ARE PATIENTS’ RESULTS AFFECTED BY CHANGES IN QC REACTIVITY?

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NRL Symposium
Gold Coast 2019
Why Run Quality Control?

To monitor variation derived from:

- Reagent lots
- Instrument and equipment
- Calibrations and maintenance
- Operators
- Storage and transport conditions
- Environmental conditions
What would you do?
What would you do?

- Do nothing
- Re-run the QC sample
- Re-calibrate instruments
- Re-set control limits
- Contact manufacturer

Note:
Guidelines do not provide advice for this common situation.
Traditional Approaches to QC

Two populations in infectious disease serology
Are patient results affected by this drop in reactivity?
AIM

To determine whether patient results are affected by a drop in QC reactivity
25 seroconversion samples (S/Co <10) Obtained from 16 individuals Tested on 3 reagent lots  Two affected One unaffected Compared S/Co and qualitative results
RESULTS

- 24 of 25 seroconversion samples had reactivity S/Co < 12 on repeat testing
- 19/25 had S/Co < 10 on unaffected lot
- No sample had S/Co < 1.0 on unaffected lot
- Three samples had S/Co < 1.0 on both affected lots
- One sample had S/Co < 1.0 on one affected lot only
RESULTS
## RESULTS

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Seroconversion Panel Number</th>
<th>Sample Identification</th>
<th>anti-HCV Assay Lot Number (S/Co)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unaffected</td>
</tr>
<tr>
<td>1</td>
<td>N/A</td>
<td>62027488</td>
<td>1.44</td>
</tr>
<tr>
<td>6</td>
<td>N/A</td>
<td>K00983</td>
<td>1.67</td>
</tr>
<tr>
<td>9</td>
<td>SCP-HCV-009</td>
<td>SCP 009-06</td>
<td>1.78</td>
</tr>
<tr>
<td>10</td>
<td>SCP-HCV-001</td>
<td>SCP 001-15</td>
<td>2.31</td>
</tr>
<tr>
<td></td>
<td>QConnect BLUE (DM18210)</td>
<td></td>
<td>3.15</td>
</tr>
</tbody>
</table>

- All but one result on affected lot was S/Co ≥ 0.78
- Non-affected lot reactivity was S/Co < 2.3
- Results indicate an extremely early seroconversion
CONCLUSION

- Patient results may be affected by a decrease in reactivity of QC
- **BUT**
  - Only very early seroconversions
  - Extremely rare in clinical testing
  - Level lasts ~48 hours only
  - Other sources of variation may also have similar effect
CONCLUSION

- QConnect limits detected variance
- Underlines the importance of using QConnect to monitor testing performance
- Requires peer comparison
- Use on lab specific results may miss significant events