

Floyd, Tour de France 2006

- Drug test
- Not positive



Floyd Landis

ABC Slide Show

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Prepared by Arnie Baker, MD.

Baker is a retired San Diego physician. He is a long-time Landis coach and advisor.

While in active medical practice, Baker had over a decade experience in medical peer review and quality assurance.

Baker has written about bicycling medicine for the lay public, International Olympic Committee, and medical community.

No Basis for Positive

- A. Positivity criteria not met
 - B. Lab errors – sample mislabeled
 - C. Specimen contaminated
 - D. Testing unreliable
- Doesn't make sense
 - ◆ Samples before and after okay
 - ◆ No evidence episodic testosterone works

We have identified dozens of problems with Floyd Landis's allegedly positive doping test.

What we'll show here are some of the most important and easily understood basic problems.

Sample Clearly Mislabeled

- No way to clearly determine it's his
- T/E results page

ANALYSE / RESULTAT - CONFIRMATION

478/07 994474

et Epitestost : 432 Ion

ce 1 : Testosterone:

Echantillons A et B / Samples A et B

Code Flacon / et container: n° / bott:

BUR995474

ne insuffisant / Insufficient urine

ENREGISTREMENT

Code: E-PCR-AB2

Personnel: A

Date: 04/04/2006

Page: 1/1

FICHE D'ANALYSE - RESULTAT - CONFIRMATION SEMI-QUANTITATIVE T/E dans urines

Personne: 1787 07074

Echantillon: 1787 07074

Site de qualification: T/E dans l'urine

Concentration de la référence 1: Testosterone: 100 Epitestosterone: 3 T/E Ratio: 4

Concentration de la référence 2: Testosterone: 100 Epitestosterone: 30 T/E Ratio: 4

Code	Identifiant	Site de qualification	Concentration
AB27	1787074	1787074	24070
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410
AB27	1787074	1787074	130410

RESULTAT DE L'ANALYSE

Personne	Concentration Testosterone	Concentration Epitestosterone	Ratio T/E en urines
1787074	43.2	19.8	2.18
1787074	43.6	19.8	2.20
1787074	43.2	19.8	2.18
Moyenne	43.3	19.8	2.19
Limite supérieure	1.5	0.2	7.5
Limite inférieure	43.3	19.8	2.18

Partie à remplir par le responsable

Modèle de déclaration de rapport T/E en urines: A

Identifiant (dans le tableau) pour le rapport T/E: 432

Valeur basée sur le rapport T/E: 2.18

Valeur basée sur le rapport T/E: 14.3

Annulé:

Incomplet:

Rejeté:

Contrôle des concentrations de Testosterone et d'Epitestosterone par le personnel du laboratoire: PARAFFE

Date: 04/04/2006

USADA 0288

The lab made many errors in its analysis.

One of the easiest examples of lab error to see involves sample identification or labeling.

This is the page summarizing the testosterone and epitestosterone results from the A sample.

The sample number has two parts: The lab identification number and the athlete's identification number.

The lab identification number is wrong.

The lab identification number is 178/07—not 478/07.

The athlete's identification number is wrong. 994474 is not Floyd's number.

Floyd's number is the number in the barcode label taken from his attestation page. It is 995474.

Process Violates WADA Rules

- “Any forensic corrections... should be done with a single line through and the change should be initialed and dated by the individual making the change.”

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WADA Rules

“Any forensic corrections that need to be made to the comment should be done with a single line through and the change should be initialed and dated by the individual making the change. No white out or erasure that obliterates the original entry is acceptable.” [1]

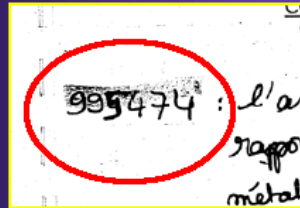
Ignorance is not an excuse: “All personnel should have thorough knowledge of their responsibilities including the security of the Laboratory, confidentiality of results, Laboratory Internal Chain of Custody protocols, and the standard operating procedures for any method that they perform.” [2]

[1] WADA Laboratory Internal Chain of Custody. TD2003LCOC. (2003).

[2] WADA International Standard for Laboratories. 29, (2004),

Clear WADA Rule Violation

- Sample number overwritten



LINDO	ENREGISTREMENT	Conditions : E-Fibre-100-9/2014
		Versions : A 155
		Doc : 01/03/2004 117

FICHE COMPLÉMENTAIRE POUR LA CONCLUSION DES RÉSULTATS ANALYTIQUES

Nombre de la feuille: 1

Nombre de Labe: ASB/12

Analyses commandées:

Analyses Conventioneles Chimie GC Chimies Conventioneles Chimie LC
Analyses Conventioneles Immunochimie
Analyses Toxicologiques Chimie GC: O HES X112013C
Chimies Toxicologiques Biologie EPO
Chimies Toxicologiques Biologie (U Quant): 18000

CONCLUSION: à noter et signer sur le Remarquable technique.

995474: L'analyse de l'échantillon par spectre de masse de rapport isotopique (C_{15}) indique une origine anorgane des métabolites de la testostérone, cohérente avec une prise de testis en de 2 sur de 200 picogrammes. L'origine exogène des métabolites de la testostérone a été éliminée sur la base d'un appariement isotopique de 3,99% et 6,14%, respectivement pour les métabolites androstène et 5 α androstane-3 β . Seul de produits de 2 HHA: appariement isotopique > 3% ($\pm 0,8%$, interne au laboratoire).
pH \pm 5,2 de 1,025
le 25/09/06

USADA 0009

This page summarizes the results of the A sample.

The sample identification number has been overwritten.

Again, Floyd's number is the number in the barcode label taken from his attestation page.

Sample Number Questionable

- Specimen transport record
- Chain of custody issues

994 190	
990 145	
996 198	
995 474	
990 144	
994 179	

Echantillons A et B / Samples A et B
 Code Flacon / et container n° / bott:
 BUR995474
 ne insuffisant / Insufficient urine

Code de Barre	Code de Flacon	Code de Barre	Code de Barre
994 190			
990 145			
996 198			
995 474			
990 144			
994 179			

RECEPTION AU LABORATOIRE
 Date et heure: 20-11-2015 14:55
 Nom: FLOYD
 Signature: [Signature]
 Cadeau: LABORATOIRE NATIONAL DE DÉPISTAGE DU DOPAGE
 1010 - Avenue Laurier
 1000 CHICAGO, IL 60606-7099
 Tél. 312 543 2800 Fax 312 543 2801
 www.laboratoire-national.com

TRANSPORTEUR
 Nom: STANLEY
 Signature: [Signature]

USADA 9024

This is the chain-of-custody documentation of the transport of Floyd's sample from stage 17 to the laboratory.

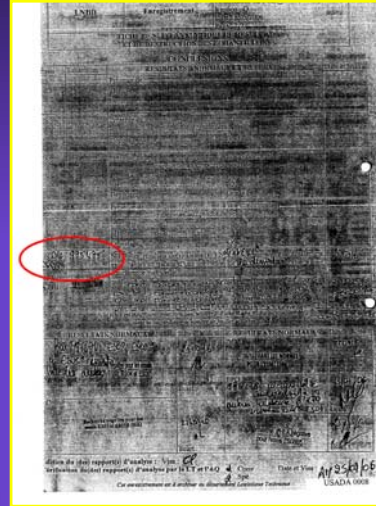
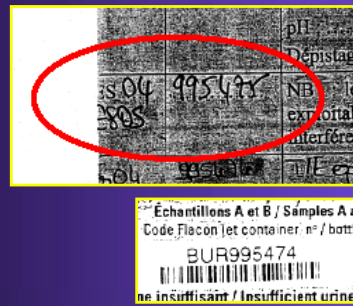
Either (1) there is a number similar to Floyd's recording as having been transported, but not Floyd's, or (2) the handwriting is ambiguous.

The vast majority of people I have surveyed read the number as 995476.

Again, Floyd's number is the number in the barcode label taken from his attestation page. It is 995474.

Sample Error

- Summary sheet
- Further evidence of irregularities



This is a summary page of the lab's record of the abnormalities of the three samples (three different riders tested) from stage 17.

The poor quality of the pages is how we received the document.

Again, Floyd's sample number isn't right: The handwritten number is 995475.

Contamination Recognized

- “The urine Sample is not collected under sterile conditions, and where the circumstances are favourable, the microbes present in the Sample can cause changes to the profile of the urinary steroids.”

- ◆ WADA Technical Document TD2004EAAS

WADA recognizes that contaminated or degraded specimens cannot be fairly examined, and should be discarded.

Degradation can result from many factors – including bacterial contamination, improper storage, biological or other chemical contaminants (such as blood), and adulteration.

WADA Contamination Rule Clear

- “The concentration of free testosterone and/or epitestosterone in the specimen is **not to exceed 5%** of the respective glucuroconjugates.”
 - ◆ WADA Technical Document TD2004EAAS

WADA rules are that if contamination or degradation levels of free testosterone or epitestosterone exceed 5%, the sample should not be analyzed.

Specimen Clearly Contaminated

	Epitestosterone	Reference
Free	0.44	USADA0283
Conjugates	5.7	USADA0288
Ratio	7.7%	(> 5%)

- No basis to proceed according to WADA rules

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Remember: More than 5% means the specimen is contaminated or degraded and should not be used.

Just like food with mold or maggots, such a sample should not be used.

The table shows the math: 7.7% degraded epitestosterone.

According to WADA protocol, since the epitestosterone level exceeds 5% (it is 7.7%) the specimen should not have been evaluated for an adverse analytic finding.

It should have stopped here.

The relevant screenshots are on the next page.

Contaminated/Degraded Proof

The image displays two analytical reports. The left report shows a table of results with a circled entry for Epitestosterone. The right report shows a table of results with a circled entry for Epitestosterone and a separate table of concentrations.

#	Peak Name	Ret. Time	Signal	Area	Target Response	Amount	Units
1	Epitestosterone	20.87	301.3	3924981	11645	100.00	ng/mL
2	Epitestosterone	19.82	432.4	11645	0.44	0.44	ng/mL

Subst.	Concentration	Unit
Epitestosterone	5,9	ng/mL
Epitestosterone	5,8	ng/mL
Epitestosterone	5,6	ng/mL
Epitestosterone	5,7	ng/mL

Here are the relevant screenshots used to calculate degradation from Floyd's B sample.

Again, the specimen was clearly contaminated. There was no basis to proceed, according to WADA rules.

Lab T/E Uncertainty Standards

- Epitestosterone
 - ◆ 30%
- Testosterone
 - ◆ 20% uncertainty

Remplir par le responsable

pour l'Epitestosterone : **30%** pour la Testosterone : **20%**

Résultat : Normal

Inclassable -

Partie à remplir par le responsable

Sur le rapport T/E (si applicable) : 30% pour l'Epitestosterone / 20% pour la Testosterone
 Sur le rapport T/E : 20% pour l'Epitestosterone / 30% pour la Testosterone
 Sur le rapport T/E : 30% pour l'Epitestosterone / 30% pour la Testosterone

Concentration en Testosterone et Epitestosterone aux 3 (ENC-8) :
 Sur la référence : 30%
 Sur la référence : 20%
 Sur la référence : 30%
 Concentration corrigée de Testosterone : 30%
 Concentration corrigée d'Epitestosterone : 20%

USADA 0101

By the lab's own methods, repeated sampling of testosterone levels should be within 20%, and repeated sampling of epitestosterone levels should be within 30%.

Radically Inconsistent

Test	Testosterone	Epitestosterone	Reference
1 st	61.37*	5.2*	USADA0092
2 nd	172.23	17.59	USADA0212
	181% error	238% error	

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Here are two confirmation examinations of testosterone and epitestosterone, by the same method, from the A sample.

These variations cast doubt on the lab's ability to repeatably and accurately test a sample for these substances.

* Reference result. Percent error is a math term: The difference between a value and a reference value, divided by the reference value.

Another way to look at it: The values in the second row of numbers are about 300% greater than the numbers in the first row of numbers.

Unreliable Testing



1st Test
1 Bottle



2nd Test
2.8 Bottles

Relative
Measurement

Here is another way to look at the two confirmation examinations of testosterone from the A sample.

If the amount in the first test is represented by 1 waterbottle, the amount in the second test is represented by 2.8 waterbottles.

Again, these variations cast doubt on the lab's ability to repeatably and accurately test a sample for these substances.

Unacceptable Error: Clear Proof

© 2008 Agilent Technologies

Data File Path: D:\MSDCHEM\JULY09\0471
 Data File Name: 1767474.D
 Operator: JB
 Date Acquired: 7/24/2008 13:28
 Auto Method File: MAND7
 Sample Name: 1767 89474 In
 Vial Number: 4
 Calibration Title: Quantification T/E (2 points)
 Last Calibration Update: Mon Jul 21 11:16:48 2008

#	Peak Time	Ret. Time	Signal	Name	Target Response	Amount	Units
1	10.70	20.48	301.3	17methyltestosterone	5595490	100.00	ng/mL
2	18.36	432.4	432.4	epitestosterone	307234	5.20	ng/mL
3	18.36	432.4	432.4	testosterone	3513238	61.37	ng/mL

Control de rapport T/E
 Substance Concentration
 T/E 11.8

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Name	Target Response	Amount
17methyltestosterone	5595490	100.00
epitestosterone	307234	5.20
testosterone	3513238	61.37

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Data File Path: D:\MSDCHEM\JULY09\0471
 Data File Name: 1767474.D
 Operator: JB
 Date Acquired: 7/22/2008 18:02
 Auto Method File: MAND7
 Sample Name: 1767 89474 In
 Vial Number: 10
 Calibration Title: Quantification de rapport T/E
 Last Calibration Update: Mon Jul 21 12:34:34 2008

#	Peak Time	Ret. Time	Signal	Name	Target Response	Amount	Units
1	10.70	20.48	301.3	Methyltestosterone	1397200	100.00	ng/mL
2	18.36	432.4	432.4	epitestosterone	244818	17.59	ng/mL
3	18.36	432.4	432.4	testosterone	2621497	172.23	ng/mL

Control de rapport T/E
 Substance Concentration
 T/E 8.8

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Name	Target Response	Amount
Methyltestosterone	1397200	100.00
epitestosterone	244818	17.59
testosterone	2621497	172.23

Here are the relevant screen shots.

By the laboratory's own standards, its testing was unacceptable.

Variable T:E Results

- Radically inconsistent

Test	Testosterone	Epitestosterone	T:E Ratio	Reference
1 st	49.7	11.1	4.4	USADA0057
2 nd	61.37	5.2	11.8	USADA0092

When the sample was screened for T:E ratio, the calculated ratio was 4.4.
When the sample was tested to confirm the ratio, it was 11.8.

Variable Results T:E Ratio

© 1999 Datacube/Quest Diagnostics, Inc.

Data File Path: D:\MSDCOL\LAB\04047
 Data File Name: 1787474.D
 Operator: JH
 Date Acquired: 12/20/08 13:28
 Acquisition Method File: MAN27
 Sample Name: 1787 89474 H
 Vial Number: 4
 Instrument Name: MSD 11
 Calibration File: Quantitation TE (2 points)
 Last Calibration Update: Mon Jul 21 11:18:48 2008

#	Peak Type	Ret Time	Signal	Name	Target Response	Amount	Units
17	TEST	17.14	201.3	Testosterone	307234	5.20	ng/ml
18	TEST	18.78	172.9	Epitestosterone	3513238	61.37	ng/ml

Calcul de rapport T:E
 Surface Concentration
 T:E 11.8

Name	Target Response	Amount
17méthyltestostérone	307234	100.00
epitestosterone	307234	5.20
testosterone	3513238	61.37

Page 1 of 1 © 1999 Datacube/Quest Diagnostics, Inc. 7040306 5/17/04 USADA 0092 83

© 1999 Datacube/Quest Diagnostics, Inc.

Data File Path: D:\MSDCOL\LAB\04047
 Data File Name: 1787474.D
 Operator: MAN27
 Acquisition Method File: MAN27
 Sample Name: 1787 89474 H
 Vial Number: 4
 Instrument Name: MSD 11
 Calibration File: Quantitation des stéroïdes anabolisants
 Last Calibration Update: Mon Jul 21 11:18:48 2008
 Ficheur voir autre 284916.D

#	Peak Type	Ret Time	Signal	Name	Target Response	Amount	Units
17	TEST	17.14	201.3	Testosterone	307234	5.20	ng/ml
18	TEST	18.78	172.9	Epitestosterone	3513238	61.37	ng/ml

17.14 5.1
Testosterone
Epitesto
Androsterone

#	Peak Type	Ret Time	Signal	Name	Target Response	Amount	Units
17	TEST	17.14	201.3	Testosterone	307234	5.20	ng/ml
18	TEST	18.78	172.9	Epitestosterone	3513238	61.37	ng/ml

Surface	Concentration	Valeurs normalisées
Andr (B) (1787)	0.0	< 12.0
TE (E)	0.1	> 4
Testosterone	45.7	Concentration > 200
Epitestosterone	11.4	Concentration > 200
Androsterone	1.00	Concentration > 10000
Androstenedione	21.0	Concentration > 200
SHAN	0.0	Concentration > 20
EST	0.0	Report > 3
Andr (E) (18)	0.4	Report > 3
SHAN (E) (18)	0.0	Concentration > 10
THC (M)	0.0	Concentration > 10
Subst (B) (THC) (1787)	0.0	Concentration > 10
Carbol (THC)	1.0	Concentration > 10
THC (F) (18)	0.1	Concentration > 10
11 OH (M) (THC)	1.0	Four info (M&M)
THC (M)	0.0	

USADA 0057 52

Here are the relevant screen shots.

Carbon Isotope Ratio

- No positive indicated
 - ◆ “Exogenous” testosterone test
 - ◆ So-called “foolproof” test (it’s not)
 - ◆ But Floyd’s test isn’t even positive!

This is the test that has been played up in the press as the gold standard, the test that cannot be challenged: The exogenous test, or proof of synthetic testosterone.

No test is infallible, and the CIR test does have problems.

However, the test wasn't even positive, as we'll show in the next slides.

Isotope Ratio Criteria

- Criteria clearly not met
 - ◆ 4 testosterone breakdown products examined
 - ◆ Look for absolute numbers > 3.8
 - ◆ All must be abnormal for test to be conclusive

- Floyd has only one abnormal

According to published studies and WADA's own protocols, the metabolites or break-down products should be abnormal.

For more details and discussion about the criteria for a positive test, see lawyer Howard Jacob's dismissal motion to the Anti-Doping Review Board.

Test Criteria Not Met

- Not positive

Blu		Echantillon	
$\Delta\%$	$\Delta\% + 0,8\%$	$\Delta\%$	$\Delta\% + 0,8\%$
-1.08	-1.22	-2.02	-1.14
-0.08	-2.71	-3.51	-2.63
-0.67	-1.85	-2.65	-1.98
-1.60	-5.59	-6.39	-5.51

Considering the criteria for positive (3.0) and stated accuracy of the lab (± 0.8) isotope absolute values must be higher than 3.8.

Only one of Floyd's four breakdown products examined even arguably met the criteria to determine a positive result.

Best Test Negative

■ 5 β Adiol- 5 β Pdiol

	Blu		Echantillon	
	$\Delta\%$	$\Delta\% + 0,8\%$	$\Delta\%$	$\Delta\%$
Etio - 11 Kétoétio	-1.08	-1.22	-2.02	
Andro - 11 Kétoétio	-0.08	-2.71	-3.61	
5 β Adiol - 5 β Pdiol	-0.67	-1.85	-2.65	
Deh Adiol - 5 β Pdiol	-1.60	-5.59	-0.39	

The strongest, or most robust indicator of anabolic steroid misuse (according to the scientific literature), the 5 β Adiol- 5 β Pdiol value, does not meet the criteria for a positive test.

It has an absolute value of 2.65.

Testosterone Level Low

- Total testosterone in Floyd's urine: small amount



Floyd: 45.4



High: > 200

There are some other points to take into consideration:

The total amount of testosterone in Floyd's urine was calculated as 45.4 nanograms per milliliter. This is well below the value of 200 that is considered high.

If a high amount is 1 waterbottle, Floyd's amount is represented by a less than $\frac{1}{4}$ of a waterbottle (23%).

In other words, there was not much testosterone in Floyd's urine.

Not Anonymous Objective Test

- Lack of blinding
- Lab knew Floyd
- From identity of his hip cortisone

Médicaments déclarés avoir été pris récemment / Drugs declared to have been recently used:
(éventuellement nom du médecin prescripteur)

Cortisone
Cortisone

Confirmation / Confirmation

BREVET DE VERBAUX DE CONTRÔLE ANTIDOPAGE / DOPING CONTROL FORM

USADA 0228

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Subject identification to the lab in any study is a problem. Laboratories are supposed to conduct tests without the knowledge of whose sample they are testing.

I am not arguing that the lab was biased—I don't know that.

However, since Floyd was known to have a therapeutic use exemption for the steroids used to treat his dead hip, and since this information was not redacted from his doping control form, sample identification was a relatively simple matter.

This part of the testing process should be improved to help the credibility of the process for all.

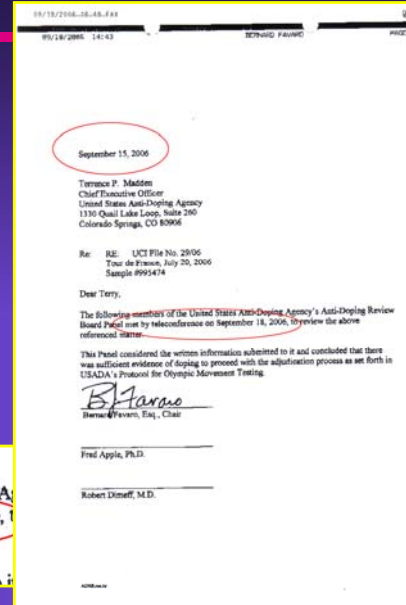
Review Board

- Due process?
- When did they decide?

September 15, 2006

Dear Terry,

The following members of the United States Anti-Doping Agency Board Panel met by teleconference on September 18, 2006, to review the above referenced matter.



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Something about the process.

Floyd didn't accurately provide an explanation for his allegedly positive test initially – because he had not received the documentation package; he didn't know what the problems were.

After an initial two-week review of the document package, his lawyer Howard Jacobs submitted a dismissal request to the Anti-Doping Review Panel. This request was denied. The denial letter is dated three days before the meeting took place.

Typographical error? Perhaps – at least that is what USADA now claims.

Of course, any agency, board, or lab can make errors. USADA did. The French lab did.

What we have shown in the previous slides is that the whole process has been full of errors.

Summary: Test Not Positive

- A. Positivity criteria not met
- B. Sample mislabeled
- C. Specimen contaminated/degraded
 - ◆ Untestable
- D. Testing unreliable
- E. **All of the above**

In summary:

There are many problems and errors in the USADA documentation package.

In this slide show we have examined a few of the important lines of evidence showing that:

Floyd Landis's doping test is *not* positive.

Floyd, Tour de France 2006

- Drug test
- Not positive



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End