Investigation of Discordant EQA Findings

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Disclosures of Interest and Permissions

- Employed by Hamilton Health Sciences, Hamilton
- Committee member for Quality Management Program - Laboratory Services
  - QMPLS is the organization responsible for EQA and accreditation for medical laboratories in Ontario.
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Learning Objectives

- Understand the importance of EQA in maintaining the quality of the laboratory service.
- Identify the steps required in an investigation of EQA discordant results.
- Identify and discuss examples of good, adequate and inadequate investigations

- You have just received notice from your EQA provider that you have a “discordant result”. You are now required to perform and investigation and submit the results to your EQA provider
- What do you do? See the next slide and choose all appropriate responses.

1. Curse those guys from the EQA organization as a bunch of nosey busybodies that have no clue what goes on in a busy Clinical Chemistry Laboratory.
2. Ignore it – this evidence is contrary to your own evidence of good laboratory performance.
3. Call your instrument/reagent vendor and ask that a service man be dispatched immediately.
4. Call your instrument/reagent vendor and ask for their advice on how to respond.
5. Undertake a thorough and systematic investigation to identify the root cause, then develop and institute a corrective plan to ensure that this problem is unlikely to occur again.

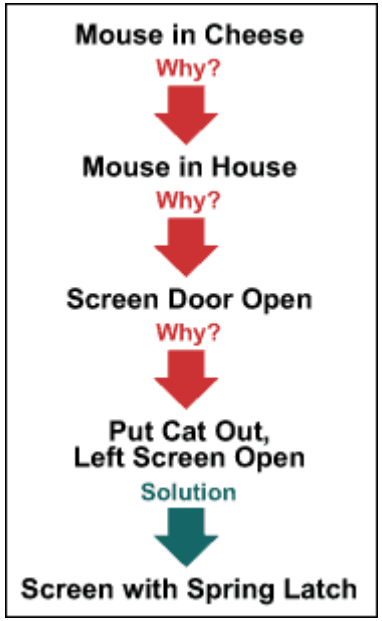
How to Examine a Problem

- First – clearly understand the problem that needs to be solved
- Second – put in place measures that solve the problem and prevent it from happening again
- Third – continue to monitor the process to be sure that your solution has worked.

"There is a mouse eating the cheese"

Ask why 5 times

Dig deeper in to the problem until the real problem is identified.



5 Why's Worksheet

Define the Problem:

Why is it happening?

1. → Why is that?

2. → Why is that?

3. → Why is that?

4. → Why is that?

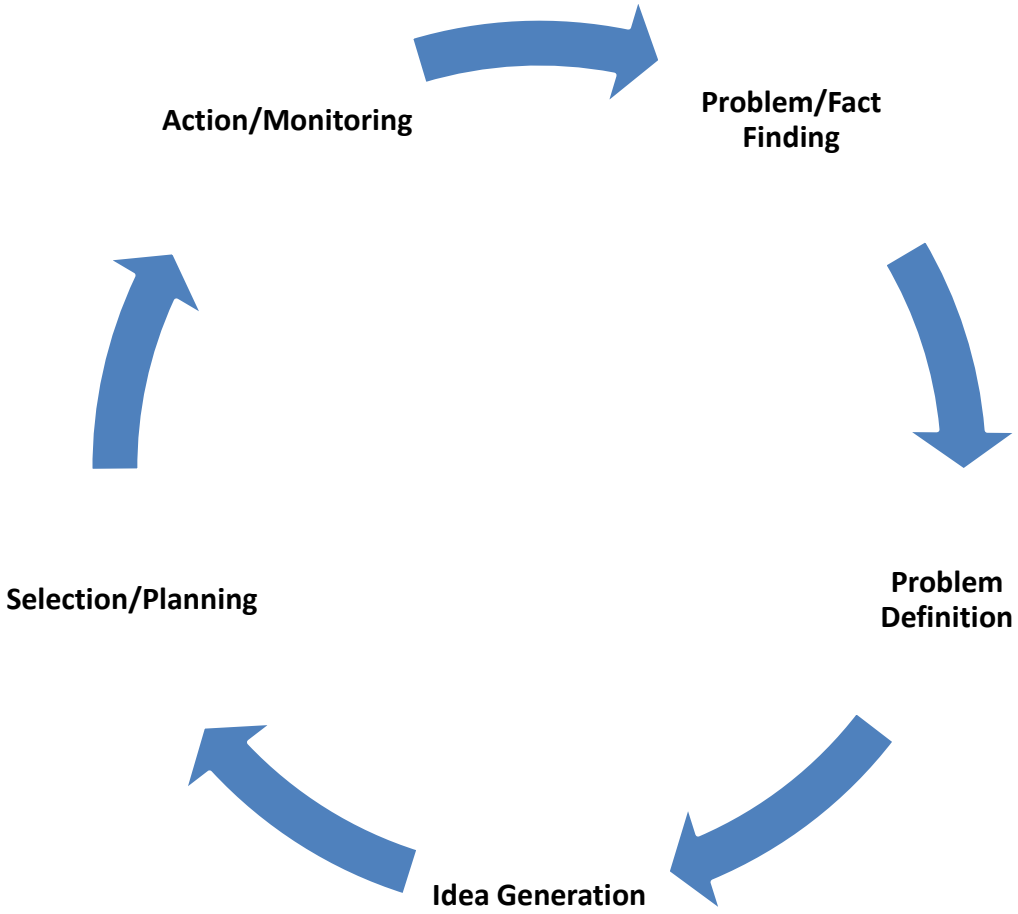
5.

Caution: If your last answer is something you cannot control, go back up to previous answer.

Circular Approach

Encourages continuous problem solving

Did putting a latch on the screen door keep the mice out?



ROOT CAUSE ANALYSIS WORK SHEET

Pre-analytical		
Possible Cause	What to Check	Remedial Action
Analytical		
Possible Cause	What to Check	Remedial Action
Post-Analytical		
Possible Cause	What to Check	Remedial Action

QMPLS Approach

- A worksheet is attached to every discordant finding
- Contains a series of questions that are intended to
  - Help the laboratory with the root cause analysis.
  - Reassure QMPLS of the quality processes of the laboratory in question.
- Extra vials of survey material may be available to laboratories.

QMPLS Approach

1. Was the sample re-tested after receipt of the survey results? If yes, please describe findings.
1. Was a replacement sample requested from QMPLS? If yes, please describe findings.
2. Please comment on your investigation of what happened.
3. Please indicate root or contributing cause(s) of problem, if known.
4. Please identify corrective and preventive action(s).
5. Enter Discordant Finding code.

QMPLS Coding System

Coding the problem allows QMPLS to look for patterns and common problems that may require attention at a higher level+ level.

Most commonly used codes

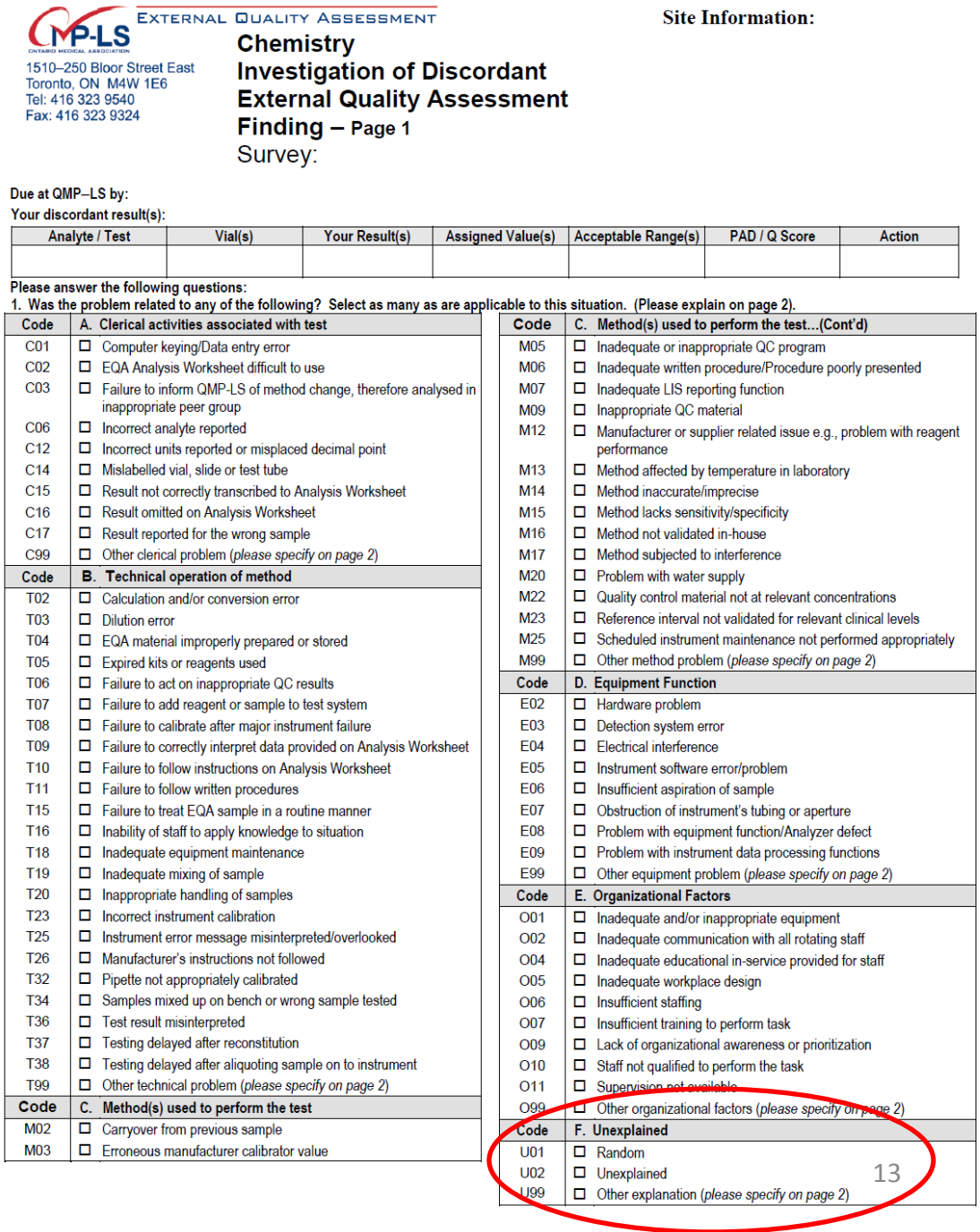
RANDOM

UNEXPLAINED

Continued unwarranted use of the "unknown" or "random error" codes is sure to raise eyebrows at QMPLS.

"Random error" is an acceptable response if the investigation clearly identifies that the error is random.

"Unknown" is not an acceptable response for a poorly done investigation. If a thorough and systematic investigation that rules out most (if not all) causes of the error, "unknown" is a reasonable response.



QMP-LS External Quality Assessment

1510–250 Bloor Street East
Toronto, ON M4W 1E6
Tel: 416 323 9540
Fax: 416 323 9324

Site Information:

Chemistry
Investigation of Discordant
External Quality Assessment
Finding – Page 1
Survey:

Due at QMP–LS by:

Your discordant result(s):

Analyte / Test	Vial(s)	Your Result(s)	Assigned Value(s)	Acceptable Range(s)	PAD / Q Score	Action

Please answer the following questions:

1. Was the problem related to any of the following? Select as many as are applicable to this situation. (Please explain on page 2).

Code	A. Clerical activities associated with test
C01	☐ Computer keying/Data entry error
C02	☐ EQA Analysis Worksheet difficult to use
C03	☐ Failure to inform QMP-LS of method change, therefore analysed in inappropriate peer group
C06	☐ Incorrect analyte reported
C12	☐ Incorrect units reported or misplaced decimal point
C14	☐ Mislabelled vial, slide or test tube
C15	☐ Result not correctly transcribed to Analysis Worksheet
C16	☐ Result omitted on Analysis Worksheet
C17	☐ Result reported for the wrong sample
C99	☐ Other clerical problem (*please specify on page 2*)
Code	**B. Technical operation of method**
T02	☐ Calculation and/or conversion error
T03	☐ Dilution error
T04	☐ EQA material improperly prepared or stored
T05	☐ Expired kits or reagents used
T06	☐ Failure to act on inappropriate QC results
T07	☐ Failure to add reagent or sample to test system
T08	☐ Failure to calibrate after major instrument failure
T09	☐ Failure to correctly interpret data provided on Analysis Worksheet
T10	☐ Failure to follow instructions on Analysis Worksheet
T11	☐ Failure to follow written procedures
T15	☐ Failure to treat EQA sample in a routine manner
T16	☐ Inability of staff to apply knowledge to situation
T18	☐ Inadequate equipment maintenance
T19	☐ Inadequate mixing of sample
T20	☐ Inappropriate handling of samples
T23	☐ Incorrect instrument calibration
T25	☐ Instrument error message misinterpreted/overlooked
T26	☐ Manufacturer's instructions not followed
T32	☐ Pipette not appropriately calibrated
T34	☐ Samples mixed up on bench or wrong sample tested
T36	☐ Test result misinterpreted
T37	☐ Testing delayed after reconstitution
T38	☐ Testing delayed after aliquoting sample on to instrument
T99	☐ Other technical problem (*please specify on page 2*)
Code	**C. Method(s) used to perform the test**
M02	☐ Carryover from previous sample
M03	☐ Erroneous manufacturer calibrator value

Code	C. Method(s) used to perform the test...(Cont'd)
M05	☐ Inadequate or inappropriate QC program
M06	☐ Inadequate written procedure/Procedure poorly presented
M07	☐ Inadequate LIS reporting function
M09	☐ Inappropriate QC material
M12	☐ Manufacturer or supplier related issue e.g., problem with reagent performance
M13	☐ Method affected by temperature in laboratory
M14	☐ Method inaccurate/imprecise
M15	☐ Method lacks sensitivity/specificity
M16	☐ Method not validated in-house
M17	☐ Method subjected to interference
M20	☐ Problem with water supply
M22	☐ Quality control material not at relevant concentrations
M23	☐ Reference interval not validated for relevant clinical levels
M25	☐ Scheduled instrument maintenance not performed appropriately
M99	☐ Other method problem (*please specify on page 2*)
Code	**D. Equipment Function**
E02	☐ Hardware problem
E03	☐ Detection system error
E04	☐ Electrical interference
E05	☐ Instrument software error/problem
E06	☐ Insufficient aspiration of sample
E07	☐ Obstruction of instrument's tubing or aperture
E08	☐ Problem with equipment function/Analyzer defect
E09	☐ Problem with instrument data processing functions
E99	☐ Other equipment problem (*please specify on page 2*)
Code	**E. Organizational Factors**
O01	☐ Inadequate and/or inappropriate equipment
O02	☐ Inadequate communication with all rotating staff
O04	☐ Inadequate educational in-service provided for staff
O05	☐ Inadequate workplace design
O06	☐ Insufficient staffing
O07	☐ Insufficient training to perform task
O09	☐ Lack of organizational awareness or prioritization
O10	☐ Staff not qualified to perform the task
O11	☐ Supervision not available
O99	☐ Other organizational factors (*please specify on page 2*)
Code	**F. Unexplained**
U01	☐ Random
U02	☐ Unexplained
U99	☐ Other explanation (*please specify on page 2*)

QMPLS Scoring system is based on Percent Allowable Difference, or PAD

$$PAD = ([x - xa]/APL) \times 100$$

Where x is the participant response, xa is the "Assigned Value," and APL is the Allowable Performance Limit.

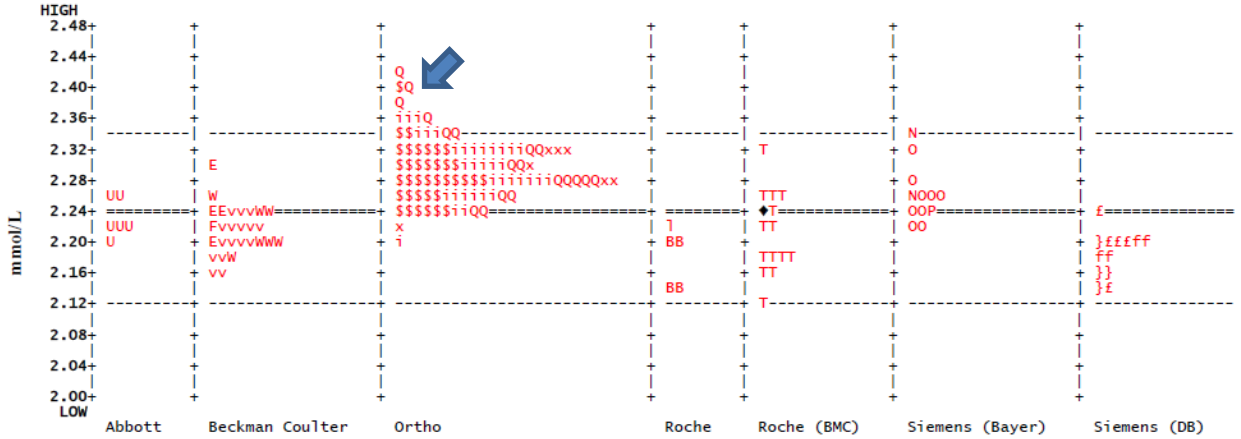
	Current Survey Rules	**Action Required**
	I PAD I $\leq$ 100	No Action Required
W1	I PAD I > 100 & $\leq$ 150 for single result	Investigate and retain documents internally
A1	I PAD I > 150 for single result	Investigate and submit to QMPLS
A2	I PAD I > 100 for $\geq$ 2 results on same analyte	Investigate and submit to QMPLS
A3	I PAD I > 100 for $\geq$ 2 results on same analyte in last 2 of 3 surveys	Investigate and submit to QMPLS

Example # 1
Manufacturer Group: Ortho Clinical Diagnostics
Analyte: Total Calcium

Vial #	Analyte	Result	Target	Range	PAD Score	Action Code
1	Calcium	2.40 mmol/L	2.23	2.12 – 2.34	155	A2
2	Calcium	3.36	3.05	2.90 – 3.20	207	A2
3	Calcium	2.40	2.26	2.15 – 2.37	127	A2

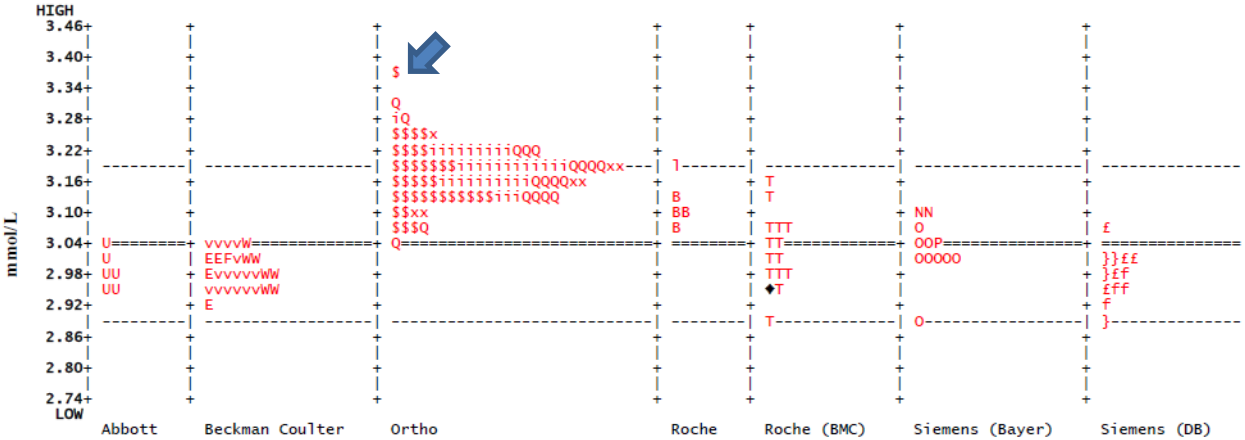
Calcium, Total - VIAL 1

N: 177 Grouped By Reagent Assigned Value: 2.23 Allowable Limits: 2.12 - 2.34



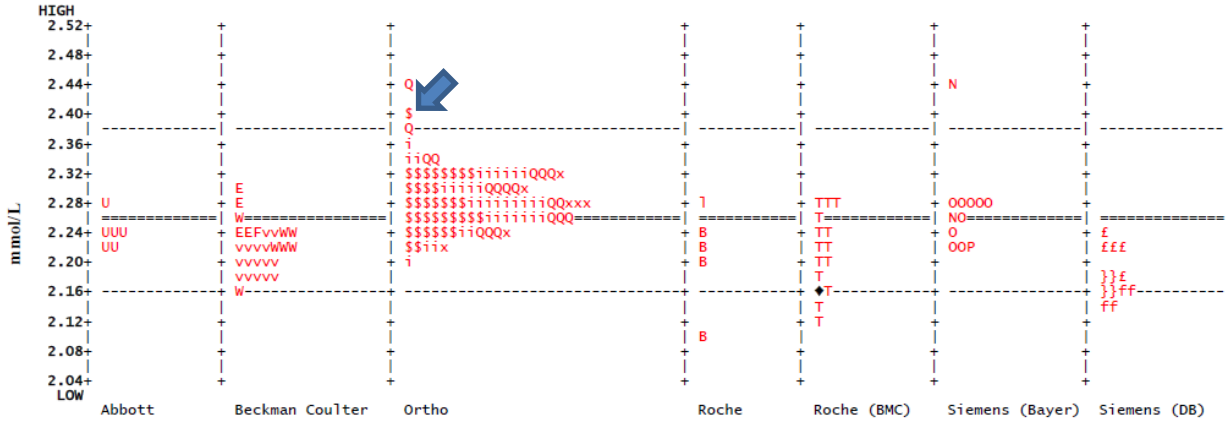
Calcium, Total - VIAL 2

N: 177 Grouped By Reagent Assigned Value: 3.05 Allowable Limits: 2.90 - 3.20



Calcium, Total - VIAL 3

N: 177 Grouped By Reagent Assigned Value: 2.26 Allowable Limits: 2.15 - 2.37



INVESTIGATION SUMMARY

Investigation

- Review of calibration and QC data determined results were acceptable.
- Re-calibration using different Calibration lot # but same slide lot #.
- Re-assay of the QMPLS vials – no change in values.
- After consultation with manufacturer, major maintenance performed.
- Before and after patient correlation revealed a slight drop in results. QMPLS vials retested; results now acceptable.
- Manufacturer has decreased routine maintenance visits from every six months to once per year. Several key maintenance procedures that must be done every six months are now being done only every year.

Sample Retest: After major maintenance and re-calibration

Vial 1	2.26 mmol/L	All results now in acceptable range
Vial 2	3.14 mmol/L	
Vial 3	2.28 mmol/L	

Root Cause: Change in maintenance schedule resulted in failure to perform critical procedures.

Corrective action: Items performed by service rep yearly will be performed by laboratory staff every 6 months.

DF Code: T18 Inadequate equipment maintenance

Example #2

Calcium

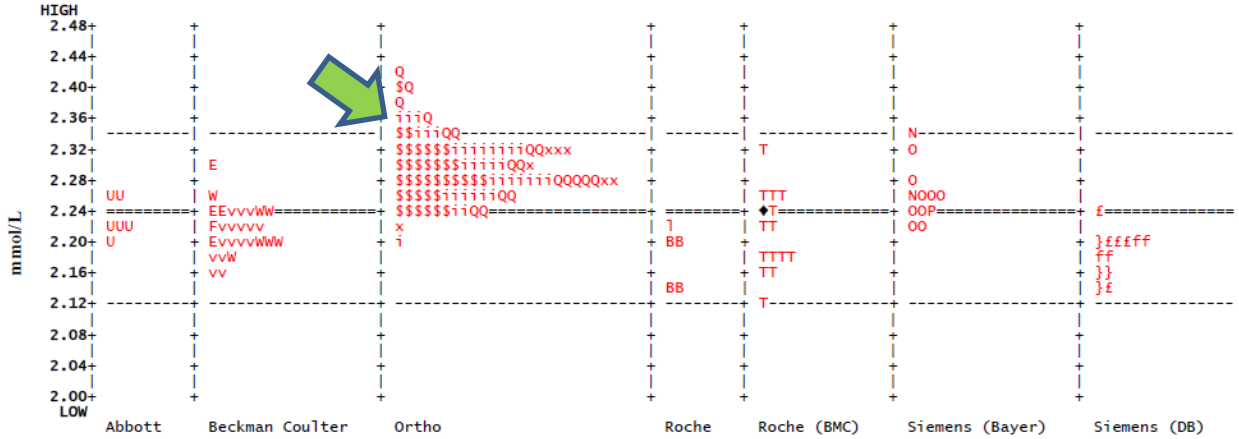
Vial #	Analyte	Result	Target	Range	PAD Score	Action Code
1	Calcium	2.36 mmol/L	2.23	2.12 – 2.34	118	A2
2	Calcium	3.27	3.05	2.90 – 3.20	147	A2

Manufacturer Group – Ortho Clinical Diagnostics

Note: Calcium target values are determined by analysis at
2 external reference laboratories.

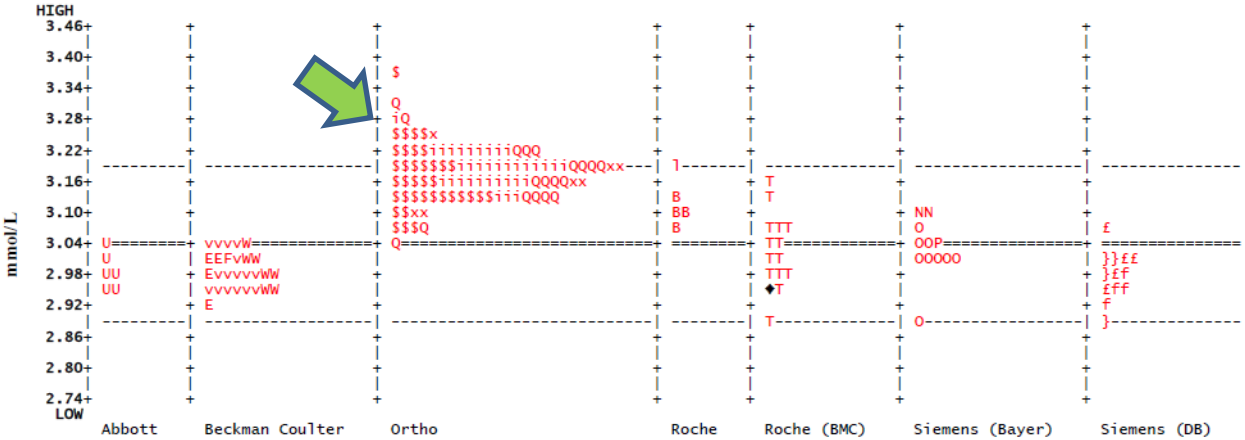
Calcium, Total - VIAL 1

N: 177 Grouped By Reagent Assigned Value: 2.23 Allowable Limits: 2.12 - 2.34



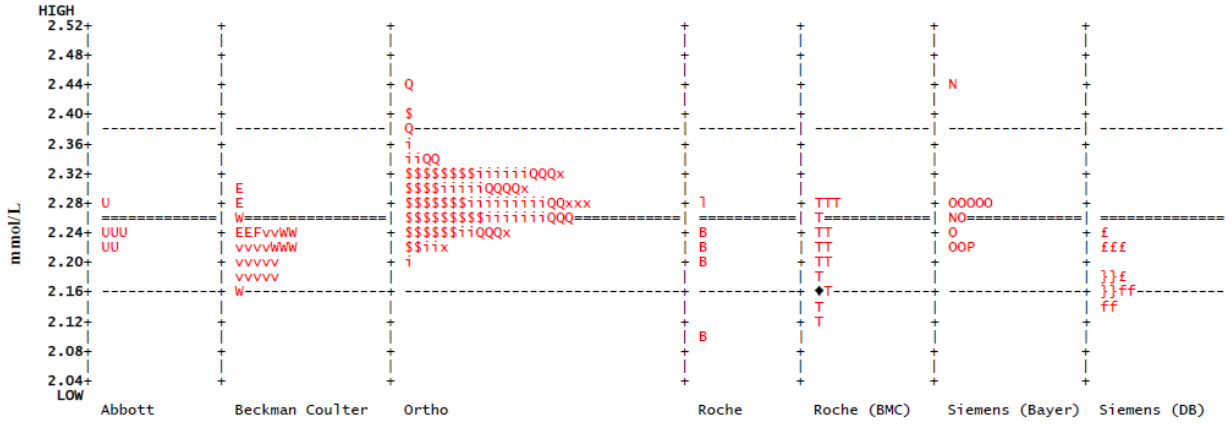
Calcium, Total - VIAL 2

N: 177 Grouped By Reagent Assigned Value: 3.05 Allowable Limits: 2.90 - 3.20



Calcium, Total - VIAL 3

N: 177 Grouped By Reagent Assigned Value: 2.26 Allowable Limits: 2.15 - 2.37



INVESTIGATION SUMMARY

Sample Retest: Vial 1 - 2.33, Vial 2 - 3.19

Investigation:
•Retest results within acceptable “your” acceptable range
•QC was running within acceptable parameters
•No contributing error determined from our investigation

Root Cause: No specific cause noted. Our method running slightly higher than other methods.

Corrective Action: We will continue to monitor QC closely

DF Code: U01 Random

Your comments on this investigation?

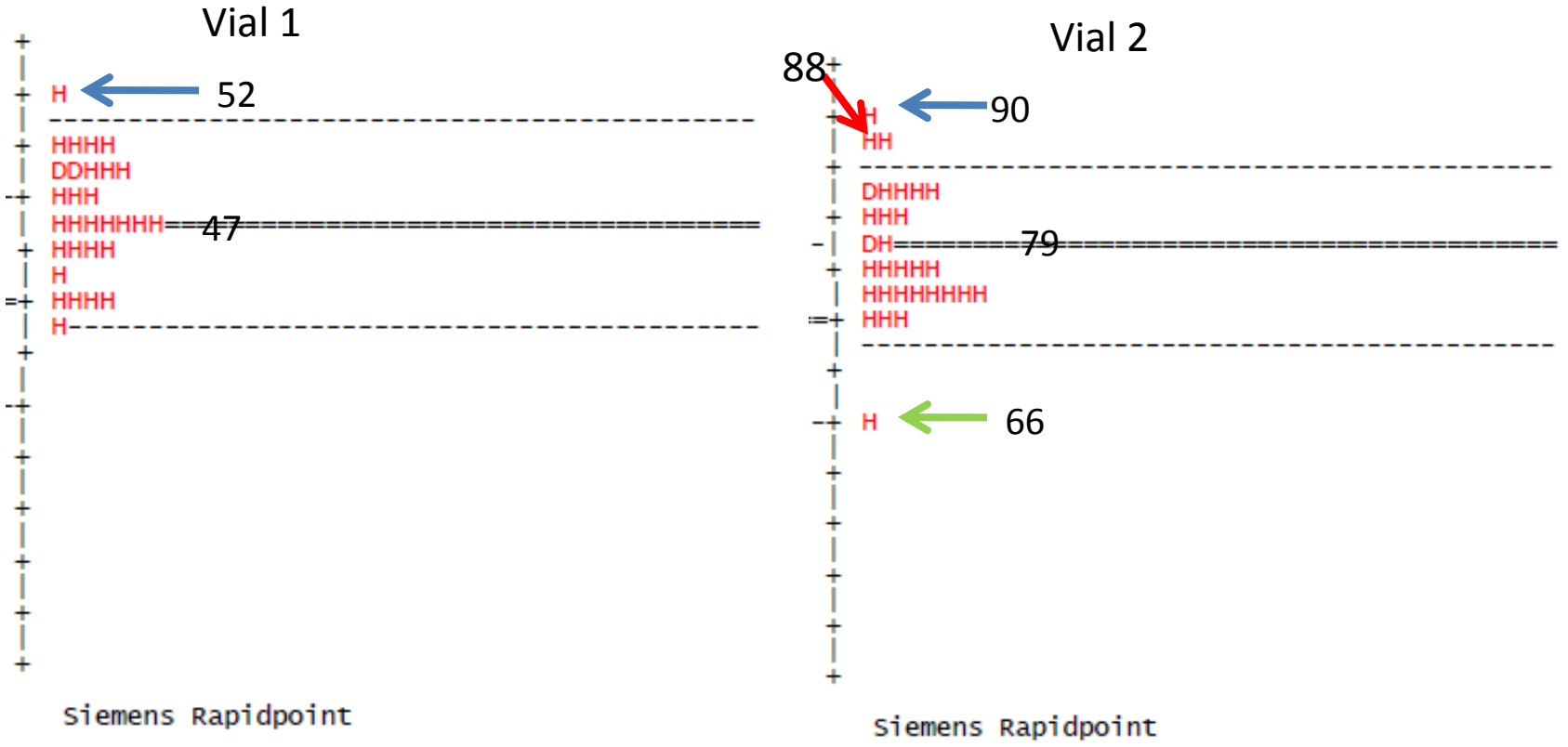
Example #3

BLOOD GASES

Multiple instruments tested. Discordant findings noted for 3 instruments. Three separate investigations undertaken and reported.

Instrument #	Vial #	Analyte	Result	Target	Range	PAD Score	Action Code
1	2	pCO_2	66 mm Hg	79	72 - 86	-186	A3
2	2	pCO_2	88	79	72 - 86	129	A3
3	1	pCO_2	52	47	43 - 51	125	A3
3	2	pCO_2	90	79	72 - 86	157	A3

Manufacturer Group: Siemens Rapidpoint



Instrument #1

Instrument #2

Instrument #3

Investigation Summary

	Instrument 1	Instrument 2	Instrument 3
Sample Retest	**Retested immediately as per critical value policy 68 mm Hg** *Still too low*	**Retested immediately as per critical value policy 80 mm Hg – now within acceptable range**	**Retested immediately as per critical value policy Vial 1 – 48 mm Hg Vial 2 - 84 mm Hg Both results now within acceptable range**
Investigation	**Testing performed by POCT operator QC and split sample testing did not show problems Latest instrument calibration verification acceptable**	**Testing performed by POCT operator QC and split sample testing did not show problems Latest instrument calibration verification acceptable**	**Testing performed by POCT operator QC and split sample testing did not show problems Latest instrument calibration verification acceptable CAP Proficiency testing acceptable.**
Root Cause	**Due to high pCO_2 loss of CO_2 to room air due to poor specimen handling may have contributed**	**Unknown – likely due to random error due to high pCO_2 concentration**	**Unknown – likely some inaccuracy and imprecision at high pCO_2 concentrations**
Corrective action	**Continue to monitor QC & split sample performance Continue to work in conjunction with POCT operators**	**Continue to monitor QC & split sample performance Continue to work in conjunction with POCT operators**	**Continue to monitor QC & split sample performance Continue to work in conjunction with POCT operators**
DF Code	**T99 – other technical error**	**U 01 – random error**	**M14 – method inaccurate or imprecise**

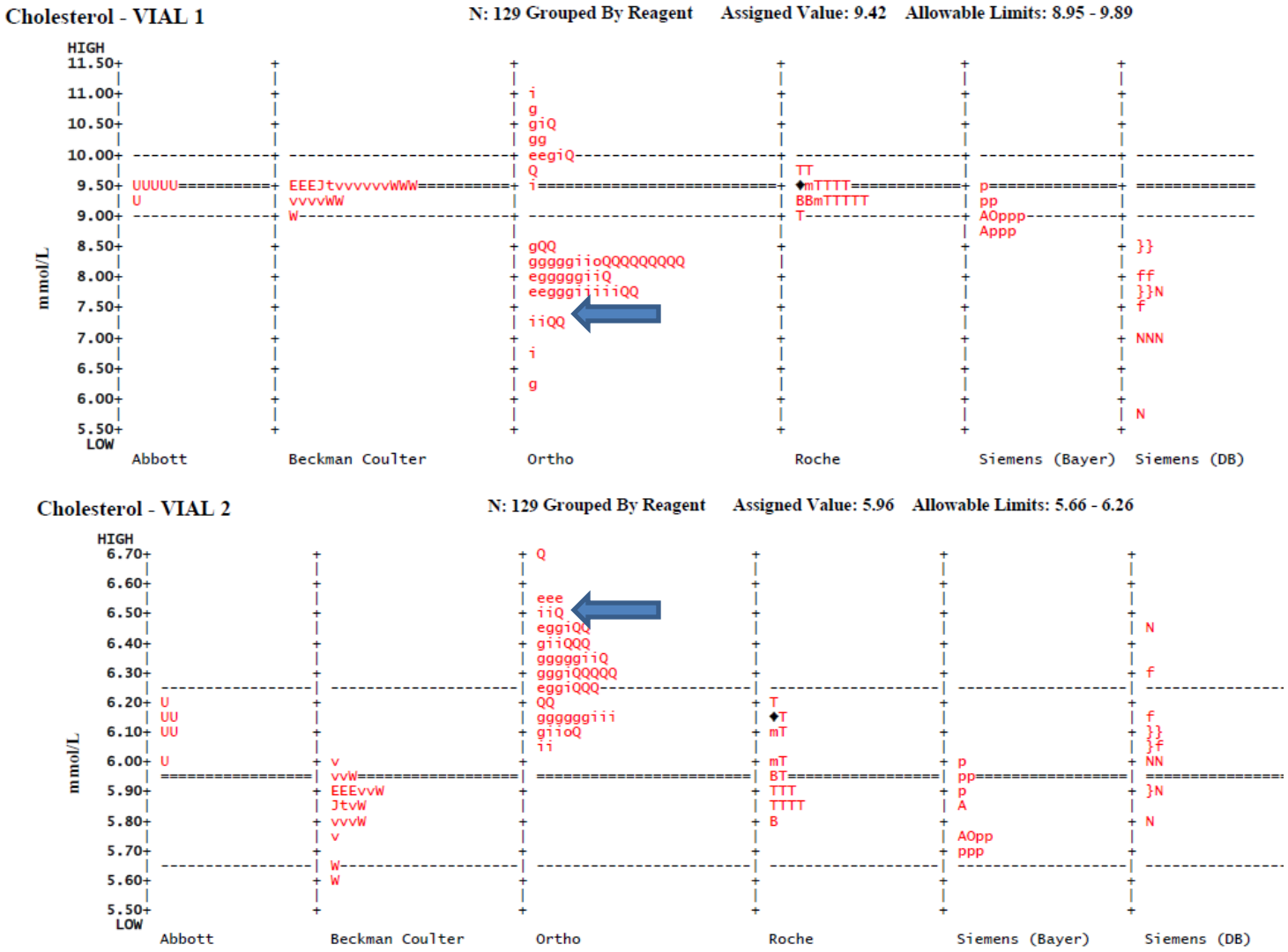
Example # 4

Cholesterol

Vial #	Analyte	Result	Target	Range	PAD Score	Action Code
1	Cholesterol	7.63	9.42	8.95 – 9.89	-381	A3
2	Cholesterol	6.53	5.96	5.66 – 6.26	190	A3

Manufacturer Group: Ortho Clinical Diagnostics

A3 code indicates flags in 2 of 3 previous surveys



Note: samples for this survey are single donor, fresh, never frozen samples.
Target values established by 2 external reference laboratories

Sample Retest: Repeated using same lot # reagent
Vial #1 – 8.34 mmol/L Still low
Vila #2 – 6.89 mmol/L Still high

Investigation:
Review of histogram shows poor performance by all OCD users.
OCD hotline contacted. Hotline requested fax of laboratory results for this survey
No trouble shooting done with hotline advisor at this time. They informed the lab that OCD specialists were preparing a letter of explanation.
Sent 10 samples to outside laboratory that also uses OCD instrument. Results showed a positive bias across the range of results
Root Cause:
Currently awaiting a letter from OCD that we hope has addressed recent poor performance of Cholesterol on QMPLS LIPS 1101survey.
When received, letter will be reviewed closely and suggestions promptly acted upon. Letter will be uploaded to QMPLS.

Corrective Action:
Two lot #s re-calibrated (current and one other) using same lot # of calibrator.
The 10 samples sent out were reanalyzed using both reagent lot #s
Results correlated well lot-to-lot, better correlation with outside lab but slight positive bias remains.
Will continue to work with OCD and hope that a solution is found.
Patient comparisons between current and new lot #s of reagents will be instituted.
Regular comparison of patient results with peer laboratories will be considered.

DF Code: M12 – manufacturer or supplier related issue e.g. problem with reagent performance

Conclusions

- EQA and external proficiency testing are essential components of a good quality system
- A well performed problem analysis can help to identify issues that affect the quality of your laboratory.
- Corrective action and surveillance can ensure that the problem does not repeat itself.

Thank-you

Further questions or comments?