MTN-020 LC:
HIV Testing Case Study and Study Closeout

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HIV Case Study

• A clinical research site had some irregular HIV testing results.

• Additional Testing was performed at the MTN Virology Core which revealed some false negative testing results (shown on next Slide).

• This triggered an LC site visit.
<table>
<thead>
<tr>
<th>Study Visit</th>
<th>Site Testing Result</th>
<th>LC Virology Laboratory Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 16</td>
<td>Unigold Negative, Determine Negative</td>
<td>Unigold Positive, HIV RNA = 912 copies/ml</td>
</tr>
<tr>
<td>Month 17</td>
<td>Missed Visit</td>
<td>NA</td>
</tr>
<tr>
<td>Month 18</td>
<td>Unigold Positive, Determine Positive</td>
<td>NA</td>
</tr>
</tbody>
</table>
## HIV Case Study-Cont.

<table>
<thead>
<tr>
<th>Site Practice</th>
<th>Package Insert Direction</th>
<th>Major Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deviation 1: Technician added 2 drops of wash solution</td>
<td>Add 4 drops of wash solution</td>
<td>2 drops of wash may be enough to make the internal control line become positive while not moving the patient sample into the test area.</td>
</tr>
<tr>
<td>Deviation 2: Technician used cold wash solution directly from refrigerator</td>
<td>Allow wash solution to come to room temperature for 20 minutes before use</td>
<td>Cold reagent will slow down the test reaction.</td>
</tr>
<tr>
<td>Observation #</td>
<td>Sample</td>
<td>Drops Wash Solution Added</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Positive Control</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Positive Control</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Positive Control</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Positive Control</td>
<td>2</td>
</tr>
</tbody>
</table>
## HIV Case Study-Cont.

<table>
<thead>
<tr>
<th>Observation #</th>
<th>Sample</th>
<th>Drops Wash Solution Added</th>
<th>Wash Solution Temperature</th>
<th>Result 10-12 Minutes (Valid Read Time)</th>
<th>Result Change Post 12 Minutes (Post Valid Read Time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Participant</td>
<td>4</td>
<td>Room Temp</td>
<td>Positive</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>Participant</td>
<td>4</td>
<td>Cold</td>
<td>False Negative</td>
<td>Positive between 12-13 minutes</td>
</tr>
<tr>
<td>7</td>
<td>Participant</td>
<td>2</td>
<td>Room Temp</td>
<td>False Negative</td>
<td>No change at 15 minutes</td>
</tr>
<tr>
<td>8</td>
<td>Participant</td>
<td>2</td>
<td>Cold</td>
<td>False Negative</td>
<td>Positive at 13 minutes</td>
</tr>
</tbody>
</table>
HIV Case Study-Conclusions

• EQA and QC can be 100% successful even while test procedural errors are occurring.

• Procedural errors greatly increase the risk of false negative results in early seroconversion samples or other samples with low antibody titers.

• Package insert directions must be followed carefully to maximize performance.