

## SPECIAL ADVISORY • JUNE 2018

The following test changes will be effective on the dates indicated below. Please note that the changes are listed in bold and italicized. Additional information regarding the changes will be provided where applicable.

### TEST CHANGE 1: Cytopathology, ThinPrep® Pap Test

Description of Change:	<i>All gyn ThinPrep® Pap tests that require glacial acetic acid reprep due to obscuring blood will no longer be called to the client requesting permission for reprep. Once glacial acetic acid reprep has been performed on the specimen vial, no further ancillary testing can be performed off of the specimen vial. If glacial acetic acid reprep is performed on the specimen vial, this information will be notated on the final Cytology report.</i>
Effective Date:	06/15/2018
Includes:	<ul style="list-style-type: none"> <li>Examination of laboratory-prepared ThinPrep® Pap test</li> <li>HPV Plus 16 &amp; 18</li> <li>Reflex HPV DNA High Risk on ASCUS only</li> <li>HPV DNA High Risk primary screen in combination with ThinPrep® Pap test out of vial</li> <li>HPV DNA High Risk only (for specimens sent without ThinPrep® Pap test)</li> <li>Chlamydia and/or Neisseria Gonorrhoea by Amplified Probe</li> <li><i>See Chlamydia by Amplified DNA Probe and Neisseria Gonorrhoea by Amplified DNA Probe.</i></li> </ul>
Methodology:	<ul style="list-style-type: none"> <li>ThinPrep® 2000 System Ancillary Test Options (out of vial)</li> <li>Real-time PCR</li> <li>Gen Probe® Aptima Amplified Deoxynucleic Acid (DNA) (CT/NG)</li> </ul>
Testing Schedule:	Routine, Monday to Friday, no holidays
Report Availability:	7 to 10 days
Specimen Requirements:	<p><b>MINIMUM VOLUME:</b></p> <ul style="list-style-type: none"> <li>Exfoliated cells collected according to the ThinPrep® liquid-based specimen preparation guidelines</li> </ul> <p><b>CONTAINER:</b></p> <ul style="list-style-type: none"> <li>ThinPrep® vials filled with PreservCyt® Solution</li> </ul> <p><b>COLLECTION:</b></p> <ul style="list-style-type: none"> <li>Vials <b>MUST</b> be labeled with patient's full name and second identifier (e.g., DOB, MRN, SSN). First initial and last name is not acceptable. See special instructions for Cytobrush/Spatula Collection listed under Specimen Collection, Preparation and Handling section of the Lab Handbook.</li> <li>Transport ThinPrep® vials within one week of collection.</li> </ul>
Special Instructions:	<ul style="list-style-type: none"> <li>Submit specimen with a completed Gyn Cytology requisition form (HNL-30) or one of the laboratory-appropriate electronic forms.</li> <li>Ancillary Test Options (out of vial) are performed only from a ThinPrep® vial.</li> <li>Maturation Index, if desired, must be obtained from a lateral vaginal wall scrape.</li> <li>Patient should avoid douches for 48 to 72 hours prior to collection.</li> </ul> <p><b>NOTE:</b> The following additional criteria are required for Ancillary Test Options (out of vial) HPV DNA. There must be a minimum of 4 mL of fluid available after processing the ThinPrep® Pap test HPV DNA. The specimen cannot be older than 30 days. For Chlamydia and/or Neisseria Gonorrhoea by Amplified Probe, the specimen cannot be older than 14 days.</p>
Reference Range:	Bethesda 2001 Terminology
Clinical Utility:	To detect intraepithelial lesions, neoplastic lesions and some infectious agents

## TEST CHANGE 2: Cytopathology, ThinPrep® Plus Imager Pap Test

Description of Change:	<i>All gyn ThinPrep® Pap tests that require glacial acetic acid reprep due to obscuring blood will no longer be called to the client requesting permission for reprep. Once glacial acetic acid reprep has been performed on the specimen vial, no further ancillary testing can be performed off of the specimen vial. If glacial acetic acid reprep is performed on the specimen vial, this information will be notated on the final Cytology report.</i>
Effective Date:	06/15/2018
Includes:	<ul style="list-style-type: none"> <li>• Examination of laboratory-prepared ThinPrep® Pap test</li> <li>• HPV Plus 16 &amp; 18</li> <li>• Reflex HPV DNA High Risk on ASCUS only HPV DNA High Risk primary screen in combination with ThinPrep® Pap test out of vial HPV DNA High Risk only (for specimens sent without ThinPrep® Pap test)</li> <li>• Chlamydia and/or Neisseria Gonorrhoea by Amplified Probe <i>See Chlamydia by Amplified DNA Probe and Neisseria Gonorrhoea by Amplified DNA Probe.</i></li> </ul>
Methodology:	<ul style="list-style-type: none"> <li>• ThinPrep® 2000 System Ancillary Test Options (out of vial)</li> <li>• Real-time PCR</li> <li>• Gen Probe® Aptima Amplified Deoxynucleic Acid (DNA) (CT/NG)</li> </ul>
Testing Schedule:	Routine, Monday to Friday, no holidays
Report Availability:	5 to 7 business days
Specimen Requirements:	<p><b>MINIMUM VOLUME:</b></p> <ul style="list-style-type: none"> <li>• Exfoliated cells collected according to the ThinPrep® liquid-based specimen preparation guidelines</li> </ul> <p><b>CONTAINER:</b></p> <ul style="list-style-type: none"> <li>• ThinPrep® vials filled with PreservCyt® Solution</li> </ul> <p><b>COLLECTION:</b></p> <ul style="list-style-type: none"> <li>• Vials <b>MUST</b> be labeled with patient's full name and second identifier (e.g., DOB, MRN, SSN). First initial and last name is not acceptable. See special instructions for ThinPrep® Collection Techniques followed by Quick Reference Guide for Cytobrush/Spatula Collection and Broom-Like Device Protocol listed under Specimen Collection, Preparation and Handling section of the Lab Handbook.</li> <li>• Transport ThinPrep® vials within one week of collection.</li> </ul>
Special Instructions:	<ul style="list-style-type: none"> <li>• Submit specimen with a completed Gyn Cytology requisition form (HNL-30) or one of the laboratory-appropriate electronic forms</li> <li>• Ancillary Test Options (out of vial) are performed only from a ThinPrep® vial.</li> <li>• Maturation Index, if desired, must be obtained from a lateral vaginal wall scrape.</li> <li>• Patient should avoid douches for 48 to 72 hours prior to collection.</li> <li>• Manual screening is performed on unsuccessful screen events. Cytology report reflects unsuccessful Imager screen.</li> </ul> <p><b>NOTE:</b> The following additional criteria are required for Ancillary Test Options (out of vial) HPV DNA. There must be a minimum of 4 mL of fluid available after processing the ThinPrep® Pap test HPV DNA. The specimen cannot be older than 30 days. For Chlamydia or Neisseria Gonorrhoea by Amplified Probe, the specimen cannot be older than 14 days.</p>
Reference Range:	Bethesda 2001 Terminology
Clinical Utility:	To detect intraepithelial lesions, neoplastic lesions and some infectious agents

**FOR ADDITIONAL INFORMATION, PLEASE CONTACT HNL'S CYTOLOGY DEPARTMENT AT 484-425-5854.**