Challenging QC

NRL Symposium, Gold Coast, Australia

October 2019
Challenging QC Case Studies

Series of cases to demonstrate -

- What to look for
- Common variation seen with QC use
- How to troubleshoot scenarios
- Step-wise investigations!
- Don’t need to have right answer first time

NRL has a troubleshooting checklist

Before we get started on the Case Studies

- How the Polling works
- On any electronic device, key the following into your browser:
  - PollEv.com/nrl2019
- Let’s practice…
The capital city of Australia is...?

- Sydney
- Melbourne
- Canberra
- Gold Coast
- Wellington
The capital city of Australia is...?

Sydney A
Melbourne B
Canberra C
Gold Coast D
Wellington E
Scenario 1
Scenario 1

NRL Limits - Upper

NRL Limits - lower

Laboratory: SK1  From: 01-Nov-2018 to 14-Feb-2019  Assays: Abbott ARCHITECT Anti-HCV
Analytical Method: EQC EQC Lot Number: DM18021

Trend: KiLoL Number: Test Process: Detection  6709L100  92220L100  94298L100

NRL Range: 2.20 to 3.50
What is the likely cause of the results in Scenario 1?

- There is no problem at all
- This is reagent lot variation
  - The QC is failing and needs review
  - The operators are at fault and need retraining
  - The instruments are the source of variation
What is the likely cause of the results in Scenario 1?

- There is no problem at all
- This is reagent lot variation
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Scenario 1

NRL Limits - Upper

NRL Limits - lower
Scenario 1

[Graph showing data over time with various markers and labels for different dates and trends.]
Scenario 1

Answer:

Instruments are running separately…
Scenario 1

Cut-off
Scenario 1

Cut-off
How would you deal with this?
Scenario 2
Scenario 2

Roche cobas HBsAg

Lab data by reagent lot

Which set is the issue?
Scenario 2

Roche cobas HBsAg

Lab data by instrument

Which set is the issue?
What is the likely cause of the results in the red boxes?

- This is reagent lot variation
- The QC is failing and needs review
- The QConnect Limits are wrong and need review
- There are two lots of the QC in use
- Something else is going on...
What is the likely cause of the results in the red boxes?

This is reagent lot variation

The QC is failing and needs review

The QConnect Limits are wrong and need review

There are two lots of the QC in use

Something else is going on...
Scenario 2

*Answer:* First set

Reagent lot variation…

Not a typical example!
Scenario 2

- Lab data by reagent lot
- Latter set of more concern
Scenario 2

*Answer:* Latter set

???

Lot variation with calibration changes?
How would you deal with this?
Scenario 3
What is the likely cause of the results in Scenario 3?

The QC is the source of variation

This is a reagent lot issue

The instruments are in need of calibration

Something else is going on?
What is the likely cause of the results in Scenario 3?

The QC is the source of variation

This is a reagent lot issue

The instruments are in need of calibration

Something else is going on?
Scenario 3

- QConnect HEPR lot issues?
- Assay issues? Not reagent lots so ???
- Instrument issues?
ARCHITECT anti-HBs
Lab 299
ARCHITECT anti-HBs
Lab 128
Lab 123
Positive
Ctrl 1
To scale
Lab 191
Positive
Ctrl 1
Lab 191
Positive Ctrl 2
Lab 30
Positive Ctrl 1
Scenario 3

- Likely a change in behaviour in assay
- New version of assay may be contributing
- Working with Manufacturer to find root cause
How would you deal with this?