



Analyte Issues New Ventures in 2010

Sue Scott

RCPA Chemical Pathology QAP

sue.scott@rcpaqap.com.au

www.rcpaqap.com.au/chempath

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2010 Issues & Ventures

1. Onsite Urine Toxicology Screening Program (OUTS)
2. Total Bile Acids (TBA) Program
3. Vitamin C in the Vitamins Program
4. Testosterone target value assignment in the Endocrine Program



Onsite Urine Toxicology Screening Program (OUTS)

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OUTS Program

- Following requests from laboratories a qualitative urine toxicology program is being offered in 2010
 - The AACB Urine Toxicology Working Party instrumental in implementation

Stacey Richards (Chair), NSW Racing, NSW
Trisha Andersen, Australian Scientific Enterprises, NSW
Grant Moore, Canterbury Health Services, NZ
David Rutherford, VIC
Santiago Vasquez, HAPS, NSW
John Zoanetti, SA Pathology, SA



OUTS Program

- Designed specifically for onsite and laboratories performing qualitative drugs of abuse screening
- A qualitative program only
 - Report detected or not detected
- 6 drugs are currently being offered

Amphetamine Type Substances ;
Amphetamine and Methamphetamine
Cocaine metabolites
Opiates
Cannabis metabolites
Benzodiazepines



OUTS Program

- Material is being manufactured by Australian Scientific Enterprises (ASE)
 - Human urine specimens
 - 6 linear concentration levels
 - A low and high pool (L1 and L6) & 4 intermediate levels
 - Using the AS/NZS:4308 Standard cut off limits to offer a range of concentrations from 0 ug/L through to significantly above the cut-off value for each drug
 - Can purchase either 1ml or 10ml
 - One 12 month cycle January to December
 - 1 sample per month



OUTS Program

- Specifically designed report for each participant can evaluate their results according to the cut-offs for their device
 - Target values were set using GCMS and LCMSMS methods

Printed: Mar 31 09:22:36 2010 © RCPA Quality Assurance Program Pty. Limited ABN 32 003 520 072 Prepared by: RCPA Chemical Pathology QAP Group

Due Date : 28/02/2010 **Specimen Number 1-02** **Laboratory Number**

Your Result		Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Amphetamine:	D	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Methamphetamine:	D	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Benzodiazepines:	ND	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Cannabis:	ND	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Cocaine:	D	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	
Opiates:	D	Your Method: J 80A 083 A: Thermo Fisher Scientific MicroScreen Drug Screen Cup	

Sample 1-02 Concentrations	
Amphetamine	570 ug/L
Methamphetamine	474 ug/L
Benzodiazepines	0 ug/L
Cannabis	0 ug/L
Cocaine	667 ug/L
Opiates	516 ug/L

Results

◆ Your Result ■ Your Method □ All Results ND Not Detected D Detected

Review

Evaluate your result according to the drug cut-offs for your device.

Amphetamine _____

Methamphetamine _____

Benzodiazepines _____

Cannabis _____

Cocaine _____

Opiates _____

On-Site Urine Toxicology Screening



OUTS Program

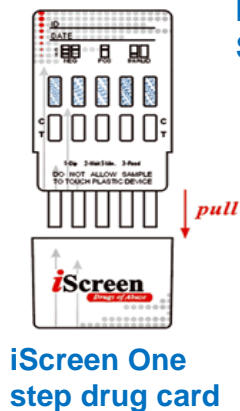
- Currently have 26 laboratories enrolled

Company Name	Product	Number Enrolled
Abbott	AxSYM	2
ACON Laboratories	Mult-Drug One Step Mult-Line Screen Test Device	2
Branan Medical Corporation	QuickTox	1
Ameditech	Pro Screen Drugs of Abuse	1
Biosite	Triage Meter	1
BioRad	Tox/See	2
Inverness Medical	Innovacon Multi-Drug One Step Multi Line	2
Inverness Medical	Sure Step 6 Panel Cassette	1
Inverness Medical	Sure Step 6 Panel Cup	1
iScreen	One Step Drug Card	1
Thermo Fisher Scientific	MicroScreen Drug Screen Cup	3
Thermo Fisher Scientific	MicroCup Mult-Drug Screening Test	1
Thermo Fisher Scientific	MicroCheck Mult-Drug Screening Test	1
Thermo Fisher Scientific	MicroTox Drug Screen Cassette	1

6 laboratories recently enrolled & have started reporting results this month



OUTS Program



Inverness Medical Sure Step6 Panel cassette



Branan QuickTox



Thermo Fisher Scientific Micro Tox Multi Drug Screening Test

Bio-Rad Tox/See





OUTS Program

- When looking at the results can review
 - Accuracy; did we get the right result
 - Comparison using category 3 of the QAP method classification system
 - Compare all results for all concentration levels
 - Precision or repeatability; same result on the same concentration level on more than 1 occasion
 - Will review results obtained on concentration level 6 which has been analysed on 2 separate occasions this year

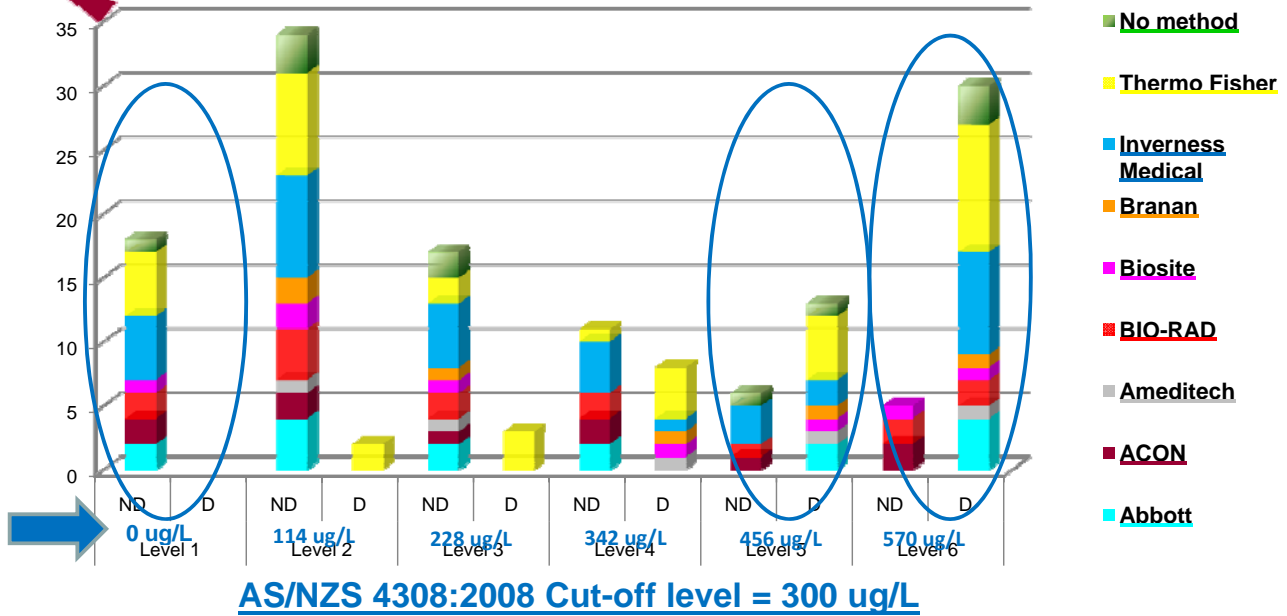


OUTS Program

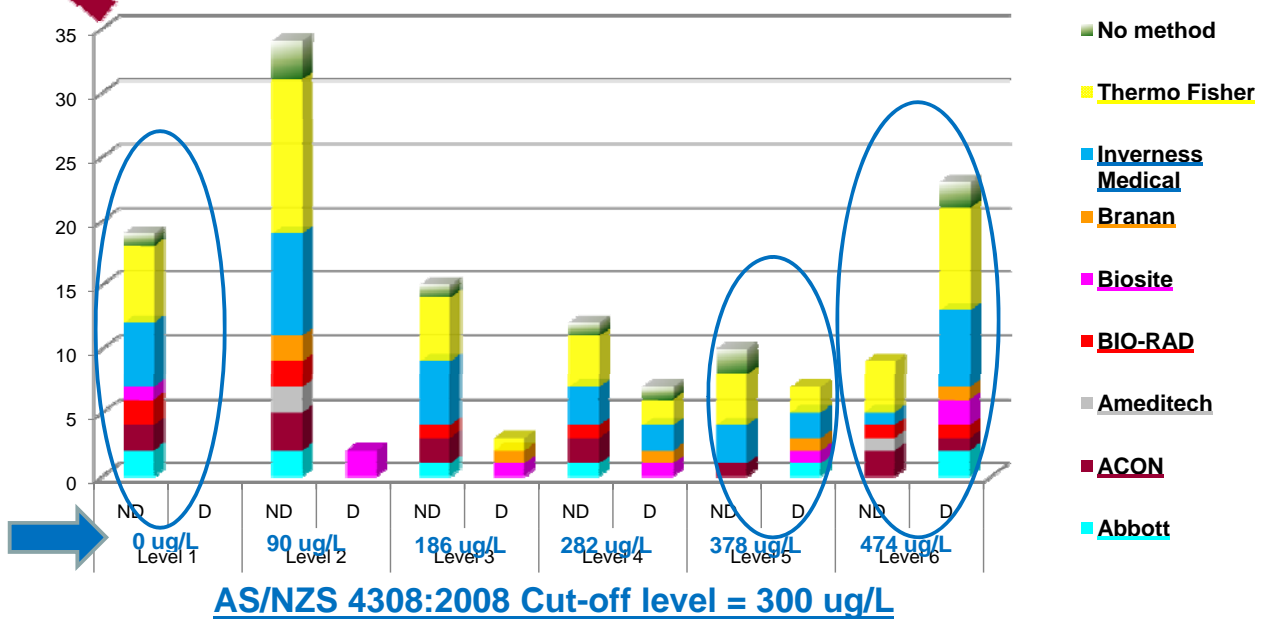
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Amphetamine

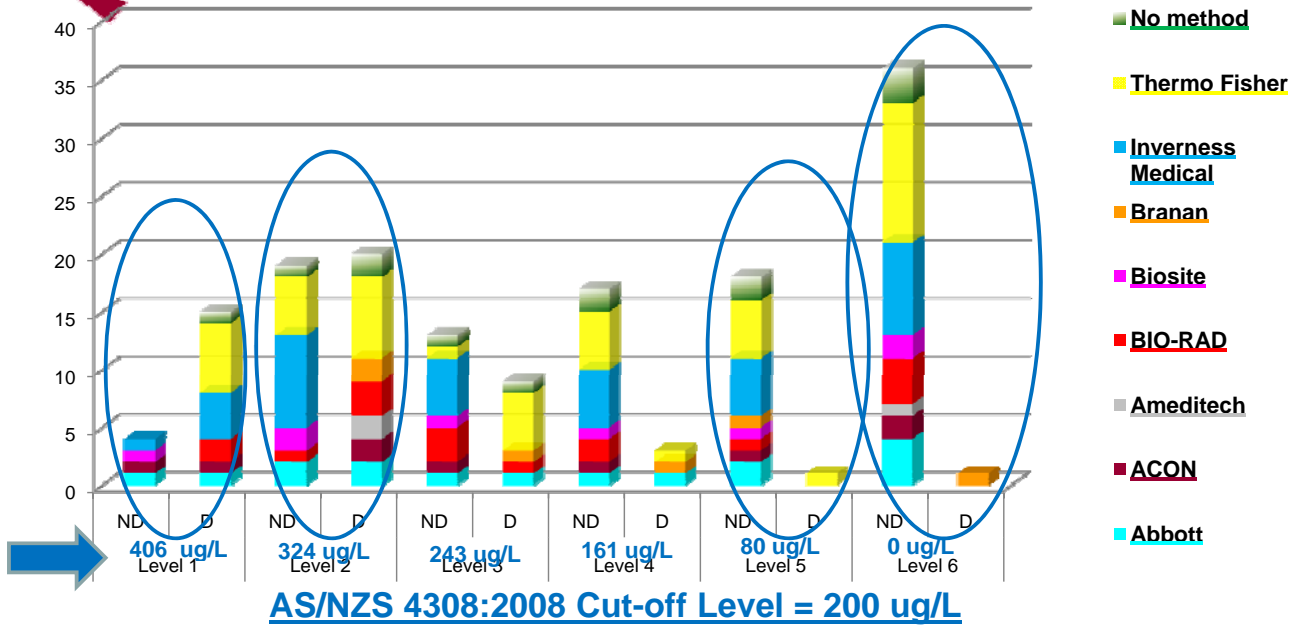


Methamphetamine

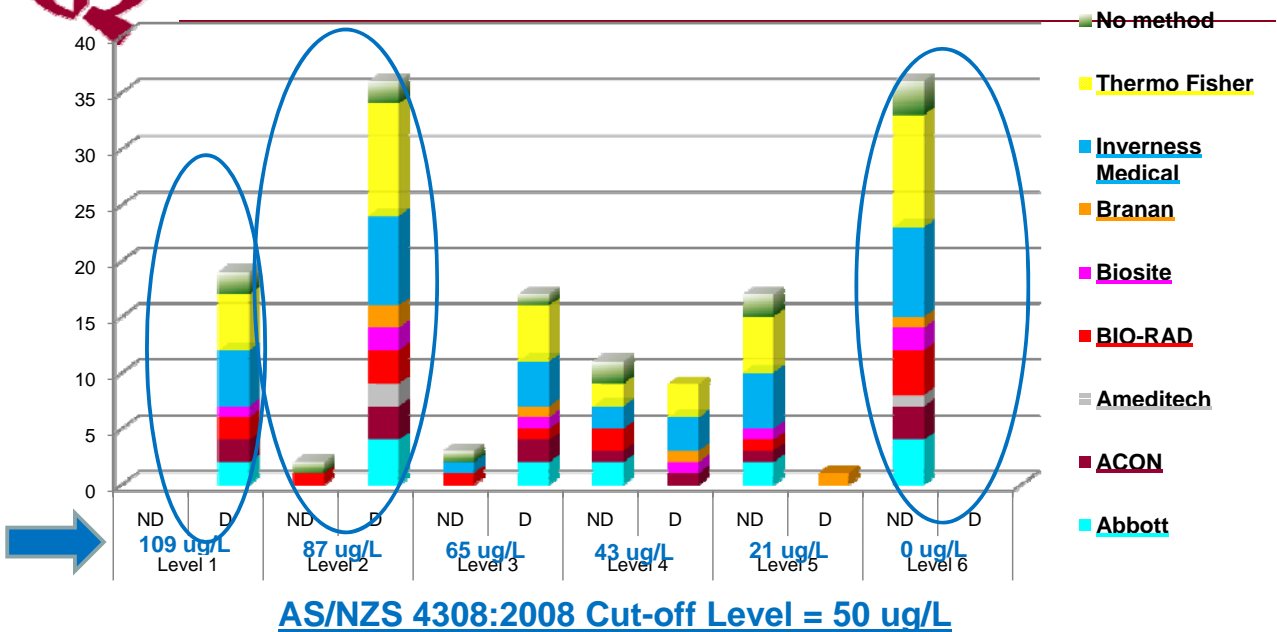




Benzodiazepines

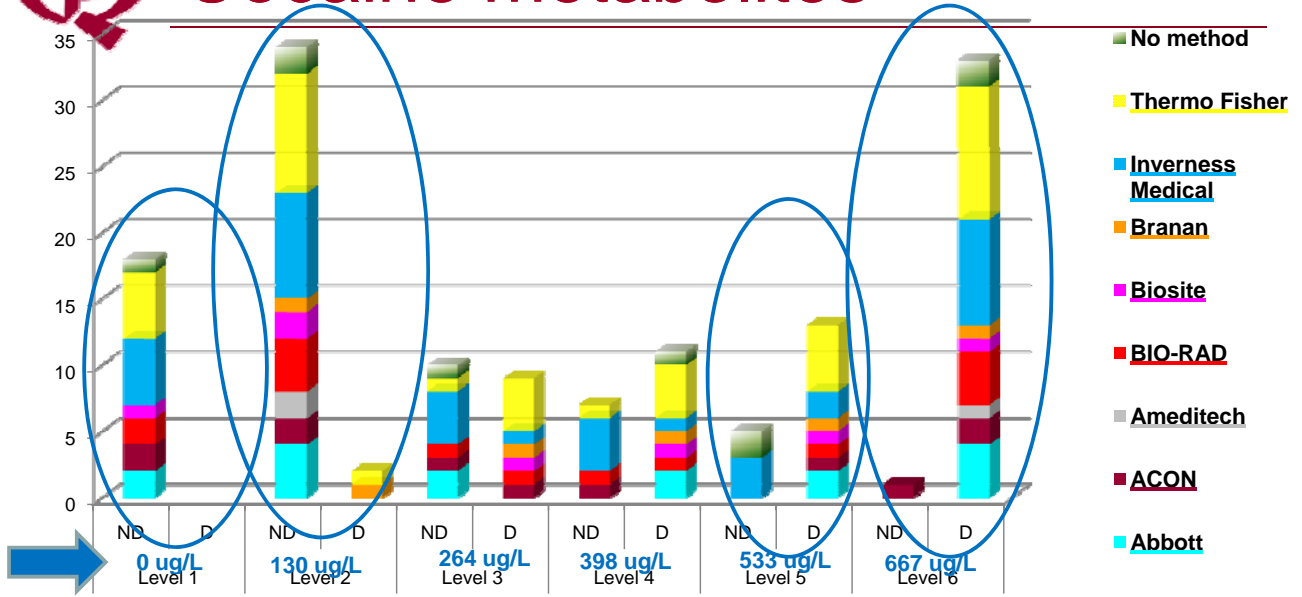


Cannabis metabolites





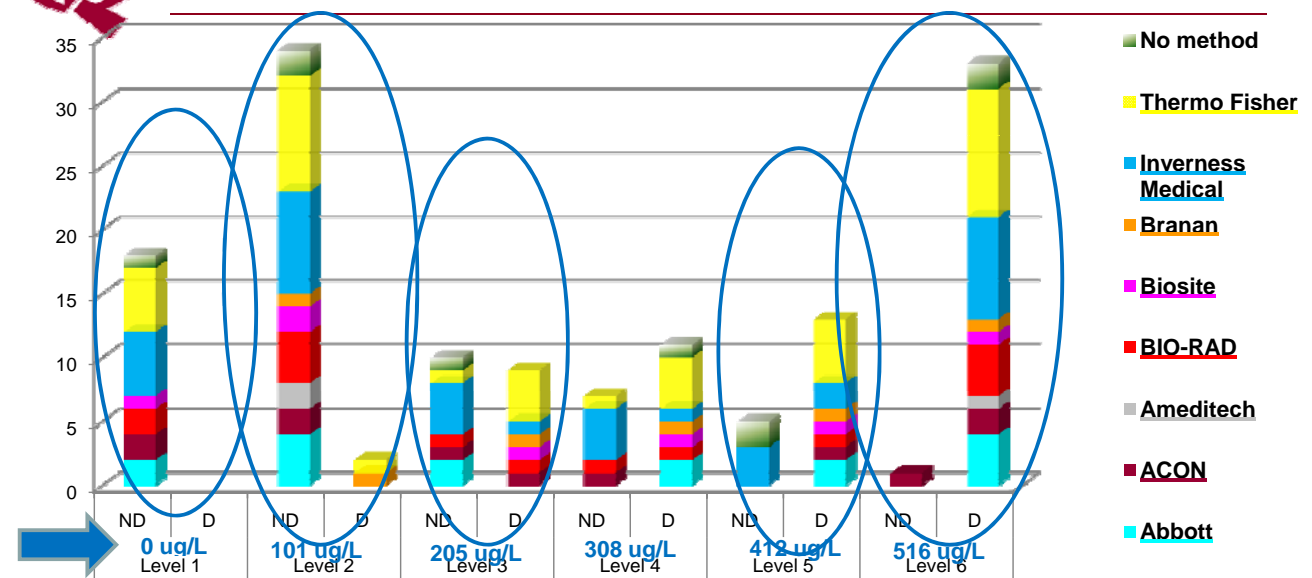
Cocaine metabolites



AS/NZS 4308:2008 Cut-off Level = 300 ug/L



Opiates



AS/NZS 4308:2008 Cut-off Level = 300 ug/L



OUTS Program

- When looking at the results can review
 - Accuracy; did we get the right result
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OUTS Program

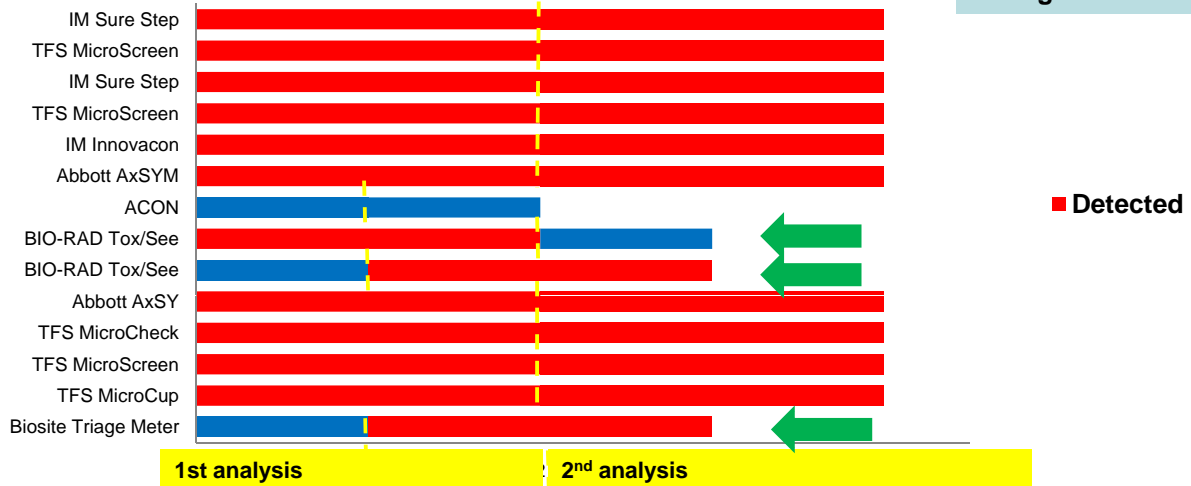
- When looking at the results can review
 - Accuracy; did we get the right result
 - Comparison using category 3 of the QAP method classification system
 - Compare all results for all concentration levels
 - Precision or **repeatability**; same result on the same concentration level on more than 1 occasion
 - Will review results obtained on concentration level 6 which has been analysed on 2 separate occasions this year



Repeatability – Amphetamine

Concentration Level 6

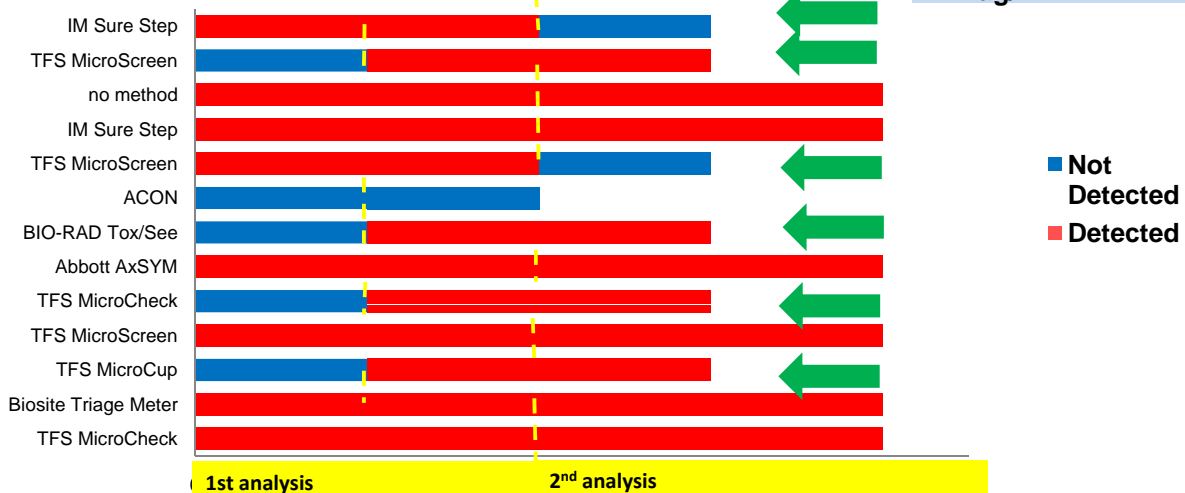
Amphetamine = 570 ug/L



Repeatability - Methamphetamine

Concentration Level 6

Methamphetamine = 474 ug/L

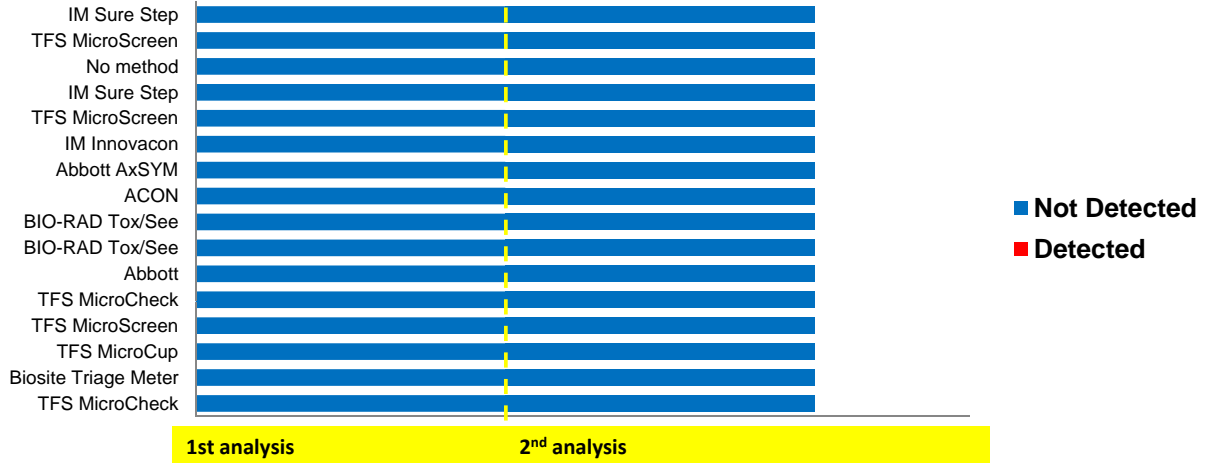




Repeatability - Benzodiazepines

Concentration Level 6

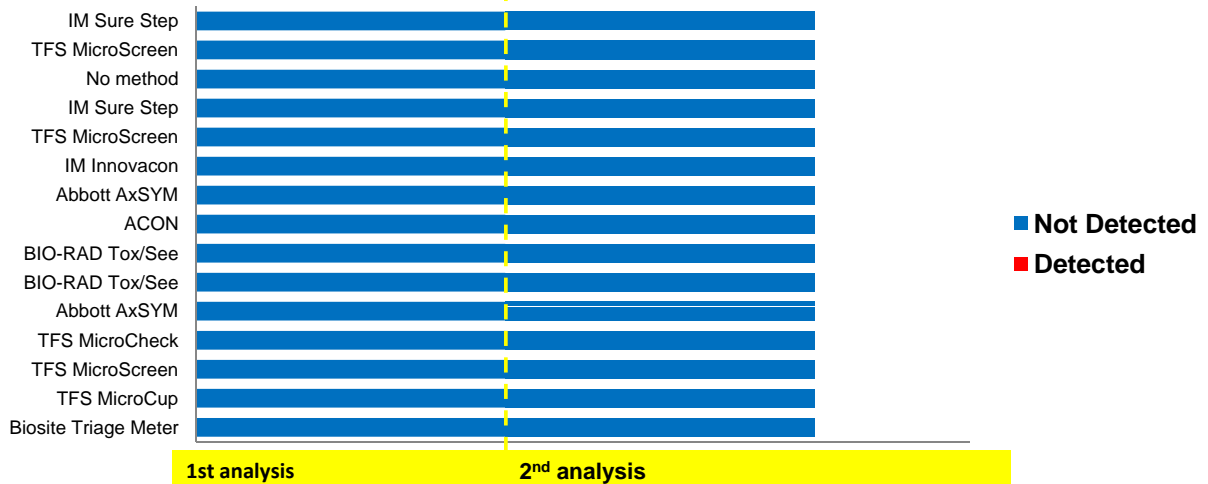
Benzodiazepines = 0 ug/L



Repeatability – Cannabis metabolites

Concentration Level 6

Cannabis metabolites = 0 ug/L

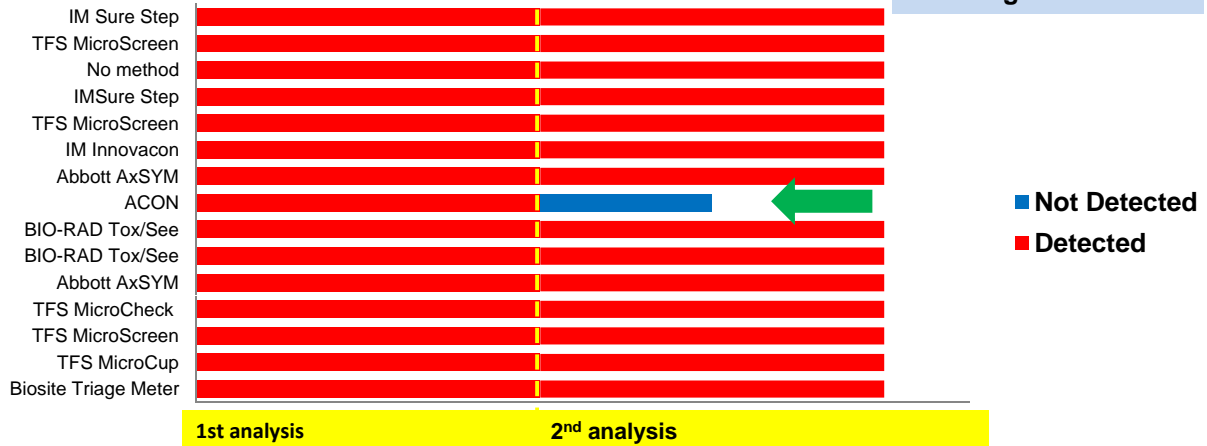




Repeatability – Cocaine metabolites

Concentration Level 6

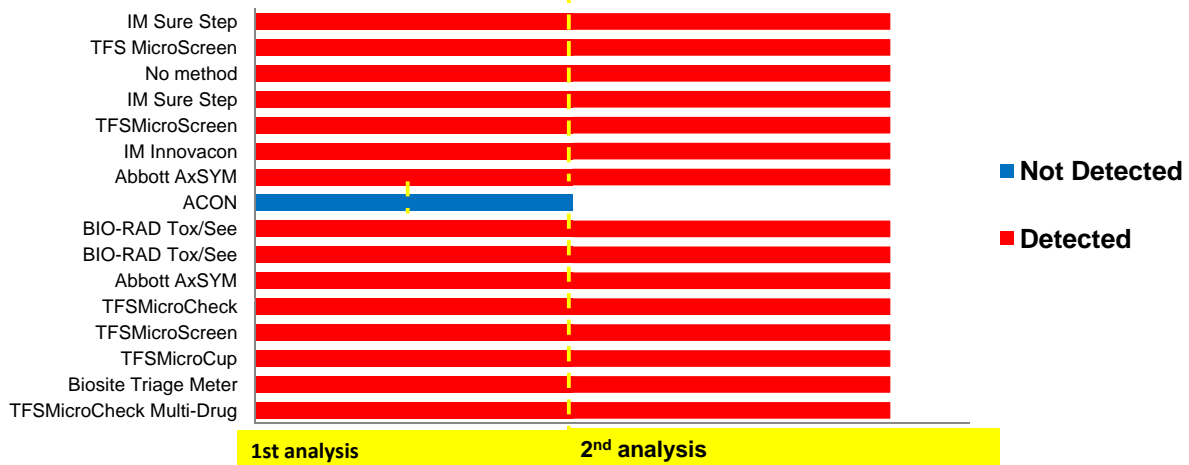
Cocaine metabolites = 667 ug/L



Repeatability - Opiates

Concentration Level 6

Opiates = 516 ug/L





Conclusion

- At the completion of the first cycle to look again at the accuracy and repeatability will be very interesting
- This program is being offered again in 2011
 - Looking forward to a growth in this market

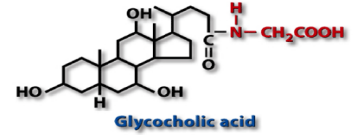


Total Bile Acids Program (TBA)



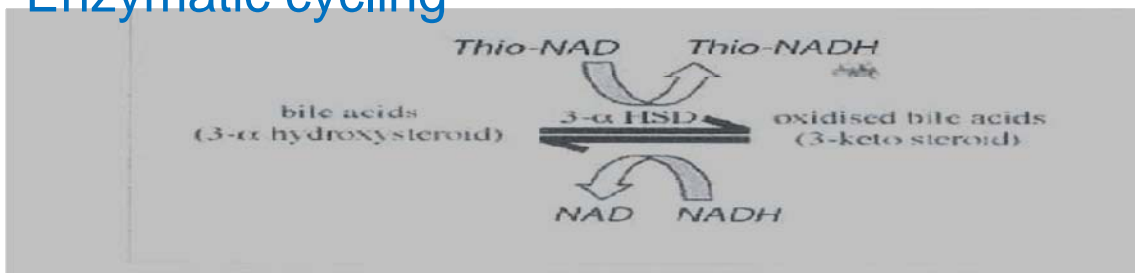
Total Bile Acids (TBA)

- Due to participant request
- Offered for the first time in 2010
 - Currently have 22 laboratories enrolled in the program
- Manufactured by ASE to QAP specifications
 - Linear material consisting of a low and high pool with 4 intermediate levels
 - L1 (low pool) = 3-8 $\mu\text{mol/L}$
 - L6 (high pool) = 75-85 $\mu\text{mol/L}$



TBA Method Classifications

- In research in 2009 found 2 methods in use
 - Enzymatic cycling (Category 1 = B)
 - Enzymatic colourimetric (Category 1 = A)
- Enzymatic cycling

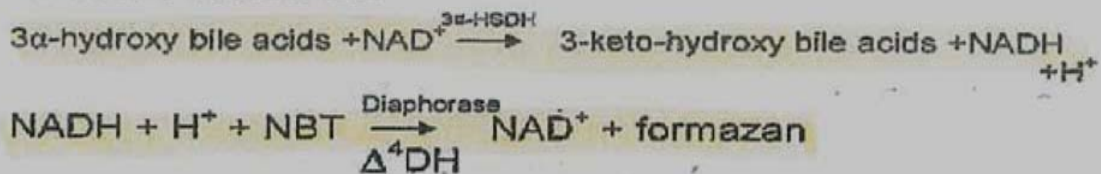




TBA Method Classifications

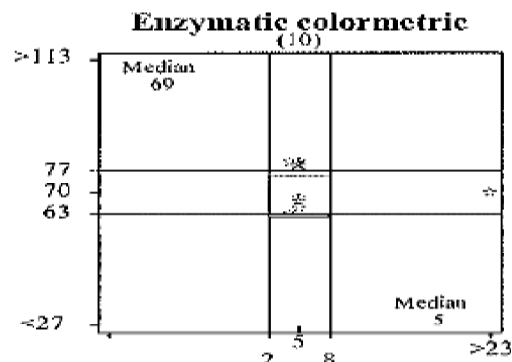
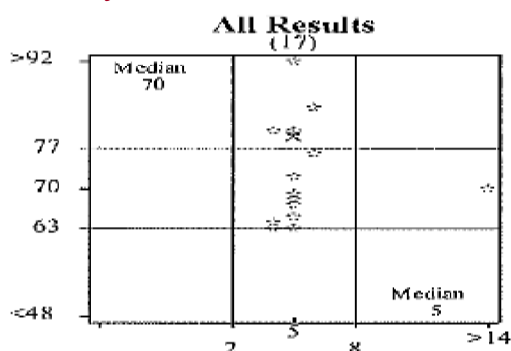
- In research in 2009 found 2 methods in use
 - Enzymatic cycling (Category 1 = B)
 - Enzymatic colourimetric (Category 1 = A)
- Enzymatic colourimetric assay

ASSAY PRINCIPLE



TBA Method Classifications

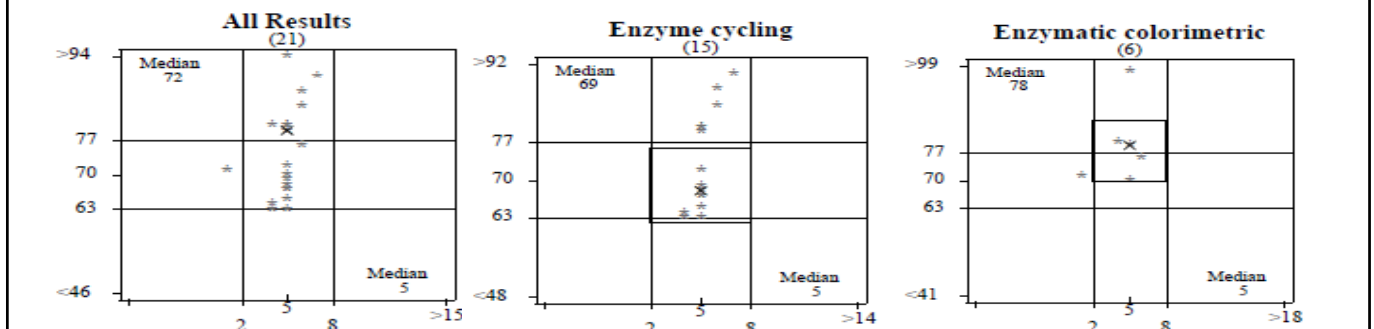
- Many laboratories were incorrectly classified for Category 1
 - Appeared to be a greater number of laboratories using an enzymatic colorimetric method





TBA Method Classifications

- After contacting majority of laboratories discovered incorrect classification of category 1
 - Majority of labs were in fact using an enzymatic cycling method



TBA Method Classifications

- Through talking to participants and reviewing the methods in use in laboratories discovered a few laboratories also had incorrect method classifications for category 3 Reagents
 - A number of labs classified as using Inverness Medical reagents when in fact they were Vital Diagnostics



TBA Program Information Circular



RCPA QUALITY ASSURANCE PROGRAMS PTY LIMITED
ABN 32 003 520 072

RCPA Chemical Pathology Program
In association with the Australasian Association of Clinical Biochem

Bile Acids Program Program Information Circular Method Classifications for Total Bile Acids 7 July 2010

Dear Participant

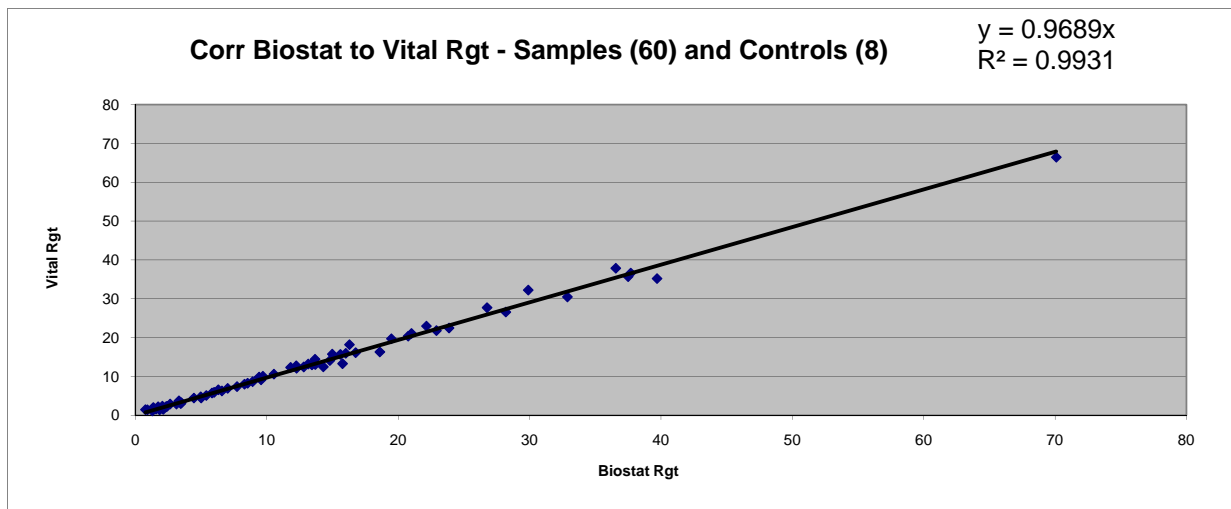
Following discussions with reagent manufacturers of the Total Bile Acid assay it became apparent there were some issues with the current method classifications pertaining to a number of laboratories enrolled in the Total Bile Assay Program. These issues included:

1. Classification of the Analytical Principle (Category 1)

Currently there are two assays being offered for the measurement of Total Bile Acids. The first assay is a colorimetric assay where the 3-alpha hydroxy bile acids are converted to the corresponding 3-keto bile acids and the reaction involves the formation of a dye which is read at a selected wavelength. The correct classification for this principle is A, Enzymatic colorimetric. The second assay incorporates a more complex enzyme cycling method to amplify the signal produced. There is a forward and a reverse reaction to maximise the detection of Total Bile Acids present. The correct method classification for this principle is B, Enzyme cycling. For some manufacturers offering the Total Bile Acids assay they have more than one generation of assay available. Depending on the generation of assay chosen the analytical principle may be either Enzyme colorimetric or Enzyme cycling. Therefore great care needs to be taken when classifying the analytical principle for all reagent kits.



TBA Comparison



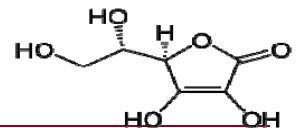


Vitamin C

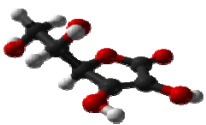
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Vitamin C



- Vitamin C has been included in the 2010 Vitamins Program
 - Participant request for some time
 - With the support of the AACB Vitamins Working Party able to offer this analyte this year
 - Kirsten Hoad, presented a review of the Vitamins QAP Program including Vitamin C performance yesterday





Vitamin C

- Manufacturer consulted for 2010 production
 - Australian Scientific Enterprises (ASE)
 - Specifications set for low pool (Level 1) and high pool (Level 6)
- 13 laboratories enrolled in 2010 Program
 - 13 laboratories are reporting results
 - 9 labs by HPLC, 1 lab by 2,4 dinitrophenylhydrazine and 1 lab by colourimetric.
 - 5 labs are using their own reagent, 1 lab is using BDH/Merck, 1 lab is using Chromsystems, and 1 lab Immunodiagnostik.

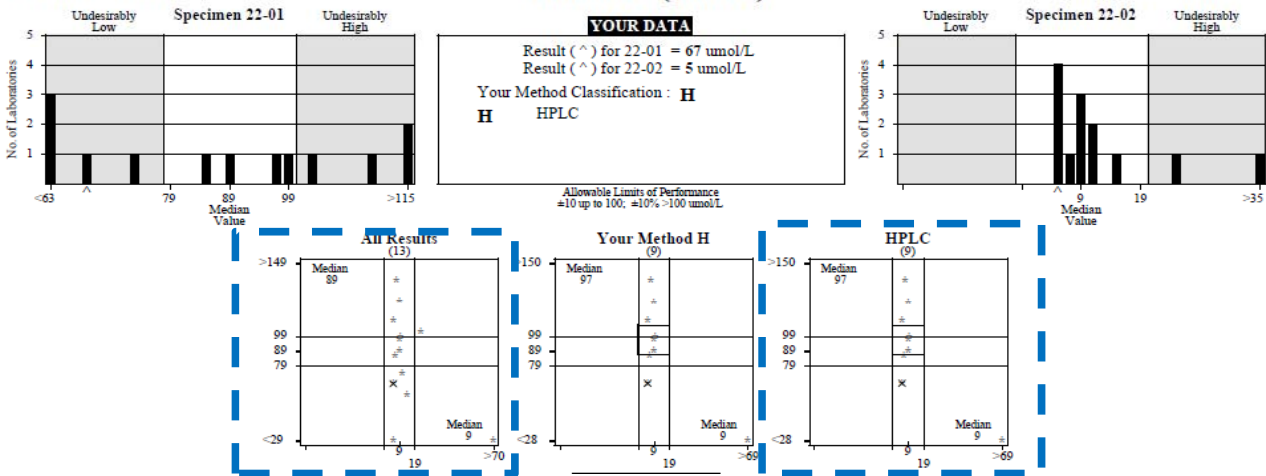


Vitamin C

Due Date : 1/02/2010

Vitamin C (umol/L)

Laboratory Number





Testosterone

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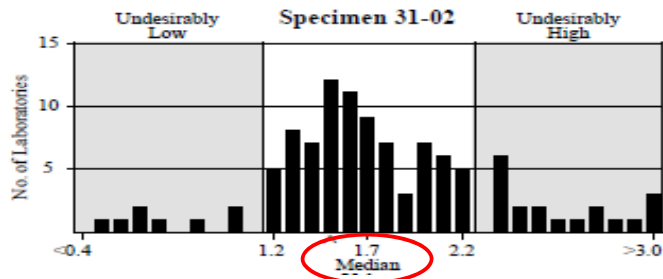
Testosterone

- This year providing target values for testosterone in the Endocrine Program
 - These were set by WEQAS using a validated reference procedure for the determination of **testosterone** concentrations (**nmol/L**) in human serum using Gas Chromatography Mass Spectrometry
 - Will be looking at setting targets again in 2011

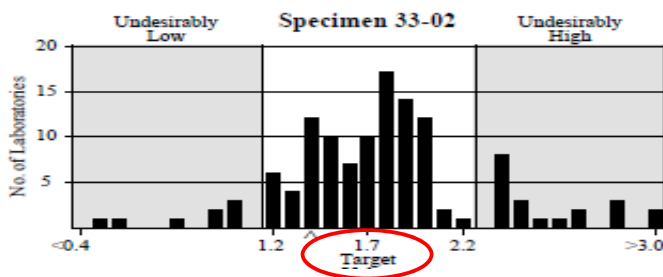


Testosterone

Level 1 2009

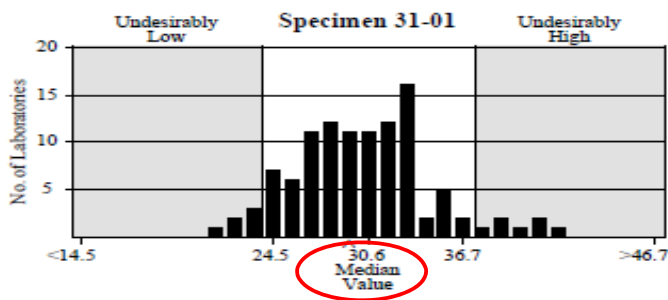


Level 1 2010

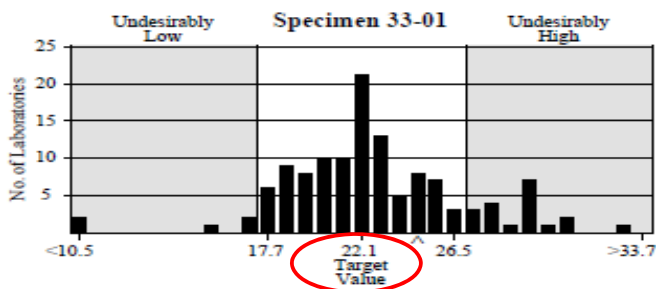


Testosterone

Level 6 2009



Level 6 2010





Chemical Pathology QAP

New Ventures

- We will continue to investigate new programs
- We will continue to improve on the programs being offered
- Thank you