



**STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT**

**Cepheid Infinity Upgrade and SA Complete Complexity Change**

Description:	Microbiology at MC upgraded the Cepheid 48 with a new instrument and increased available modules to twenty-four. The SA Complete assay will change from high complexity (Not FDA approved) to a moderate complexity (FDA approved). Specimens that are collected on patients less than 22 years of age are not valid for testing by PCR.
Implementation Date:	Tuesday August 28, 2018
Performing Locations:	<p><b>Click on the boxes that apply:</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Annie Penn Hospital</li> <li><input checked="" type="checkbox"/> Moses Cone Hospital</li> <li><input type="checkbox"/> Med Center at High Point</li> <li><input checked="" type="checkbox"/> Wesley Long Hospital</li> <li><input checked="" type="checkbox"/> Women's Hospital</li> <li><input checked="" type="checkbox"/> Alamance Hospital</li> <li><input type="checkbox"/> Med Center at Mebane</li> </ul>
Affected Locations:	<p><b>Click on the boxes that apply:</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Annie Penn Hospital</li> <li><input checked="" type="checkbox"/> Moses Cone Hospital</li> <li><input checked="" type="checkbox"/> Med Center at High Point</li> <li><input checked="" type="checkbox"/> Wesley Long Hospital</li> <li><input checked="" type="checkbox"/> Women's Hospital</li> <li><input checked="" type="checkbox"/> Alamance Hospital</li> <li><input type="checkbox"/> Med Center at Mebane</li> </ul>

<p>Affected Departments:</p>	<p><b>Click on the boxes that apply:</b></p> <p><input type="checkbox"/> Blood Bank  <input type="checkbox"/> Cytology  <input type="checkbox"/> Flow Cytometry  <input type="checkbox"/> Histology  <input checked="" type="checkbox"/> Microbiology  <input type="checkbox"/> Phlebotomy  <input type="checkbox"/> Point of Care  <input checked="" type="checkbox"/> Rapid Response Lab  <input type="checkbox"/> Respiratory Therapy  <input type="checkbox"/> Specimen Processing</p>
<p>Specimen Type:</p>	<p>COPAN Red Top Swab</p>
<p>Updated Clinical Lab Procedures:</p>	<p>Greensboro/Reidsville:  <a href="#">MICRO-2819-MC GeneXpert Infinity 48System Operating Procedure</a>  <a href="#">MICRO-2804-MC Cepheid GeneXpert Infinity Maintenance</a>  <a href="#">MICRO-2804L-MC GeneXpert Infinity Maintenance Log</a>  <a href="#">MICRO-2837A-CH Cepheid GeneXpert Dx MRSA SA COMPLETE</a>  <a href="#">QM-1742F19-CH Cepheid Infinity Direct Observation Form</a>  <a href="#">QM-1742F16-CH Gene Xpert Direct Observation Form</a>  <a href="#">QM-1614-CH Quality Assurance and Quality Control Review</a></p> <p>Burlington:  <a href="#">MICRO-726 Xpert SA Nasal Complete</a></p>
<p>Retired Clinical Lab Procedures:</p>	<p>N/A</p>
<p>Notification to Client:</p>	<p><b>Click on the boxes that apply:</b></p> <p><input type="checkbox"/> Section Not Applicable</p>

	<p><input checked="" type="checkbox"/> Memo Needed</p> <p><b>Distribution of Memo:</b></p> <p><input checked="" type="checkbox"/> Medical Staff Alamance and Greensboro/Reidsville</p> <p><input type="checkbox"/> Allied Health Professionals (PA, Nurse Practitioners)</p> <p><input type="checkbox"/> Anesthesia</p> <p><input type="checkbox"/> Annie Penn (Primary Source Physicians)</p> <p><input type="checkbox"/> Dentist</p> <p><input type="checkbox"/> Emergency Department/Urgent Care Centers</p> <p><input type="checkbox"/> Family Practice</p> <p><input type="checkbox"/> Infectious Docs #ID Docs          (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam)</p> <p><input type="checkbox"/> OB/GYN</p> <p><input type="checkbox"/> Pathology</p> <p><input type="checkbox"/> Pediatricians</p> <p><input type="checkbox"/> Psych</p> <p><input type="checkbox"/> Radiology</p> <p><input type="checkbox"/> Surgery</p> <p><input checked="" type="checkbox"/> #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)</p> <p><input checked="" type="checkbox"/> Kenny Miller, Nursing Professional Development Specialist sent a Clinical Practice Alert to Cone Health Nursing staff system wide on Friday August 17, 2018.</p> <p><input checked="" type="checkbox"/> Pharmacy - Send to DeAnne Brooks &amp; Jim Hasspacher</p> <p><input type="checkbox"/> #IM Residents</p> <p><input checked="" type="checkbox"/> Melissa Morgan</p> <p><input type="checkbox"/> Phlebotomy Managers and Supervisors</p> <p><input type="checkbox"/> Point of Care: Sheila, Kim &amp; Marty</p>
<p>Accreditation Section:</p>	<p><b>Click on the boxes that apply:</b></p> <p><input type="checkbox"/> Section Not Applicable</p> <p><input checked="" type="checkbox"/> CAP Test menu change needed          Greensboro/Reidsville sites CAP test menu will have MRSA/SA nucleic acid amplify (not FDA approved) test activity id 3525 removed.</p> <p><input type="checkbox"/> CMS Analyte form change needed</p> <p><input type="checkbox"/> Proficiency Testing surveys changes needed or ordered</p>
<p>Laboratory IT section:</p>	<p><b>Click box and type needed changes/additions:</b></p> <p><input type="checkbox"/> Section Not Applicable</p> <p><input checked="" type="checkbox"/> LIS changes          Testing has shown that all that is needed to connect the interface is to update the network addresses in SQ and on board the Infinity.</p> <p><input type="checkbox"/> Reference range change/addition</p> <p><input type="checkbox"/> Technical Failure change/addition</p> <p><input type="checkbox"/> Critical Value change/add</p>

	<p><input checked="" type="checkbox"/> Text comments needed                  Comment will be updated  <input type="checkbox"/> Specimen collection instructions  <input type="checkbox"/> Need to monitor TAT  <input type="checkbox"/> CPT code for tests(s)</p>
<p>Technical Staff Update:</p>	<p>On Tuesday August 28<sup>th</sup>, MC will go live with their upgraded Infinity 48. This new instrument has increased to 24 modules and will allow for the addition of new assays as they become available.</p> <p>The surgical PCR assay (SA complete) has an age limitation. Testing may only be performed on patients 22 years or older. Providers are instructed to order a nasopharyngeal culture if the test is needed on patients less than 22 years of age.</p> <p>The SA complete assay will change from High Complexity (FDA not approved) to Moderate Complexity (FDA approved). At this time, CLTs will continue not to perform the SA complete assay. CLTs will be trained to perform this test in the future.</p> <p>Moses Cone location will need to perform a new IQCP for the new Cepheid Infinity. Quality Controls will need to be perform on all tests if IQCP plan is not completed by August 28, 2018.</p> <p>Annie Penn, Wesley Long, and Women' Hospital will need to perform a reassessment of their current IQCP plan for the GeneXpert Instrument. Quality Controls will need to be perform on SA complete if IQCP plan is not completed by August 28, 2018.</p>
<p>STOP Initiator:</p>	<p>Jeff Beaman MT (ASCP), MHA</p>

Alamance Medical Director Signature:	Quality Department will obtain signature: <i>Judith B. Williams</i> 8/21/18
Med Center at Mebane Medical Director Signature	Not applicable
Greensboro/Reidsville Medical Director Signature:	<i>Julie Peterson, MD</i> 8/24/18



TO: Cone Health Medical Staff

FROM: Joshua Kish, MD, FCAP, FASCP  
Chief of Pathology, Cone Health  
John Patrick, MD, FCAP, FASCP  
Greensboro and Reidsville Hospital Laboratories Medical Director, Cone Health

*Joshua B. Kish, MD 8/20/18*  
*John Patrick, MD 8/20/18*

RE: Changes to Surgical PCR Testing

Date: August 23, 2018

Effective August 28, 2018, the Clinical Laboratory at Moses Cone Hospital will upgrade our PCR instrumentation. Due to manufacturer's limitations, the *Staph aureus* surgical PCR test performed at all hospital locations is not appropriate for patients less than 22 years of age. A nasopharyngeal culture may be ordered on patients less than 22 years of age if the test is needed.

Please call or email if there are any concerns or comments: 336-832-7821 or contact Jeff Beaman, Manager of Microbiology [jeff.beaman@conehealth.com](mailto:jeff.beaman@conehealth.com).