FRCPath Clinical Biochemistry

Part 2, Module 1, Paper 1 - OSPE Exam

This is a three-hour objective structured practical examination (OSPE) where candidates are required to answer a series of 19 questions using a selection of material provided wither in paper format or as images/tables on an IPad. The selection of material will include:

- analytical outputs (e.g. electrophoretic strips, chromatography scans)
- clinical scenarios (e.g. sample requirements, investigation protocol questions)
- quality control and/or external quality assurance data
- analytical, physiological or pharmacological calculations
- One question will test communication skills using responses made in writing.

Candidates are given approximately 9 minutes per question with an additional 9 minutes at the end. This makes a total of 3 hours. Candidates can attempt the questions in any order and can decide how much time they wish to spend on specific questions within the 3 hour time window. Each question is marked out of 20, making a total of 380 marks, which is then proportionally reduced to give an overall percentage mark.

Practice Questions

The following questions have been retired from the OSPE question bank and will not appear again in their exact current format. The topic areas remain very much in scope for future exams.

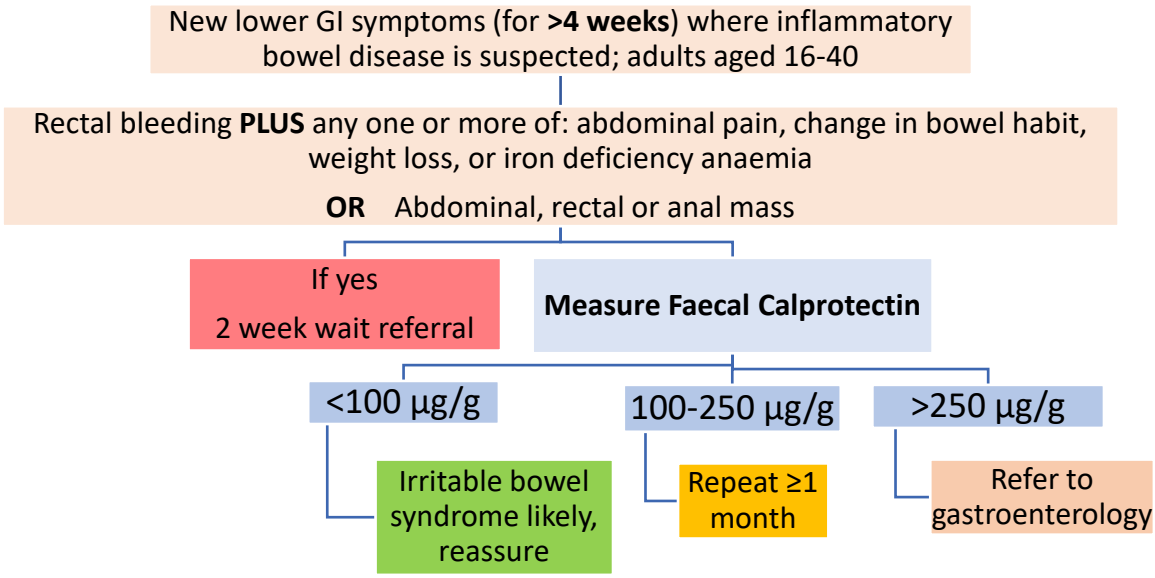
Dr Tim Lang – FRCPath Clinical Biochemistry OSPE Lead

Dr Bernie Croal – FRCPath Clinical Biochemistry Panel Chair

February 2023

Question 1

This is the local faecal calprotectin screening pathway. If you were vetting the following requests, please indicate whether you would 'accept' or 'reject' the request and provide a suggested comment for those you would reject.



Patient A: 6 months old with diarrhoea [4 marks]

Reject: Not indicated in this age group.

Patient B: 22 years old post exotic travel with 2 weeks of diarrhoea [4 marks]

Reject: Not indicated at this stage, consider testing if diarrhoea persists beyond 4 weeks and microbiological and other tests are negative.

Patient C: 45 years old with new onset abdominal pain [4 marks]

Reject: Not indicated in this age group.

Patient D: 34 years old with abdominal pain and diarrhoea, previous result 150 µg/g 6 weeks ago. [2 marks]

Accept

Patient E: 82 years old with significant frailty with change of bowel habit and iron deficiency anaemia, too unwell for colonoscopy. [4 marks]

Reject: Not indicated in this age group Or Not indicated for cancer screening.

Patient E: 28 year old '?IBS'. [2 marks]

Accept

Question 2

A research nurse contacts your laboratory about a series of inflammatory marker results from a control group of healthy volunteers in an interventional study. They ask if there is a problem with your assay as some of the results are unexpectedly abnormal?

Patient	CRP (mg/L) (<10)	BMI
1	4	34
2	16	45
3	5	36
4	8	31
5	3	33
6	15	35
7	11	30
8	3	35
9	12	33
10	5	34

a) Comment on these results. [10 marks]

Any of [2 points each]:
4 patients have CRP >9 mg/L

- **Patients are all obese ie BMI >30**
- **CRP is a non-specific marker of inflammation**
- **Positive correlation between serum CRP levels and body mass index**
- **Prevalence of high CRP is 5-35% of obese patients**
- **40% of the cohort have a raised CRP**
- **This may be random sampling error**
- **Too few people to tell if there is positive bias in the assay**
- **Would check IQC, EQA and average of normal**
- **CRP is extremely skewed in the 'normal' population so theoretically yes this is very abnormal (but see obese reason above and sampling error)**
- **Check sample stability, storage, specimen tube quickly to ensure no preanalytical error**

b) You are asked to verify a manufacturer's new reference range in your laboratory for ALT (10-40 IU/L). Comment on the collated results below: [10 marks]

Patient Result
36
24
45
23
14
17
32
54
12

16
34
24
21
39
6
39

Any of these [2 points each]:

- **Only 16 patient samples**
- **Need 20 samples to validate reference range (CLSI standard)**
- **To accept reference range 2 or less must not be outside the reference range**
- **3/16 results are outside the stated reference ranges**
- **Repeat with another 20 patient samples**
- **You would need to check who the patients were e.g. ages, sex, known liver disease, alcohol, BMI.**
- **The range 10-40 is known to contain a large number of people with chronic liver disease, it is set to avoid too many 'positive' signals.**
- **Check you are using the correct range depending if you have pyridoxine or no pyridoxine in the reagents?**
- **Check the specimen tube type is validated on the assay**
- **Sampling error argument again**

Question 3

A 28-year-old patient presents to the local Accident and Emergency Department at 01:30 hours with apparent inebriation. His partner tells medical staff he consumed two 70cL bottles of wine (13.5% ABV) during the evening. Emergency enzymatic assay analysis of ethanol reveals a concentration of 370 mg/dL on a blood sample taken at 02:00 hours.

At 09:00 hours, the consultant asks you to measure the alcohol content of the blood sample again as the ethanol result during the night does not correspond with the witnessed amount of alcohol ingested, or the observed biochemistry results. You agree to do this using the gold standard technique of headspace gas chromatography (GC). The laboratory's GC method is linear to 400 mg/dL.

a) Using the chromatograms provided, calculate the concentration of ethanol in both the patient's blood specimen and the ethanol QC.

[16 marks, 8 marks for sample and 8 for QC]

Answer using peak area: Sample = (1024898/1874952)/(561758/1550510) x 200

= (0.547/0.362) x 200 = 302 mg/dL

QC = (568203/1861020)/(561758/1550510) x 200

= (0.305/0.362) x 200 = 168.5 mg/dL

[8 marks]

Answer using peak height: Sample = (869712/864651)/(476471/719727) x 200

= (1.005/0.662) x 200 = 304 mg/dL

QC = (480375/863383)/(476471/719727) x 200

= (0.556/0.662) x 200 = **168.1 mg/dL**

[8 marks]

b) Is the QC acceptable and can the patient's result be reported? [2 marks]

QC is acceptable [2 marks]

c) Is there any difference in the ethanol measurements between the two methods? [2 marks]

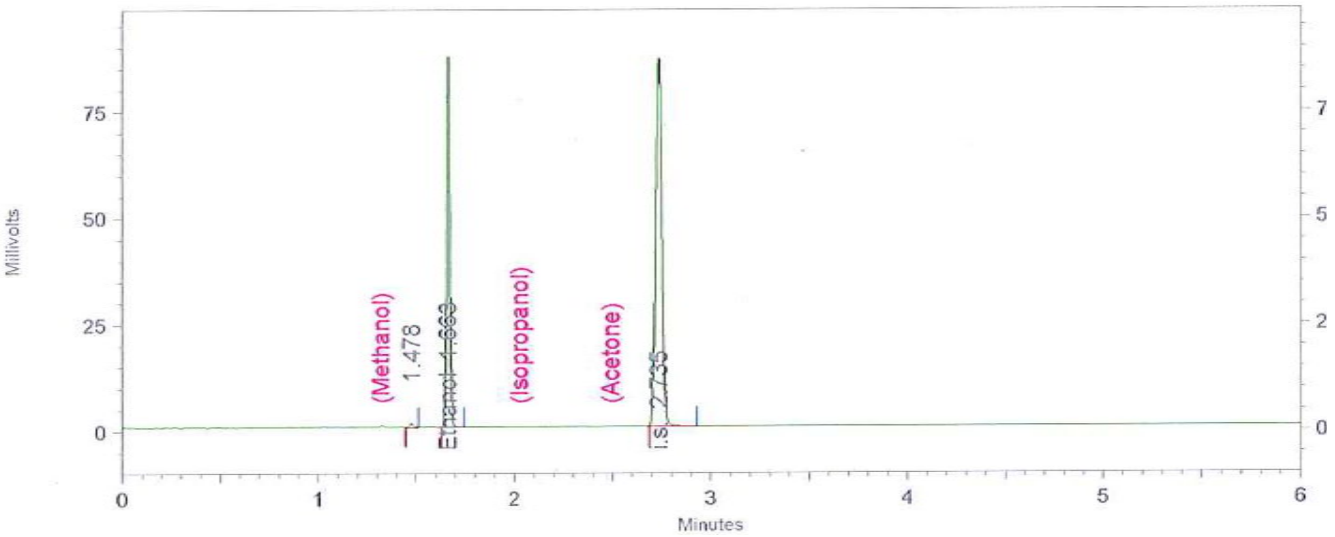
Difference of around 68 mg/dL between the two methods [2 marks]

Question 3

Gas chromatography results:

Patient sample 931491

931491
C:\ChromQuest\Projects\Default\Data\160226931491.dat
C:\ChromQuest\Projects\alcohols2\mixed_volatile.met
26/02/2016 11:19:29 BAC1



TRACE
GC-Det
A_FID_Right
Results
(System
(26/02/2016
11:26:39)
(Original))

Name	Retention Time	Area	Height
Methanol			
Ethanol	1.663	1024898	869712
Isopropanol			
Acetone			
i.s.	2.735	1874952	864351

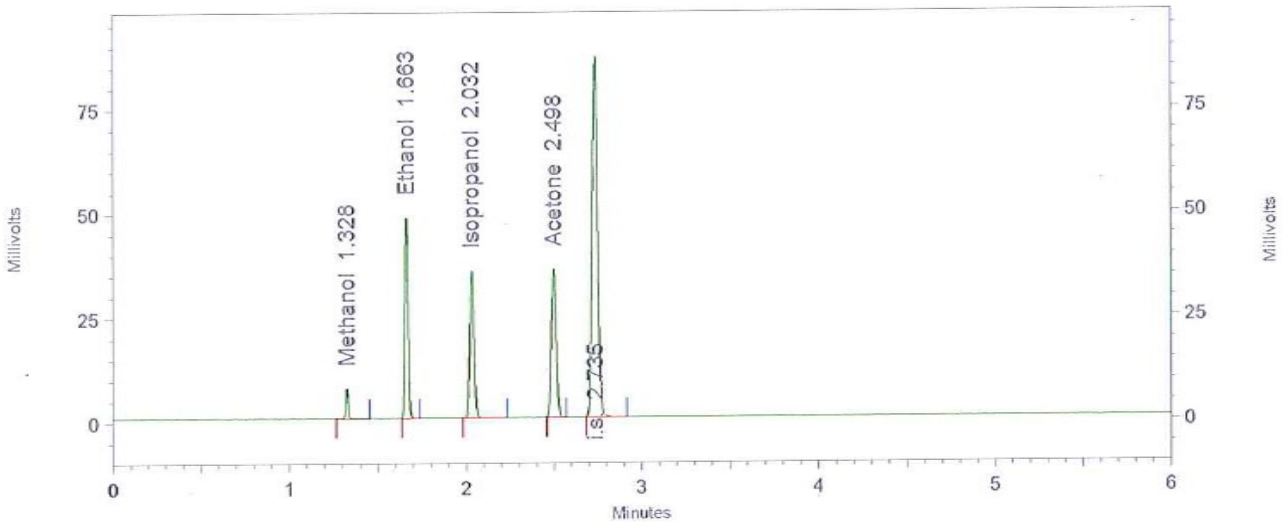
Question 3

<u>Ethanol QC</u>

QC Target concentration: 160 mg/dL

QC Acceptable range: 150-170 mg/dL

mix vol qc
C:\ChromQuest\Projects\Default\Data\160226mixvolqc.dat
C:\ChromQuest\Projects\alcohols2\mixed_volatile.met
26/02/2016 09:54:57 BAC1



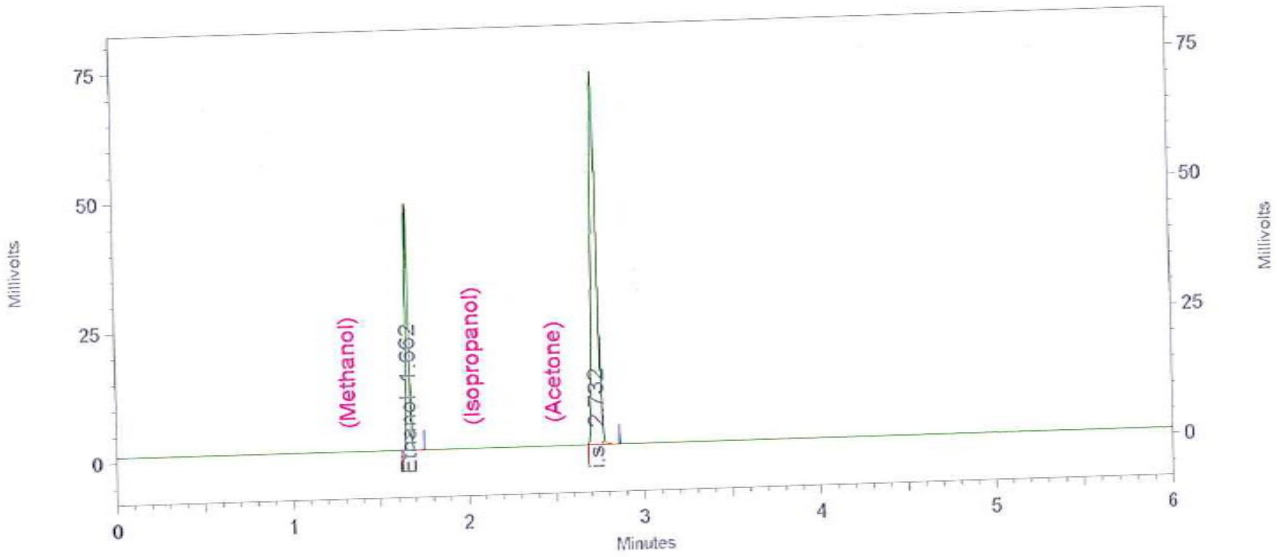
TRACE
GC-Det
A_FID_Right
Results
(System
(26/02/2016
10:02:06)
(Original))

Name	Retention Time	Area	Height
Methanol	1.328	62563	72003
Ethanol	1.663	568203	480375
Isopropanol	2.032	595820	351682
Acetone	2.498	673533	356151
i.s.	2.735	1861020	863383

Question 3

Ethanol standard 200mg/dL

etoh std 200mg/dL
C:\ChromQuest\Projects\Default\Data\Cal_160226etoh.dat
C:\ChromQuest\Projects\alcohols2\mixed_volatile.met
26/02/2016 09:23:15 BAC1



TRACE
GC-Det
A_FID_Right
Results
(System
(26/02/2016
09:30:24)
(Original))

Name	Retention Time	Area	Height
Methanol			
Ethanol	1.662	561758	476471
Isopropanol			
Acetone			
i.s.	2.732	1550510	719727

Question 4

The Sebia method for separating alkaline phosphatase isoenzymes utilises lectin to aid separating the bone and liver forms.

You are provided with a diagram of the motilities and some patient results.

a) Why are liver and bone forms of alkaline phosphatase difficult to separate by standard electrophoretic methods? [2 marks]

They are the same protein; their differences and electrophoretic mobilities only result from post translational modification (glycosylation).

b) How does lectin aid the separation? [3 marks]

All except intestinal alk phos are sialated, lectin has a strong affinity for the sialic acid residues binding to them and retarding the electrophoretic mobility. This is most marked with bone which has the highest sialation levels. (Liver and placental forms shift their mobility slightly, intestinal forms not at all)

c) Comment on the isoenzyme patterns in the paired tracks marked.
[15 marks, 3 marks each]

Patient A: 89 years old female: clinical details 'isolated raised alk phos'.

Alk phos activity 1509 iu/L (30-125), gamma GT 13 iu/L (9-65)

Predominantly bone form in markedly increased amounts (+/-?Pagets)
[3 marks]

Patient B: 83 years old male: clinical details 'Cough'

Alk phos 163, gamma GT 153

Both liver forms present in increased amounts (may comment separately on the liver 2 or macromolecular form) [3 marks]

Patient C: 69 years old female: clinical details 'none'

Alk phos 178, gamma GT 48

Main and most significant finding is increased bone form but there is detectable intestinal – which is below the level required to be called significant (can be seen post prandially in many and often in poorly controlled diabetes pts) [3 marks]

Patient D: 48 years old female: longstanding (previously investigated) stable elevation in alk phos (running between 250-350) recent further increase; cause?

Alk phos 530 gamma GT 31

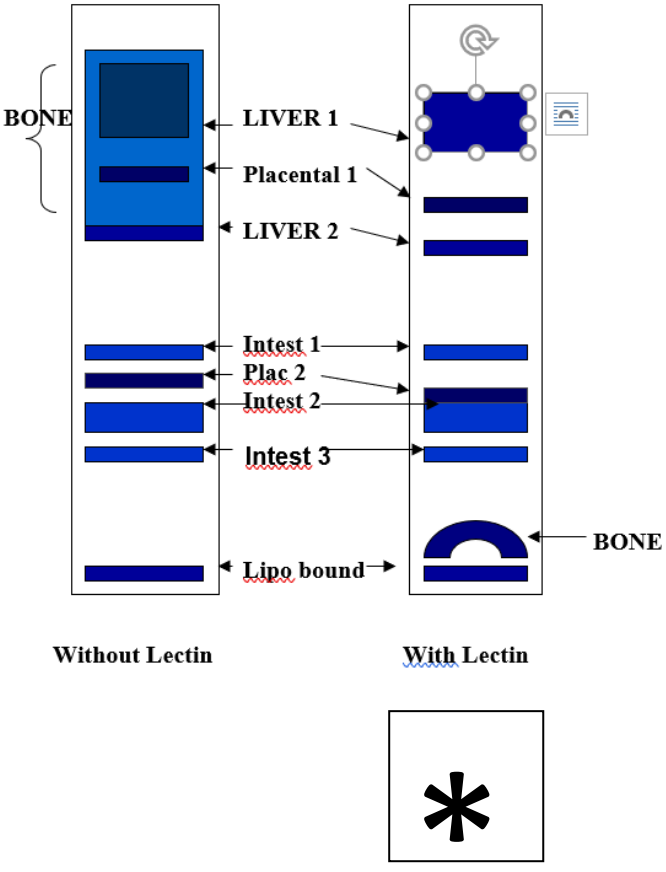
She has a marked increase in intestinal alk phos which is what her longstanding stable elevation is due to – it is familial (often confirmed by testing others in family) it has little clinical significance. They should also see that the bone form is increased and this is new, and of more clinical significance [3 marks]

Patient E: 1 years old female: Recently “under the weather”

Alk phos 8033 (ref interval at 1 year 75-300), gamma GT 13

Pattern is consistent with benign transient hyperphosphatasaemia of infancy. The exact mechanism for the increase is unclear but it related to the liver handling of proteins and often follows a viral illness. The message is essentially to reassure and monitor the fall back to basal levels: The time course is 12-16 weeks with peak activity at 6 weeks – very high levels can be seen. [3 marks]

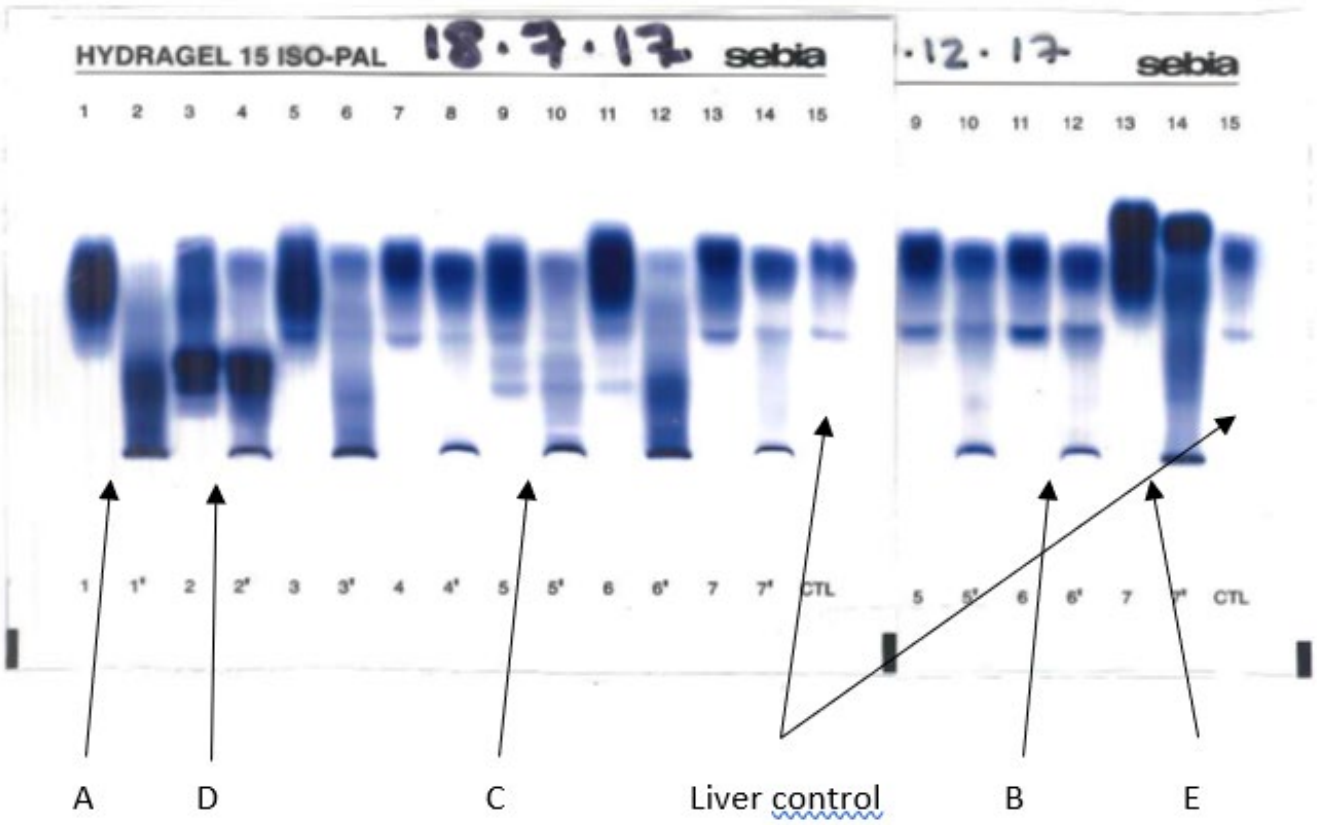
The migration patterns of the main isoenzymes are pictured below



*

Question 4

Samples are run without lectin (the first of the two lanes) and with the addition of lectin* (the 2nd marked lane e.g. Patient A is Lane 1 and Lane 1*).



Question 5

35% of patients in the 65-75 years age group with benign prostatic hypertrophy and 40% of patients with prostatic cancer have PSA concentrations above a threshold value of 4.1 µg/L. What are the positive and negative predictive values for a diagnosis of cancer in this age group using a cut-off of 4.1 µg/L if the prevalence of cancer is 5% and benign prostatic hypertrophy 25%. Assume that 2.5% of patients without any prostatic pathology have a PSA > 4.1 µg/L. [20 marks]

[2 marks]:
First set up a contingency table using the % prevalence as individual totals:

	Positives	**Negatives**	**Total**
Ca prostate			**5**
BPH			**25**
Normal			100 - (25+5) = **70**
Total			**100**

[3 marks]:
To obtain the number of positives (as % of overall total) multiply the total in each group by the % of positives in that group:

	Positives	**Negatives**	**Total**
Ca prostate	5 x 40% = **2**		**5**
BPH	25 x 35% = **8.75**		**25**
Normal	70 x 2.5% = **1.75**		**70**
Total			**100**

[3 marks]:
To obtain the number of negatives (as % of overall total) for each group subtract the number of positives from the number in that group:

	Positives	**Negatives**	**Total**
Ca prostate	**2**	5 - 2 = **3**	**5**
BPH	**8.75**	25 - 8.75 = **16.25**	**25**
Normal	**1.75**	70 - 1.75 = **68.25**	**70**
Total			**100**

[2 marks]:
As a final check add each column to give the total positives and negatives then add together to give the grand total (which should be 100):

	Positives	**Negatives**	**Total**
Ca prostate	**2**	**3**	**5**
BPH	**8.75**	**16.25**	**25**
Normal	**1.75**	**68.25**	**70**
Total	2 + 8.75 + 1.75 = **12.5**	3 + 16.25 + 68.25 = **87.5**	**100** 12.5 + 87.5 = **100**

[10 marks total]

CONTINUED ON NEXT PAGE

The positive predictive value, PV(+) is the percentage of ALL positive results which are true positives (i.e. those positive results for patients which have prostate cancer):

PV(+) = $\frac{2 \times 100}{12.5}$ = **16%** **[5 marks]**

The negative predictive value, PV(-) is the percentage of ALL negative results which are true negatives (i.e. negative results for patients who do not have prostate cancer – this will include those that have BPH):

PV(-) = $\frac{(16.25 + 68.25) \times 100}{87.5}$ = **97%** (to 2 sig figs) **[5 marks]**

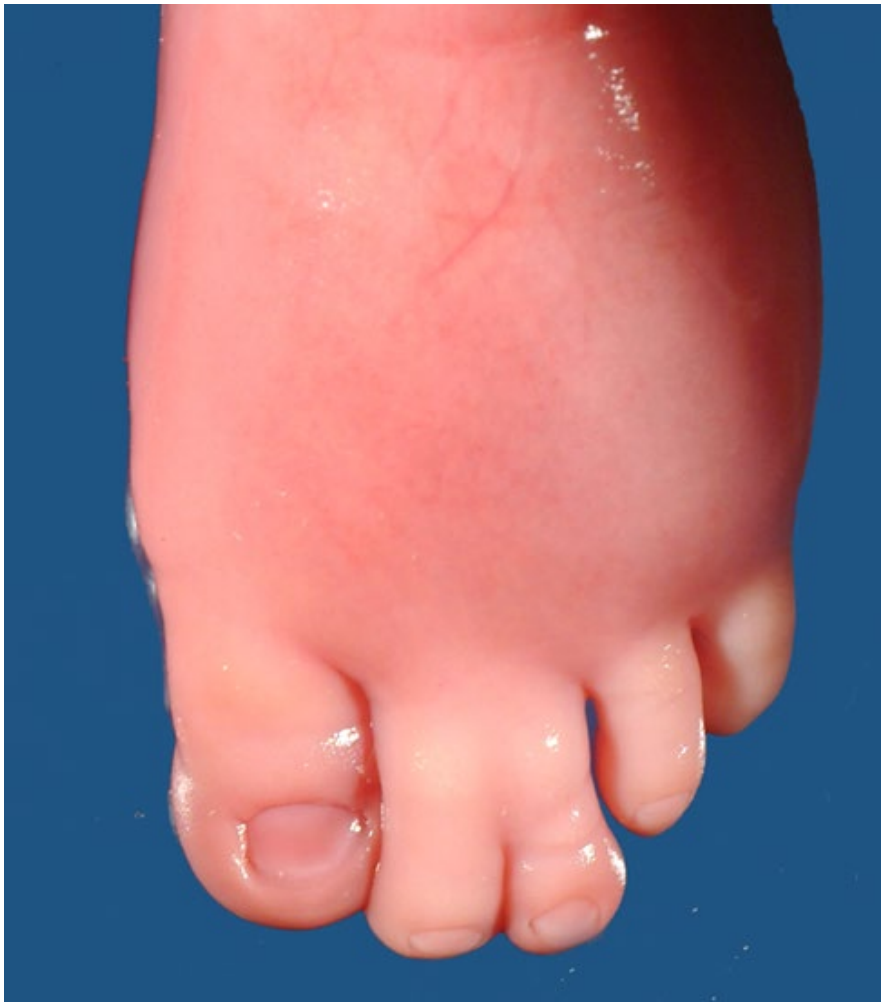
Question 6

You are provided with 4 photographs (labelled A-D). For each photograph please describe the clinical sign(s) [1 mark], suggest a likely diagnosis or potential cause [2 marks] and state the appropriate first line test for this [2 marks].

Patient 1. Baby with large head

- **Macrocephaly (large head)** **[1 mark]**
- **Urine Mucopolysaccharides or Lysosomal Enzyme Screen** **[2 marks]**
- **Mucopolysaccharidosis e.g. Hunters or Hurlers** **[2 marks]**

Patient B

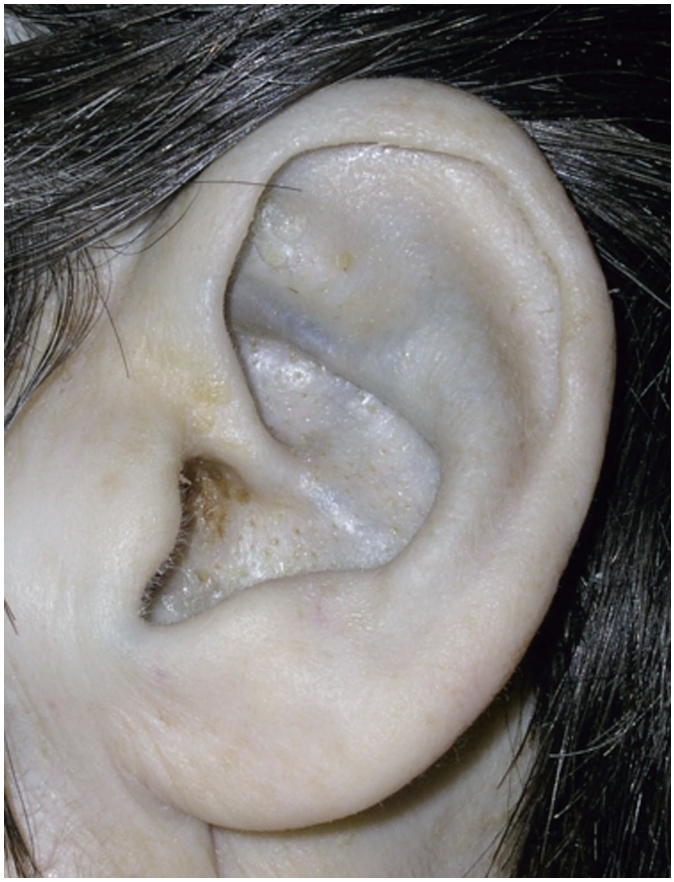


- **2-3 Syndactyly** **[1 mark]**
- **7-dehydrocholesterol** **[2 marks]**
- **Smith-Lemli-Opitz syndrome** **[2 marks]**

Patient C: Jaundiced baby

- **Pale stool** **[1 mark]**
- **Split bilirubin** **[2 marks]**
- **Conjugated Hyperbilirubinaemia (biliary atresia or severe liver disease)** **[2 marks]**

Patient 4



- **Blue/Black discolouration of ear/Ochronosis** **[1 mark]**
- **Urine Homogentisic acid detected in Urine Organic Acid** **[2 marks]**
- **Alkaptonuria** **[2 marks]**

Question 7

Patient 1 is attending their local hospital for an Insulin Stress Test. For all of the scenarios the test is being performed in a District General Hospital with no specialist units.

Patient 1

a) Describe the preparation for a patient undergoing an Insulin Stress Test [4 Marks]

Patient should be fasted overnight (water permitted) [1 mark each, or sensible other]

Recumbent during test

Must have normal ECG

Patient weighed

HRT/OCP stopped 6 weeks prior to test

If insulin dependent diabetes omit morning insulin

b) Describe the testing procedure [8 Marks]

- **Time 0: Glucose, Growth hormone and Cortisol**
- **Inject IV insulin [1 Mark]**
- **Time 30: Glucose, Growth hormone and Cortisol**
- **Time 45: Glucose, Growth hormone and Cortisol**
- **Time 60: Glucose, Growth hormone and Cortisol**
- **Time 90: Glucose, Growth hormone and Cortisol**
- **Time 120: Glucose, Growth hormone and Cortisol**

[1 point for each of the correct time points and 1 point for tests]

c) At what time should a repeat dose of insulin be given if no clinical signs of hypoglycaemia are observed? [2 Marks]

- **45 mins [2 marks]**

d) What concentration of glucose should be achieved for the test to be interpreted? [2 Marks]

- **<2.2 mmol/L**

e) Comment on the following patients being considered for this dynamic test. [4 Marks, 2 marks each]

a. A 7 year old child.

- **This test should not be done in this hospital as contraindicated as requires a specialist paediatric endocrine unit [2 marks]**

b. A 48 year old patient with epilepsy.

- **Epilepsy is an absolute contraindication [2 marks]**

Question 8

In this laboratory PTH is analysed using two Beckman DXI platforms. The reference interval is 1.3-9.3 pmol/L.

The laboratory uses a third party multi analyte QC material. Aliquots are made from a large batch and these are frozen, then thawed individually and run across both platforms daily.

You are presented with QC plots for one of the two DXI units and with data comparing and combining the performance across the two units during September 2017. You are additionally provided with EQA data from the laboratory covering performance throughout 2017.

a) Comment on the appropriateness of the QC target levels for controlling the PTH assay. [5 marks]

Pretty reasonable with QC 1 Target 1.68 towards the bottom end of the ref interval, QC 2 mid ref int at 4.29 and QC at an elevated level 13.72. [3 marks] Not ideal though as there is not one close to the top of the ref interval and the high QC would be better at a much higher level given the extent of PTH elevations seen in hyperparathyroidism. [2 marks]

b) Comment on QC performance over the time period. [5 marks]

Appalling imprecision resulting in measurement uncertainty way beyond that required for a PTH assay.

c) What is the likely explanation for these QC results? Justify your answer. [10 marks]

[2 marks] – could be the QC material… They should be able to pick up that it is a problem with the QC material itself. The EQA performance for the whole of that period is very good (particularly for imprecision) - %VAR at only 5.2% and it had actually improved over the course of 2017.

[2 marks] – look at stability and storage of QC material etc. The IFU for the QC material states specifically that no claims are made for the stability of PTH in the material, the performance in September deteriorated as we approached the overall expirary date.

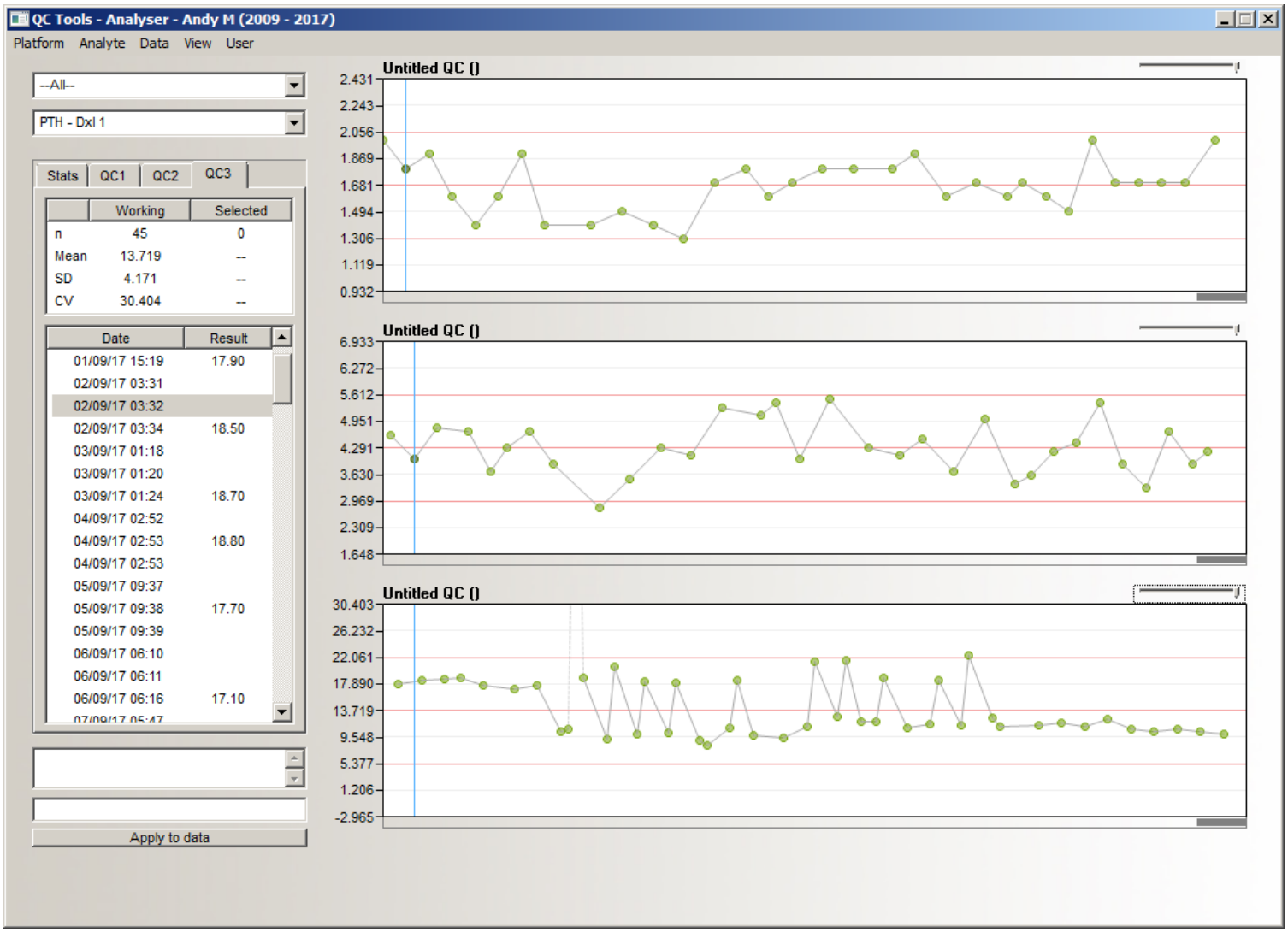
[2 marks] – if other analysers are run then compare the analysers e.g. if this an analyser or a more general QC problem. If on different sites in one site 'doing' something different if one is ok and the other not. The apparent imprecision of an analyser gathered from historical QC results is not uniquely due to the analyser itself; the stability/performance of the QC material plays an important role in the statistics, and highlights the requirement to initially identify a suitable material to control the test, and then properly store and monitor the material as it is used.

[2 marks] – to investigate QC stability do lab staff see that 'fresh' material fixes the issue? Due to the nature of QC materials (frozen/lyophyllised), it can be difficult to identify bottle-to-bottle variation, epecially when fresh bottles are used daily. The differences between bottles manifest as poor overall analyser performance, and is most likely to be identified as an issue by the lab staff performing the daily QC, rather than retrospective QC study – they identify that preparing new material 'fixes' the problem.

[2 marks] discussion of the role of patient means: For some tests (not PTH, unfortunately) it may be possible to identify this type of problem using Patient Means QC. The imprecision of 'normal' patient results will always be higher than that of the analyser (a function of the sum of both the analyser imprecision and biological variation). As such, if IQC imprecision approaches the variation seen in Patient Means data, it can be assumed that an external source of variation is finding its way into the QC data that is not due to the analyser.

Question 9

QC Chart for Beckman DX1



Question 9

UK NEQAS [Edinburgh]

UK NEQAS for PTH, ACTH and hCT | Laboratory [redacted]

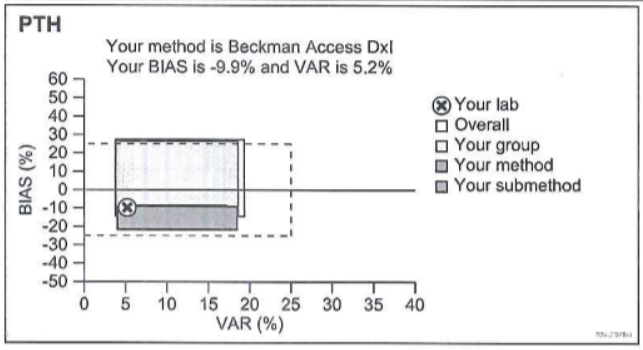
Distribution : **162** Date : 31-Oct-2017 | Page 2 of 8

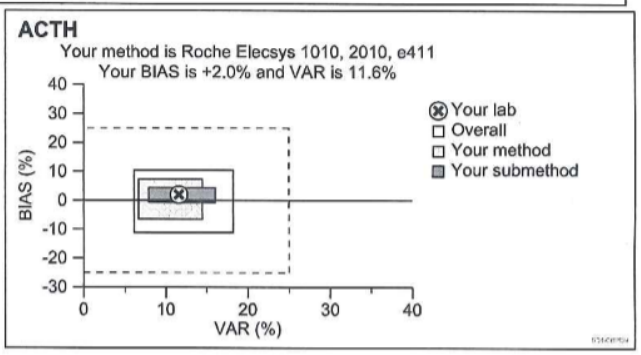
Cumulative Summary

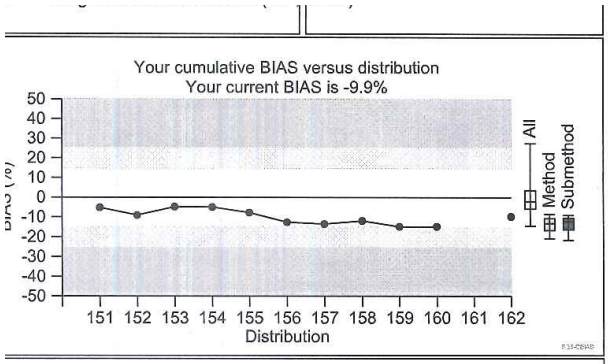
These BIAS and VAR plots are intended to give you a graphical representation of your performance relative to that of all other participants.

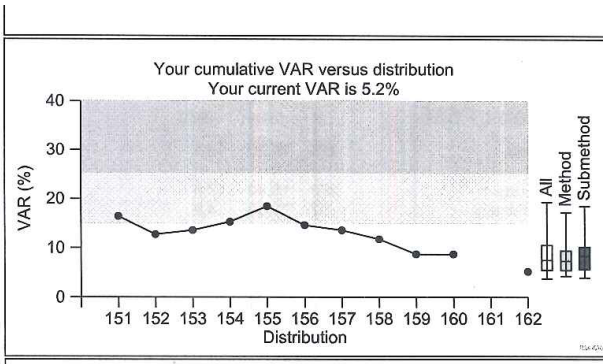
Your own, current BIAS and VAR are marked with an "X". Data for other users of your method are also plotted individually if less than ten laboratories use it. Otherwise, your method performance is shown by a shaded box bounded by the 5th and 95th centiles of BIAS and VAR. Similarly, an open box with the same bounds is plotted for All Participants.

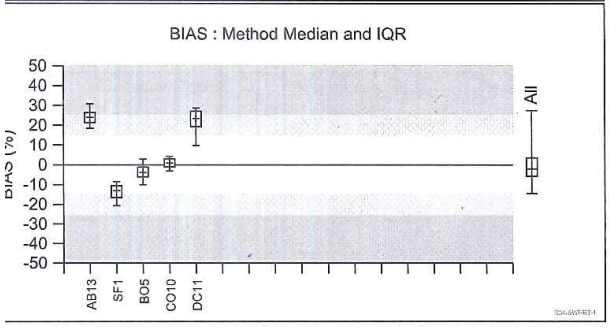
The dotted lines on the graphs for analytes expressed in concentration units and in MoMs represent the limits of acceptable performance defined by the National Quality Assurance Advisory Panel for Chemical Pathology.

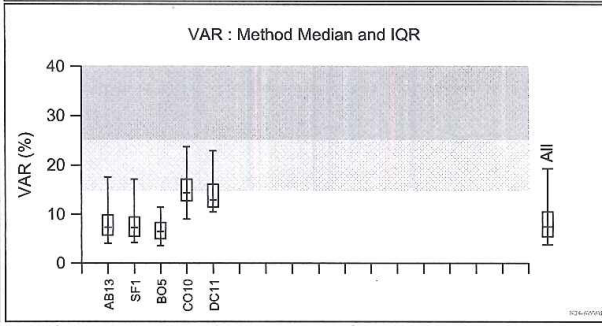












Question 10

You are given a UK NEQAS return for female testosterone of three samples which are also part of a recovery exercise.

a) What method does this laboratory use for measuring female testosterone? [2 marks]

Roche Elecsys [2 marks]

b) Comment on the performance of 'your' laboratory in relation both to other users of your method and to other methods. [6 marks]

Reasonable accuracy on this distribution [2 marks]; but overall negative slope bias against both others in same group and against ALTM (although within acceptable limits) [2 makrs]. C score good. [2 marks]

c) Comment on the A and B scores achieved by the Tandem MS method (MS2), indicating possible reasons for your observations. [4 marks]

High A score and low B score compared to other groups, both reflecting negative bias – possibly due to more specific method, less prone to interference from other steroids.

[4 marks]

In current distribution, difference appears most marked at low levels (342A). Positive bias seen in B and C samples in this distribution.

d) Calculate the recovery of testosterone for Specimen **342C**, for 'your' method (BO5) and for the Tandem MS method (MS2) and comment on your results. [6 marks]

Recovered testosterone for own method = 3.8 – 0.6 = 3.2 nmol/L

Added testosterone = 4.33 Recovery = (3.2/4.33)x100 = 73.9% [3 marks]

For MSMS, recovery = (4.72-0.5)/4.33 x 100 = 97.46% [3 marks]

e) Comment on the clinical significance of these differences between methods. [2 marks]

MSMS better able to detect changes in low concentrations of testosterone reliably; better baseline due to less interference from other steroids or reduction in matrix effects [2 marks for one sensible suggestion]

Birmingham Quality

UKNEQAS for Steroid Hormones

Distribution : 342 **Date : 15-Jul-2008**

Analyte : Testosterone [female] (nmol/L)

Lab

Pag

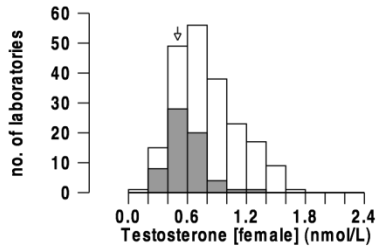
Spec.	Pool	Pool description / Treatments / Additions
342A	FT343	Normal serum [F] Base for recovery
342B	FT344	Pool FT343 + 2.17 nmol/L
342C	FT345	Pool FT343 + 4.33 nmol/L

□ All methods
■ Roche Elecsys

Your A score is	95
Your B score is	-17.7
Your C score is	11.1
The A limit is	200
The B limit is +/-	20.0
The C limit is	20.0

Specimen : 342A

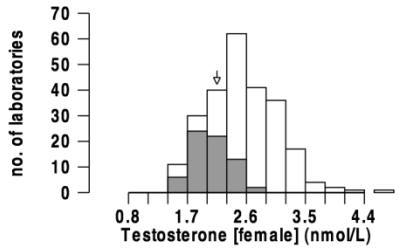
	n	Mean	SD	CV(%)
All methods	207	0.82	0.33	40.0
Abbott Architect	26	0.77	0.17	21.7
Bayer Advia:Centaur	71	1.06	0.32	30.0
Beckman Access	21	0.92	0.18	19.4
DPC Immulite 2000	7	0.76	0.27	35.8
Roche Elecsys	62	0.61	0.17	27.1
E170 Modular	47	0.59	0.16	27.5
Tandem Mass Spec	7	0.50	0.09	18.3



Your result	0.6
Target (ALTM)	0.82
Your specimen:	
%bias	-26.8
transformed bias	-103
Accuracy Index	103
Your method mean	0.61
Roche Elecsys	

Specimen : 342B

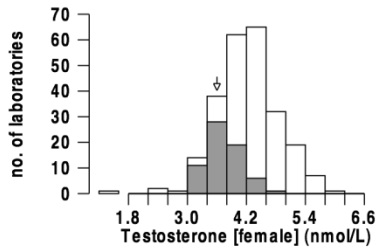
	n	Mean	SD	CV(%)
All methods	243	2.55	0.53	20.7
Abbott Architect	27	2.43	0.27	11.1
Bayer Advia:Centaur	73	3.00	0.39	13.0
Beckman Access	21	2.68	0.27	10.0
DPC Immulite 2000	28	2.71	0.41	15.0
Roche Elecsys	67	2.08	0.28	13.6
E170 Modular	51	2.06	0.29	13.9
Tandem Mass Spec	8	2.73	0.55	20.2



Your result	2.1
Target (ALTM)	2.55
Your specimen:	
%bias	-17.8
transformed bias	-124
Accuracy Index	124
Your method mean	2.08
Roche Elecsys	

Specimen : 342C

	n	Mean	SD	CV(%)
All methods	240	4.28	0.59	13.8
Abbott Architect	26	4.30	0.37	8.6
Bayer Advia:Centaur	73	4.54	0.48	10.6
Beckman Access	21	4.42	0.30	6.8
DPC Immulite 2000	28	4.58	0.61	13.4
Roche Elecsys	65	3.77	0.37	9.8
E170 Modular	49	3.74	0.37	9.9
Tandem Mass Spec	8	4.72	0.58	12.2



Your result	3.8
Target (ALTM)	4.28
Your specimen:	
%bias	-11.1
transformed bias	-91
Accuracy Index	91
Your method mean	3.77
Roche Elecsys	

This was a recovery exercise - a report will be published to the web server in due course. Pools do not contain preservative unless stated otherwise.

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Published at 18:12:16 on Friday 18 July 2008

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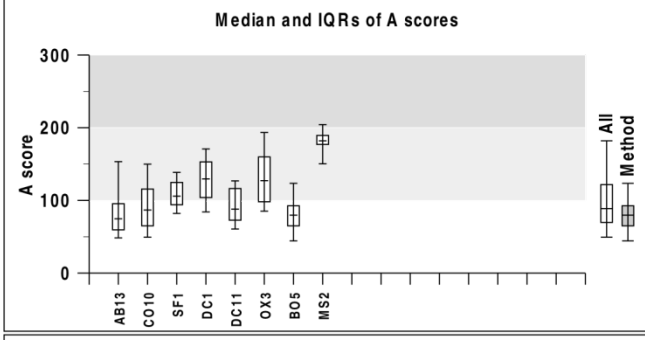
UKNEQAS for Steroid Hormones

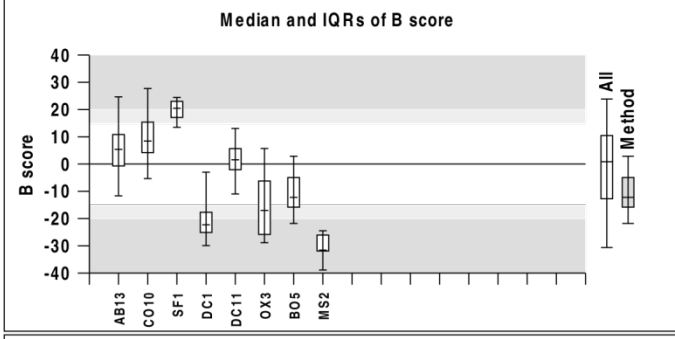
Distribution : 342 Date : 15-Jul-2008

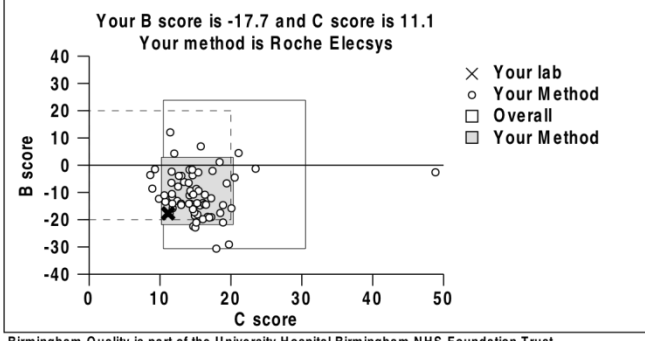
Analyte : Testosterone [female] (nmol/L)

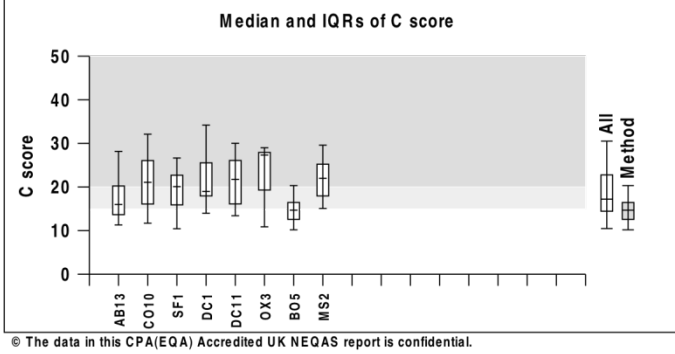
Pool (exclusion) [Type]	Distribution 337 12-Feb-2008 result	target	%bias	Distribution 338 11-Mar-2008 result	target	%bias	Distribution 339 15-Apr-2008 result	target	%bias	Distribution 340 13-May-2008 result	target	%bias	Distribution 341 17-Jun-2008 result	target	%bias	Distribution 342 15-Jul-2008 result	target	%bias
FT332 [F,V]				0.6	0.79	-24.1												
FT343 [F,R,V]																0.6	0.82	-26.8
FT333 [F,V]							0.7	0.87	-19.3									
FT340 [F,V]										0.7	0.96	-27.4						
FT338 [F,V]	0.6	0.97	-38.5										0.8	1.01	-20.8			
FT339 [F,V]				1.2	1.52	-20.8												
FT341 [F,V]										1.2	1.59	-24.3						
FT319 [F,V]	1.3	1.67	-21.9															
FT320 [F,V]							2.0	1.95	+2.8									
FT331 [F,V]													2.1	2.11	-0.4			
FT337 [F,V]													2.2	2.20	-0.1			
FT344 [F,R,V]																2.1	2.55	-17.8
FT317 [F,V]	2.5	2.77	-9.6															
FT336 [F,V]							2.6	2.81	-7.6									
FT335 [F,V]				2.7	3.53	-23.6												
FT342 [F,V]										3.1	3.83	-19.0						
FT345 [F,R,V]																3.8	4.28	-11.1
Method	BO5			BO5			BO5			BO5			BO5			BO5		
mean			-23.3			-22.8			-8.0			-23.6			-7.1			-18.6
A score	124			124			115			118			92			95		
B score	-21.7			-21.0			-20.2			-20.7			-16.7			-17.7		
C score	13.4			11.2			12.4			10.0			11.2			11.1		

F female only pool
R Recovery
V no preservative









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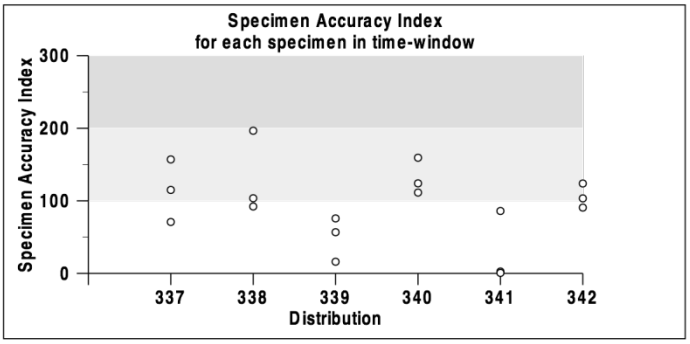
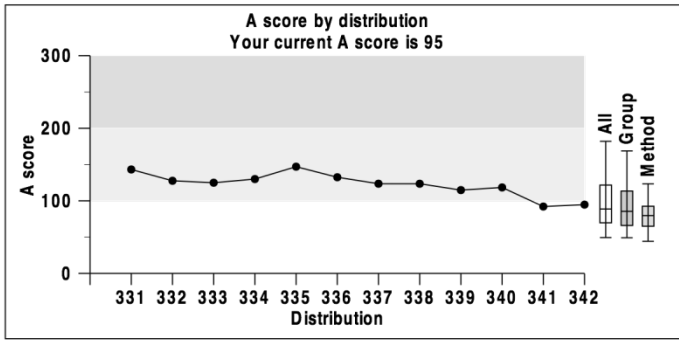
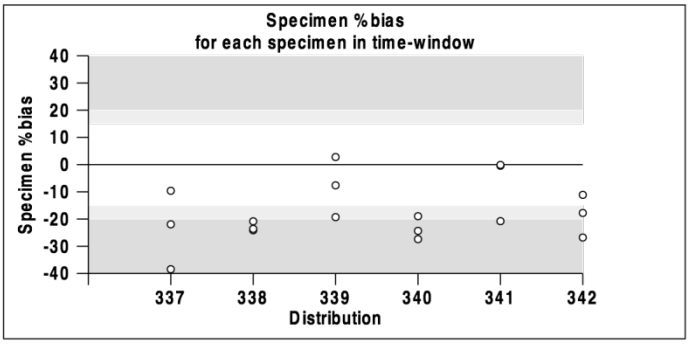
UKNEQAS for Steroid Hormones

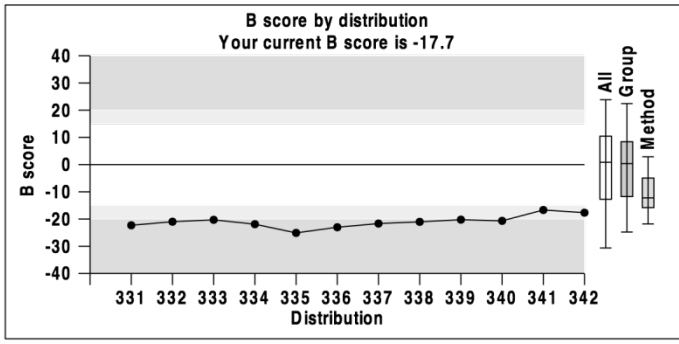
Distribution : 342 **Date : 15-Jul-2008**

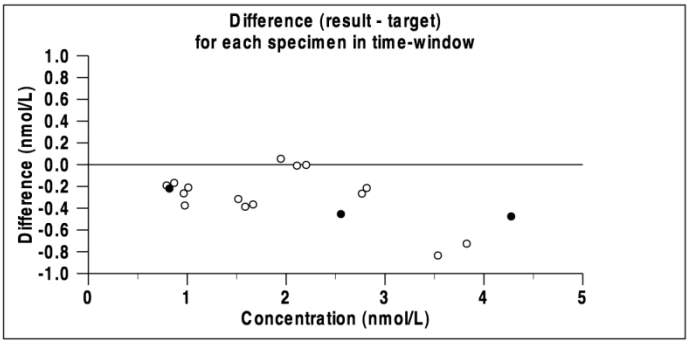
Testosterone [female] (nmol/L)

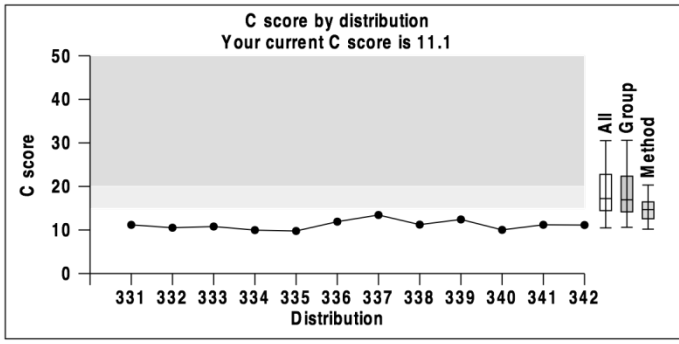


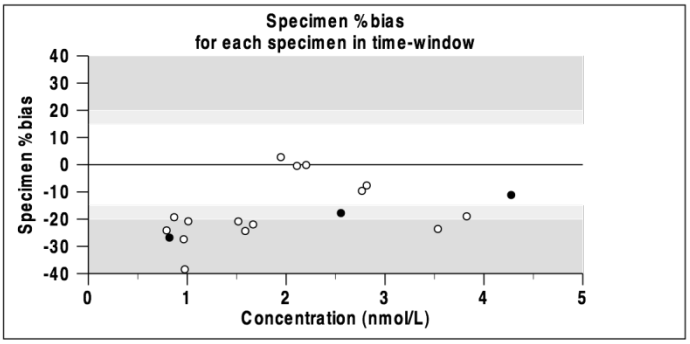


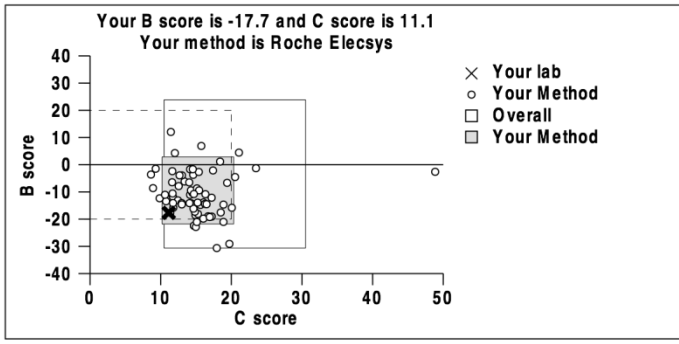


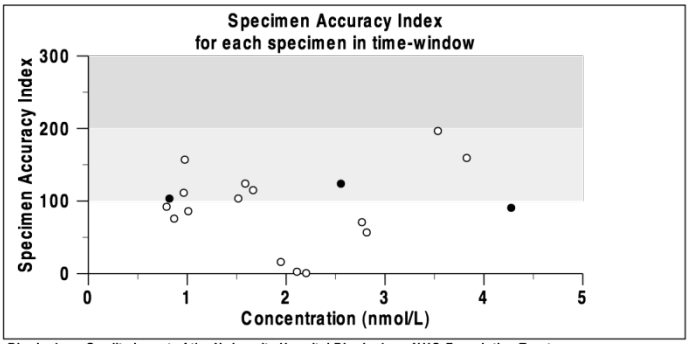


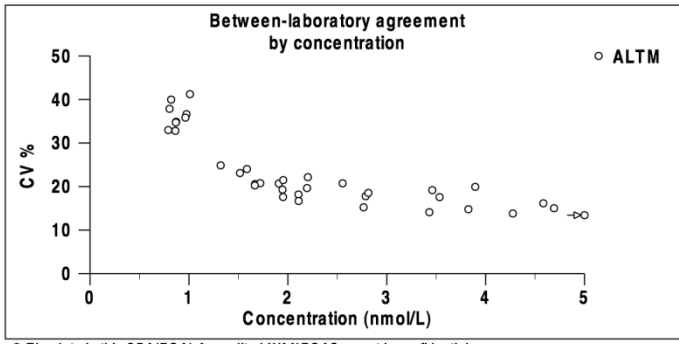












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Question 11

Your laboratory IT middleware system is hit by a cyber-attack which severely limits your service. Sample test results have no way of getting back into your LIMS except by manual input. You decide to front load analysers, analyse and then print out hard copy to be delivered to the clinical units. In addition, your electronic order comms system is unable to deliver test orders to your analysers – so a return to paper request forms is necessary.

Your estimated downtime is 2-3 days.

a) Who would you communicate this within your organisation at senior management level. [4 Marks]

This may be regarded as a Major/Critical Incident within your organisation – so medical director/hospital manager type level would need to be engaged. (overnight it will be the site practitioner and on call exec). [2 marks] Similar for Primary Care.[2]

b) Which areas within the acute hospital would you consider directly communicating with. [4 Marks]

ED, ICU/HDU, Major surgery/trauma, obstetrics, paediatrics [1 mark each for areas dealing with acutely ill patients needing rapid TATs]

c) What mitigation could be used to minimise the workload of the lab? [4 Marks]

[1 mark each for any sensible options e.g.] Classic demand optimisation methods – urgent specimens only, max out POCT as an alternative, reduce test repertoire – small test panels, minimum retesting intervals, etc. Consultant only requests. Severe sample vetting. Ask people not to not ring for results. Give A&E access (view only) to LIMs.

d) Write an appropriate communications statement for service users that outlines the problem, details the temporary process for testing and suggest possible mitigating action to reduce or prioritise workload. Approx 150 words. [8 Marks]

Communications statement should be clear, concise and avoid too much technical wording. The process for testing should clearly mention paper forms and paper printed reports as a temporary measure.

Suggested mitigation to reduce workload can take various forms but an attempt to do this should be included

Some sort of empathy for the impact this will have on services and even an apology would also be appropriate.