

 <p>STOP Notification</p>	<p align="center">Testing Kit Change for Bacterial Vaginosis and Candida Vaginosis from ASR to FDA Approved Kit</p>	
<p>When:</p>	<p align="center">Tuesday, February 25, 2020</p>	
<p>What?</p>	<p align="center">Converting from BV/CV ASR assay to BV/CV FDA approved assay</p>	
<p>Who is Affected:</p>	<p align="center">Affected Location(s)</p> <p>Alamance Cancer Center High Point Cancer Center Wesley Long Cancer Center Alamance Regional Annie Penn Hospital MedCenter @ High Point MedCenter @ Mebane x Moses Cone Hospital Wesley Long Hospital Women's Hospital</p>	<p align="center">Department(s)</p> <p>Blood Bank x Cytology Flow Cytometry Histology Microbiology Phlebotomy Point Of Care Rapid Response Lab Respiratory Therapy Specimen Processing</p>
<p>Why?</p>	<p align="center">The FDA approved the Hologic Aptima assay for BV and CV testing on the Panther. We are converting from the ASR assay to the FDA approved testing</p>	
<p>What you will need to do to prepare:</p>	<p align="center">Training from the Hologic technical specialist and verification/validation of testing methodology. The FDA approved kits</p>	
<p>Manager / Supervisor Responsibility:</p>	<p align="center">Send Post Live Documentation to IT Manager within 5 days of the effective date for test systems marked with an "X"</p>	
	<p>Sunquest</p>	<p>X WindowPath</p>
	<p>X CHL</p>	<p>Instrument / Manual Test</p>
	<p>PowerPath</p>	<p></p>
<p align="center">Manager to ensure post live documentation is completed</p>		
<p>Need Help?</p>	<p align="center">Contact your Manager / Supervisor</p>	



Liquid-Based Pap Specimens For Bacterial Vaginosis (BV) and Candida Vaginosis (CV) No Longer Accepted

This affects all inpatient and outpatient clients for Cone Health Cytology

Situation

Effective February 25, 2020 Thin Prep liquid-based pap specimens will no longer be accepted for Bacterial Vaginosis (BV) and Candida Vaginosis (CV) PCR testing. Specimens need to be collected with the Orange Aptima multi-test swab.

Background

FDA approval for BV and CV from the orange Aptima multi test swab was received. Approval was not received for BV and CV on liquid-based Pap test.

Assessment

Bacterial Vaginitis and Candida testing can no longer be performed from the Thin prep pap vial.

Recommendation

Review the proper collection method for the Aptima Orange multi test Swab. In preparation for this change. Please educate all staff and providers of this change and begin BV CV collections with the Aptima swab now. If you recall CT, NG and Trich along with BV and CV can be done with one Aptima Orange Swab collection. Beginning February 21, 2020 Bacterial Vaginitis and Candida Vaginitis orders from the Thin Prep Vial will be rejected.

Please contact the Cytology department for any questions at 336-832-7542.