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|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------|-----|--------------------------|-----------|--|
|  <p><b>STOP<br/>Notification</b></p> | <p><b>Alere HIV-1/2 Ag/Ab Combo kit comment added due to potential biotin interference</b></p>                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>When:</b></p>                                                                                                   | <p><b>Monday, July 27, 2020</b></p>                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>What?</b></p>                                                                                                   | <p><b>The comment, "Detection of p24 may be inhibited by biotin in the sample, causing false negative results in acute infection" will be added to all rapid HIV tests performed using the Alere HIV-1/2 Ag/Ab Combo kit</b></p>                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>Who is Affected:</b></p>                                                                                        | <p><b>Affected Location(s)</b></p> <ul style="list-style-type: none"> <li>Alamance Cancer Center</li> <li>High Point Cancer Center</li> <li>Wesley Long Cancer Center</li> <li><b>x</b> Alamance Regional</li> <li><b>x</b> Annie Penn Hospital</li> <li><b>x</b> MedCenter @ High Point</li> <li><b>x</b> MedCenter @ Mebane</li> <li><b>x</b> Moses Cone Hospital</li> <li><b>x</b> Wesley Long Hospital</li> <li>Women's Hospital</li> </ul> | <p><b>Department(s)</b></p> <ul style="list-style-type: none"> <li>Blood Bank</li> <li>Cytology</li> <li>Flow Cytometry</li> <li>Histology</li> <li>Microbiology</li> <li>Phlebotomy</li> <li>Point Of Care</li> <li><b>x</b> Rapid Response Lab</li> <li>Respiratory Therapy</li> <li>Specimen Processing</li> </ul> |                   |            |     |                          |           |  |
| <p><b>Why?</b></p>                                                                                                    | <p><b>Alere sent a customer bulletin that stated that the p24 antigen may be inhibited by biotin (Vitamin B7), which could cause false negative results in acute infections. The comment above was added by Alere to their package insert to ensure all users were aware of potential interference.</b></p>                                                                                                                                     |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>What you will need to do to prepare:</b></p>                                                                    | <p><b>Nothing at this time.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>Manager / Supervisor Responsibility:</b></p>                                                                    | <p>Send Post Live Documentation to IT Manager within 5 days of the effective date for test systems marked with an "X"</p> <table border="1" data-bbox="456 1608 1511 1749"> <tr> <td><b>X</b> Sunquest</td> <td>WindowPath</td> </tr> <tr> <td>CHL</td> <td>Instrument / Manual Test</td> </tr> <tr> <td>PowerPath</td> <td></td> </tr> </table>                                                                                                |                                                                                                                                                                                                                                                                                                                       | <b>X</b> Sunquest | WindowPath | CHL | Instrument / Manual Test | PowerPath |  |
| <b>X</b> Sunquest                                                                                                     | WindowPath                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| CHL                                                                                                                   | Instrument / Manual Test                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| PowerPath                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |
| <p><b>Need Help?</b></p>                                                                                              | <p>Contact your Manager / Supervisor</p>                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |                   |            |     |                          |           |  |