Approved and current. Effective starting 6/28/2019. 77420.613 (version 3.1) STOP Request/Notification Template Blank copy 3420151. Last reviewed on 6/25/2019. Printed on 1/25/2020 12:55 PM (EST). Page 2 of 2

Testing Kit Change for Bacterial Vagin and Candida Vaginitis from ASR to FI Approved Kit When: Tuesday, February 25, 2020 What? Converting from BV/CV ASR assay to BV/CV FDA approved assa Who is Affected: Affected Location(s) Alamance Cancer Center High Point Cancer Center Alamance Regional Annie Penn Hospital Microbiology Department(s) Blood Bank X Cytology Microbiology Histology MedCenter @ High Point MedCenter @ Mebane Point Of Care X Moses Cone Hospital Respiratory Therapy Specimen Processing Why? The FDA approved the Hologic Aptima assay for BV and CV testing or Panther. We are converting from the ASR assay to the FDA approved	AC
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What you will need to do to prepare:Training from the Hologic technical specialist and verification/validati testing metholdogy. The FDA approved kits	on of
Send Post Live Documentation to IT Manager within 5 days of the effective for test systems marked with an "X"	e date
Sunquest X WindowPath	
Manager / Supervisor X CHL Instrument / Manual Test	
Responsibility: PowerPath	
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Need Help? Contact your Manager / Supervisor	



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.