not the Centre but the athletes who initiated the exculpatory IRMS analysis, or in the case of the female runner, USADA.

18.19 With respect to the Centre's failure to correct the 2.0 ng/mL threshold to 2.2 ng/mL for specific gravity in sample 2366001 unnamed Athlete, Professor Latiff states:

"The specific gravity was 1.020 at screening and 1.022 at confirmation. A decision was made that the criteria for reporting were fulfilled despite the fact that the latter specific gravity measure was higher and required correction. When I reviewed the documents, I saw the higher specific gravity recorded in the confirmation analysis. Therefore, when producing the documentation package, I also added a Corrective Action Request ("CAR") which notes that a specific gravity of over 1.020 was recorded and that the Centre had failed to correct the threshold. We then proceeded to perform the adjustment to the reporting threshold for 19NA and this adjusted threshold was calculated to be 2.2ng/ml."

18.20 This explanation itself poses the following questions:

- Why was Professor Latiff's opinion not obtained before the sample was reported as an AAF with the threshold not adjusted for specific gravity?
- Why did Normaliza Hj Abd Manaf, the signatory of the AAF Certificate of Analysis, not recognize that the threshold should have been adjusted?
- Why, after producing a CAR which she says addresses the specific gravity correction error in this sample (which it did not), did Professor Latiff sign a new Certificate of Analysis for this sample in which the threshold was **still not** adjusted for specific gravity adjusting the threshold for specific gravity is required in the analysis of elevated steroid substances, including 19-NA.
- Why did the Centre not apply the 2.6 ng/ml decision limit in TD2009NA?

18.21 Further the CAR was backdated by the Centre's Quality Manager who still holds this position within the Centre.

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18.22 Professor Ayotte says;

“My opinion was that the Laboratory’s results did not support an adverse analysis analytical finding: i) the requirements of the technical documents TD2004NA and TD2009NA were not followed; ii) the concentration of 19-NA in the sample was not shown to be above the applicable threshold of 2.2 ng/mL (TD2004NA) or decision limit of 2.6 ng/mL (TD2010NA taking effect on January 1, 2010).

The Panel accepts this criticism as well founded.

* * *

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Hassan Ibrahim 2409825

Failure	ISL or SOP violation	Centre's comment	Panel's findings
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP03-v6.0 LSOP07-v11	Accept	Appropriate standards not respected. The Panel finds in particular that only 1 single positive control was run in the batch with the athlete's B sample; the quantity of 19-N/A estimated by this method was not reported on the Centre's B sample certificate of Analysis.
2. Failure to reject analysis for unacceptable QC performance (+/- 10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11	Accept, but lab operated on +/- 20% band: it simply forgot to update its SOP which have no binding force in any event	The Centre cannot claim that its competence is demonstrated by its ISO accreditation and then argue that its SOPs are not binding on it; the Panel is unconvinced that the Centre checked its quality control results at all (for reasons set out see pp. 7-9 of WADA Response to Centre's closing submissions)
3. Failure to conduct stability screen before reporting AAF	2005 Explanatory Note and TD2009NA	Accept, but 2005 Explanatory Note was not binding; the lab in any event complied with its provisions	Ignorance of TD2009NA accepted; 2005 Explanatory Note establishes standards of best practice, which the Centre did not follow (for the reasons set out in pp. 13-14 of WADA Response to Centre's closing submission) The Panel repeats, <i>mutatis mutandis</i> , its findings under 3 of the Ghaly sample.
4. Lab's stability screen procedure should have triggered IRMS	2005 Explanatory Note and TD2009NA	Accept, but 2005 Explanatory Note was not binding; the lab in any event complied with its provisions	Ignorance of TD2009NA accepted; Appropriate standards not respected; reasons given by Centre for no IRMS test not applicable in this case (19-NA/19-NE ratio<2); (for reasons set out at pp. 9-12 of WADA Response to lab's closing submissions); Centre says urine stable but the documentation shows that it was stated to be unstable; the IRMS

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			that exonerated athlete was requested by athlete
5. Use of contaminated urine for calibrations standards	N/A	N/A	N/A
6. Improper “correction” of sample value to LQC (value not based on calibration curve)	LSOP03-v6.0 LSOP07-v11	Disagree, but at hearing said that, “in a perfect world”, would have done what WADA requires	Appropriate standards not respected, indicating a problem with Centre’s analytical method’s ability to measure values accurately
7. Failure to properly adjust reporting threshold for specific gravity	N/A	N/A	N/A
8. Erroneous measurement of uncertainty	ISL 5.4.4.3.2 TD2004NA TD2009NA for 2010 cases (0.4 ng/mL guard band); LSOP07-v11; ¶7.9.5.5(4)	Accept violation of TD2009NA; reject violation of ISL because ISL does not prescribe method of measuring uncertainty; only requirement is that method be fit-for-purpose; Reject violation of TD2004NA because does not prescribe measurement method	Ignorance of TD2009NA accepted. Appropriate standards not respected: Centre improperly “corrected” the measured value of 19-NA in the sample, showing that the Centre’s measure of uncertainty really was “ <i>just an initial estimate</i> ” ; WADA provides convincing reasons to rebut Centre’s position (see pp. 15-16 of WADA’s response to Centre’s closing submissions)
9. Failure to check for pregnancy	N/A	N/A	N/A
10. Failure to check for BC pills etc	N/A	N/A	N/A

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- 18.23 The Centre's explanations for its failures in the Ghaly case imply that the failures were the product of oversights in that particular case. However, all of the same failures were also present in the analysis of Ibrahim Hassan's sample. This can only lead to the conclusion that the Centre's failures were systemic.
- 18.24 The Hassan Ibrahim case provided a second example of a backdated document (the B Sample confirmation report). The Panel is constrained to accept WADA's inference that *"This document was backdated to correct a failure by the Centre and to support an AAF report"*.

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Failure	ISL or SOP violation	Centre's comment	Panel's findings
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP03-v6.0 LSOP07-v11	Accept	Appropriate standards not respected
2. Failure to reject analysis for unacceptable QC performance (+/- 10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11	Accept, but lab operated on +/- 20% band: it simply forgot to update its SOP which have no binding force in any event	The Panel repeats, <i>mutatis mutandis</i> , its findings under 2 on the Ibrahim Hassan sample
3. Failure to conduct stability screen before reporting AAF	2005 Explanatory Note and TD2009NA	Accept, but 2005 Explanatory Note was not binding; the lab in any event complied with its provisions	Ignorance of accepted TD2009NA; 2005 reaffirmed. The Panel repeats, <i>mutatis mutandis</i> , its findings under 3 of the Ghaly sample and further relies on pp. 13-14 of WADA's Response to Centre's closing submissions which are accepted) Appropriate standards not respected: the stability assessment was done only after prompting by third

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			parties, despite fact that a CAR of 5 th April 2010 noted that it had not been done.
4. Lab's stability screen procedure should have triggered IRMS	2005 Explanatory Note and TD2009NA	Accept, but 2005 Explanatory Note was not binding; the lab in any event complied with its provisions	Ignorance of TD2009NA accepted; Appropriate standards not respected; WADA witness (Prof. Ayotte) provides convincing reason for need for IRMS analysis (19-NA/19-NE ratio<3); The Centre's witness (Dr. Kazlauskas) justification for Centre's use of overloaded peaks questionable and contradicted by other Centre witness (Professor Cowan); (The Panel also relies on pp. 9-12 of WADA Response to Centre's closing submissions).
5. Improper "correction" of sample value to LQC (value not based on calibration curve)	LSOP03-v6.0 LSOP07-v11	Disagree, but at hearing said that, "in a perfect world", would have done what WADA requires	Appropriate standards not respected
6. Erroneous measurement of uncertainty	ISL 5.4.4.3.2 TD2004NA TD2009NA for 2010 cases (0.4 ng/mL guard band) LSOP07-v11; ¶7.9.5.4(4)	Accept violation of TD2009NA; reject violation of ISL because ISL does not prescribe method of measuring uncertainty; only requirement is that method be fit-for-purpose; Reject violation of TD2004NA because does not prescribe measurement method	Ignorance of TD2009NA accepted; Appropriate standards not respected.

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Al Kowibki 231689

Failure	ISL or SOP violation	Centre's comments	Panel's findings
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP07-v11 (p 59 & 62) LSOP03-v6.0 (p 7)	N/A - no B done	N/A
2. Failure to reject analysis for unacceptable QC performance (+/-10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11 (p 62)	Disagree - accept that values do not fall within $\pm 10\%$ however standard Laboratory practice was to accept if within $\pm 20\%$ - Documentary failure only - not updating SOP to state $\pm 20\%$. Evidence of Professor Cowan that values within $\pm 20\%$ are scientifically valid. No obligation in ISL to have or comply with SOPs. No affect on reliability of analysis.	Failure to comply with SOP whose purpose is to ensure that regardless of the bench analyst, the same procedure is always followed. Unacceptable QC performance not in accordance with ISL
3. Failure to conduct stability screen before reporting AAF	2005 explanatory Note and TD2009NA	Accept re TD2009NA - as was not aware of document. Disagree re 2005 Explanatory Note - 4 criteria under note not all met, therefore no requirement to conduct stability test.	The Panel repeats, <i>mutatis mutandis</i> , its findings under 3 of Ghaly analysis.
4. Lab's stability screen procedure should have triggered IRMS	2005 explanatory Note and TD2009NA Ex A 13 A5	Same point as 3 above. Accept re TD2009NA. Disagree re 2005 Explanatory Note - 4 criteria under note not all met, therefore no requirement to conduct stability test and thus no consideration of IRMS.	Ditto
5. Use of contaminated urine for calibration	ISL 5.4.4.2.2	N/A	N/A

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standards			
6. Improper “correction” of sample value to LQC (value not based on calibration curve)	LSOP07v11 (p 59 & 62)/ LSOP03v6.0 (p 7)	Disagree - No obligation on Laboratory to either put in place SOPs or to comply with them. In any event, scientifically valid to verify LQC against CRM.	Not in compliance with SOP see #2 above, even if valid.
7. Failure to properly adjust reporting threshold for specific gravity	TD2004NA and LSOP07-v11 (p63)	N/A	N/A
8. Erroneous measurement of uncertainty	TD2004NA, TD2009NA for 2010 cases (0.4 guard band) ISL 5.4.4.3.2	Accept re TD2009NA (re 0.4 guard band). Disagree re ISL - only requirement is that method of estimation is “fit-for-purpose”. The way the Laboratory did it was “fit-for-purpose” and scientifically acceptable. Disagree re TD2004NA - it does not stipulate how measurement should be done.	Violation of 2009TDNA accepted. Panel repeats <i>mutatis mutandi</i> paragraph 8 of Ghaly analysis
9. Failure to check for pregnancy (hCG) before reporting AAF	TD2004NA LSOP07v11(p 63)	N/A - male	N/A
10. Failure to check for BC pills (tetrahyfronorethister one) before reporting AAF	TD2004NA LSOP07v11 (p63)	N/A - male	N/A

18.25 The Panel adds two points: first that Professor Latiff accepted that she would have expected that the athlete be suspended in consequence of the AAF, which underscores the need to avoid a premature (and potentially erroneous) AAF: second that the criticisms in WADA’s response to Centre’s closing submissions at pp.9-10 as to the

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Centre's inadequate reaction to its stability screen of 1st December 2010 are compelling.

Female T&F Sample 2367331

Failure	ISL or SOP violation	Centre's comments	Panel's findings
1. Failure to fully quantify the B for 19-NA	ISL 5.2.4.3.2.5 LSOP07-v11 (p 59 & 62) LSOP03-v6.0 (p 7)	N/A	N/A
2. Failure to reject analysis for unacceptable QC performance (+/-10% of nominal value)	ISL 5.4.4.1.2 ISL 5.4.7.3 LSOP07-v11 (p 62)	N/A	N/A
3. Failure to conduct stability screen before reporting AAF	2005 explanatory Note and TD2009NA	N/A	N/A
4. Lab's stability screen procedure should have triggered IRMS	2005 explanatory Note and TD2009NA	N/A	N/A
5. Use of contaminated urine for calibration standards	ISL 5.4.4.2.2	N/A	N/A
6. Improper "correction" of sample value to LQC (value not based on calibration curve)	LSOP07v11 (p 59 & 62)/ LSOP03v6.0 (p 7)	N/A	N/A
7. Failure to properly adjust reporting threshold for specific gravity	TD2004NA and LSOP07-v11 (p63)	N/A	N/A
8. Erroneous measurement of uncertainty	TD2004NA, TD2009NA for 2010 cases (0,4 guard band) ISL 5.4.4.3.2	Disagree re ISL – only requirement is that estimation is fit for purpose. TD 2004 does not stipulate how measurement should be done. Sample was collected	The Panel repeats, <i>mutatis mutandis</i> , its findings under 8 of the Ghaly sample.

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		in 2009 therefore TD2009NA does not apply.-	
9. Failure to check for pregnancy (hCG) before reporting AAF	TD2004NA LSOP07v11(p 63)	Accept that this was not completed before reporting the AAF, but it was subsequently performed pursuant to a CAR and was negative. No effect on validity of finding.	No check for hCG before reporting AAF as per 2004NA. Checked afterwards proved negative. Therefore, no analytical error but mandatory procedural step missed and as illustrated by a CAR.
10. Failure to check for BC pills (tetrahydronorethisterone) before reporting AAF	TD2004NA LSOP07v11 (p63)	The Lab did conduct this test during its initial screening analysis. While the information was not contained within the analytical report for the sample, it was in fact done and there was no evidence of the presence of THNE.	The Panel is unpersuaded by Prof. Latiff's late recall that any conscious checks were in fact performed.

19. THE ERRORS: GENERAL OBSERVATIONS

Ignorance of key documentation

- 19.1 The problem of “*unstable urine*” in 19-NA cases was first reported in 2004 in the “*Cologne Workshop: Recent Advances in Doping in Sport*,” in an article which included two WADA Centre directors as authors. It was to the effect that in rare cases, bacteria in a urine sample can break down natural steroids in an otherwise clean sample to form low levels of the prohibited substance 19-NA. It is the samples which contain these bacteria which are described as “*unstable urine*.”

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- 19.2 In May 2005, WADA published the Note which reflected that report and required an examination of the sample for features of instability before reporting or rejecting it as an AAF for 19-NA.
- 19.3 A draft of TD2009NA dealing further with unstable urine was discussed at the Centre directors' meetings in February 2009 in Amsterdam, which was attended by Professor Latiff.
- 19.4 On March 2009 and July 2009 drafts of TD2009NA were also circulated to all Centre directors for consultation by email. They were also put on the WADA website.
- 19.5 On 1st October 2010, the final version of TD2009NA was emailed to all Centre directors and also posted on WADA's website.
- 19.6 The Centre stated that it never received an email from WADA forwarding the final version of TD2009NA in September 2009 and relies on that as an explanation or excuse for non-compliance with it.
- 19.7 Professor Latiff however knew that it was "*not uncommon in our country for emails to go astray or not to be received*" and gave to WADA examples from her own experience where as she evocatively put it in an email of 10th May 2010, "*they had disappeared into cyberspace*".
- 19.8 There was evidence before the Panel that the information contained both in the Note and in TD2009NA had been publicized in earlier research papers and at conferences attended by Professor Latiff.
- 19.9 The Panel need not, however, explore whether Professor Latiff was or should have been privy to such information through such means, because it is in its view, indisputable that the Centre had an obligation to be aware of and implement both the Note and TD2009NA, as clearly mandated by the ISL (Article 1.0 entitled "Introduction, scope and references"), and as reflected in its own SOP, which says at 39 "*All WADA Technical Documents can be referred to the WADA official website*". Athletes, after all, are regularly suspended for not being aware of information that is freely available on the internet.
- 19.10 Indeed, the plea of ignorance of the existence of the latter document because of email problems in the Centre, in the Panel's view aggravated rather than mitigated the offence. The admitted awareness of such problems should have led the Centre to be

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particularly alert to double check on new technical documents, particularly when it was aware that the implementation of an updated technical document was imminent.

- 19.11 The Panel notes that the Centre's failure to update itself about key WADA documents was not a fault dependent on the content of those documents and it was adventitious that the documents dealt with 19 N/A as distinct from other substances.

Absence of harm

- 19.12 The plea that no harm was done by the errors is without weight. The causation of loss by inappropriate actions is relevant to civil claims for compensation: but not to disciplinary (or criminal) charges where it is the degree of fault and not its consequences which is relevant. Moreover, the Centre cannot claim credit for the fact no harm was done when it was the actions of others which prevented such harm from occurring. Its errors had the propensity to cause harm.
- 19.13 The Panel Notes that the Centre could not without performing such test in advance of reporting an AAF, have been confident that it was not exposing the athlete to a risk of suspension without justification.

Inadequacy of the Centre's defences

- 19.14 The Panel cannot accept certain of the other defences articulated in the various comprehensive briefs submitted by the Centre. In particular
- (i) While their clients may have the opportunity, even obligation, under WADA s.7.1 to 7.2 to check for Centre error, this cannot justify the commission of error by the Centre in the first place.
 - (ii) The characterisation of a practice at variance from its own SOP's as being excusable as long as the varied practice was itself acceptable (a) makes nonsense of the need to have SOP's in the first place (see ISL 5.4.2.2) and is (b) a recipe for confusion at the pit face of a Centre.
 - (iii) The criticism of WADA for not sending hard copies of its key documents to accredited laboratories is arguably anachronistic in an electronic age and provides no justification of the Centre's failure, already commented on, to keep up to date with matters relevant to its activity, especially by accessing

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WADA's website. The Panel recognizes that WADA might itself have noted the absence of electronic confirmation that the Centre had not received its emails and as a matter of good practice sent hard copies as well, but that does not of itself excuse the Centre.

- (iv) The doubt, without supporting evidence, cast upon the Cologne IRMS is in any event at odds with Professor Ayotte's testimony which the Panel has no reason not to accept.
- (v) The trenchant depiction of WADA as a '*classic regulatory bully*' is unwarranted. The Panel might have welcomed a somewhat further exposition of the reasons which led to the recommendation for revocation but detect no trace of improper motive.
- (vi) The suggestion that the cause of anti-doping would be undermined by closure of the Centre which is founded on the premise that the Centre is an effective and compliant laboratory. If it is **not**, as this Panel finds, that the cause of anti doping is retarded rather than advanced by its retention of accreditation.

The Centre's attitude

- 19.15 The Panel who had the advantage of seeing and hearing from Professor Latiff, while respecting her sincerity and professional pedigree, could not avoid the impression that she was unwilling to recognise the seriousness of even admitted errors, and were ultimately unconvinced that in the absence of such recognition, the problems which have afflicted the Centre would be eliminated.

20. CONCLUSION

- 20.1 The Centre is apparently the only Centre that has undergone two disciplinary panel hearings regarding its accreditation since the initiation of the accreditation process although both in 2009 and 2010 other laboratories had been suspended.
- 20.2 On any view, the Centre reported AAFs for six athletes who did not dope.

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All of these “*false positive*” reports were issued within a year of the Centre coming off suspension.

Failures of quantification and controls are particularly serious because as the Centre’s expert, Professor Cowan acknowledges, the 19-NA values reported by the Centre were “*marginal*”

Moreover, the types of Centre failures which led to these AAFs, and the Centre’s attempts at explanation, raise serious questions about

- how the Centre personnel were trained,
- how important analytical decisions were evaluated and
- how the analytical record was reviewed before samples were certified and reported as AAFs.
- the Centre’s appreciation of the importance of adherence to SOPs.
- the capacity of the Centre to admit and learn from its errors.

20.3 In the Panel’s view, all these questions, albeit derived from 6 specific cases, bear on the general reliability of the results reported by the Centre. Moreover, the 2009 problems which led to suspension were not limited to 19-NA.

20.4 The EQUAS approvals upon which reliance was placed, were given in ignorance of the trigger samples (and indeed the subsequent and disclosure samples) and the change of stance by those members of the Laboratory Committee called as witnesses to justify revocations as distinct from a lesser sanction is, in the Panel’s view, to be explained objectively by the increased analytical material to which they had access compared with what was before them in April 2010, and by their ability to assess the force-or lack of it- of the Centre’s defence and mitigation.

20.5 In the Panel’s view, the management of the laboratory is the primary source of the Centre’s problems. Matters that should have been captured in the course of reviewing analytical work are addressed only in CARs. The suspension in 2009 led to no development of the Centre’s competences through management changes or improvements. If management falls short in its primary task of administering the laboratory, then the unreliability of all types of results becomes a real possibility, and not merely a theoretical one. The TD20009NA saga is merely an illustration of the problem with management.

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- 20.6 The explanations advanced by the Centre at the hearing regarding TD and other issues betrayed an attitude which seeks to justify what was done rather than to recognize and learn from legitimate criticism therefore disabling management from implementing necessary reforms. This lack of demonstrated capacity to reform has implications not only for the specifics of NA analytical work but for other aspects of the laboratory's work which may also require adjustment. Doubt is in such circumstances, inevitably cast on the reliability of results - the *raison d'être* of an accredited laboratory.
- 20.7 The apparent willingness of laboratory personnel to back date and change written records rather than to stroke out and recod the corrected entry information, while at the same time leaving the original entry on the record, is a serious violation of accepted laboratory practice, which requires, *inter alia*, a proper paper trail chain of custody. Such violations again impinge upon the integrity and reliability of all results emanating from the laboratory and not merely those concerned with 19NA. It is a further reflection of an insufficiently careful management style
- 20.8 The practice of conducting analytical work in a manner inconsistent with the SOP's of the laboratory frustrates the very purpose of such SOP's, themselves the *sine qua non* of ISO accreditation. There were before the Panel, several examples of departure from SOP's at bench level. The Centre's explanation that it was not required to follow its SOP's is not only inaccurate, but betrays a fundamental misunderstanding of the function of SOP's; the role of laboratory personnel in their application; and the imperative of a standard technique irrespective of the identity of the technical analyst of any particular sample. A laboratory that operates outside and beyond its described SOP's inevitably generates suspicion since by its admitted conduct, it shows that it does not value the rigour required in sample analysis.
- 20.9 The particular bench work undertaken in the Female T & F trigger sample reveals plural problems.
- The Centre failed to adjust the reporting threshold on the Female T & F sample for specific gravity as required;
 - The Centre then upon being notified by the IAAF of its error adjusted the sample value rather than the threshold value;
 - Finally, the Centre in addition to adjusting the wrong value, adjusted it the wrong way – adjusting it up, rather than down.

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These are egregious errors which (i) ought to have been detected on a final review by the technical overseer or laboratory directors; (ii) reflect a lack of knowledge of procedure by the technical analyst, consequent, it may be inferred, on inadequate training in analytical technique, and the SOP's; and (iii) reveal a complete failure in the Centre's review process once the completed analytical work is being checked.

The Centre's argument that such failure had no effect on the reliability of the analysis demonstrates the Centre's inability to discriminate between a result achieved by chance and one achieved by design. This inability in itself impinges on the reliability of the laboratory's work and reflects a problem more deep seated than a technical misanalysis of nandrolone.

- 20.10 A problem analogous to that with the NA threshold described in the previous paragraph emerges in the area of detection of the possibility of either pregnancy or birth control pills in samples from female athletes.-defects in analytical process followed by, defects in the process of review and, in the subsequent correction, departures from the SOP by back dating. These errors likewise have adverse implications beyond the technical misanalysis of female urine samples.
- 20.11 The WADA Disciplinary Committee acted on the basis of the 2009 suspension and the trigger samples. The Panel has in addition four further samples improperly processed, and resulting in false positives: one of the subsequent samples reflected, exactly the same inadequacies of bench work analysis as one of the trigger samples. The conclusion must be that the problems are growing, uncorrected at bench level and above and endemic. Without reform, of which there are no real signs, the reliability of the Centre's work is suspect.
- 20.12 In the Panel's view, the entire anti-doping system presupposes that, and can only work if; WADA-accredited laboratories actually operate in accordance with the international standard for laboratories and in accordance with their SOPs.
- 20.13 The credibility of the system also requires that laboratories be seen to operate in accordance with these standards: any doubts about one laboratory could very quickly jeopardise the entire system.
- 20.14 The Panel therefore confirms WADA's revocation of the Centre's accreditation.
- 20.15 The Panel would, however, add that WADA might, as far as permitted by the regulatory framework, consider whether by appropriate mentoring and monitoring it

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could assist the Centre in reaching a position in which the Centre could make a credible application for reaccreditation and, again within that framework might accelerate the relevant procedures, if such application is made.

21. COSTS

- 21.1 Articles R65.1 and R65.3 of the Code provide that, subject to Articles R65.2 and R65.4, the proceedings shall be free, that the costs of the parties, witnesses, experts and interpreters shall be advanced by the parties; and that, in the Award, the Panel shall decide which party shall bear them, or in what proportion the parties shall share them, taking into account the outcome of the proceedings, as well as the conduct and financial resources of the parties.
- 21.2 As a general rule, the CAS grants the prevailing party a contribution toward its legal fees and other expenses incurred in connection with the proceedings. In the light of the outcome of the present procedure, the Panel considers that the Centre shall pay to WADA an amount of CHF 3'500 towards its costs and other expenses incurred in connection with this arbitration.

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ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

1. The appeal filed by Doping Control Centre, Universiti Sains Malaysia on 8 July 2010 is dismissed.
2. The award is pronounced without costs, except for the Court Office fee of CHF 500 (five hundred Swiss francs) already paid by Doping Control Centre, Universiti Sains Malaysia and which is retained by the CAS.
3. Doping Control Centre, Universiti Sains Malaysia is ordered to pay a total amount of CHF 3'500 (three thousand five hundred Swiss francs) to World Anti-Doping Agency as a contribution towards its expenses incurred in this arbitration.
4. All other and further prayers for relief are dismissed.

Lausanne, 15 June 2011

THE COURT OF ARBITRATION FOR SPORT


The Hon. Michael Beloff

President of the Panel