

SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory
 US Military HIV Research Program, Walter Reed Army Institute of Research
 9100 Brookville Road, BLDG 508, Silver Spring, MD 20910

Mycoplasma genitalium Assay Test Specification

Test Name: <i>Mycoplasma genitalium</i> Assay for Hologic PANTHER				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>The MGen Assay for the Panther system is an automated <i>in vitro</i> target amplification nucleic acid probe assay that uses target capture for the detection of <i>Mycoplasma genitalium</i>.</p> <p>Test employed: licensed commercially available: Hologic Panther System</p> <p>Reference Range: Negative</p>	<p>Hologic Aptima Unisex Swab Specimen Collection Kit for Pharyngeal, Rectal, and Endocervical Swabs</p> <p>Hologic Aptima Urine Specimen Collection Kit (filled between the black lines within 24 hours of collection)</p>	<p>Shipping: Ambient (15-30°C) Refrigerated (2-8°C)</p> <p>Test must be performed within 30 days of collection.</p>	<p>This assay is not FDA cleared or approved. HIV Diagnostic and Reference Laboratory has validated this Laboratory Developed Assay for clinical research use.</p>	<p>5 business days</p>
<p>Please note: This test was developed and its performance characteristics determined by HDRL. It has not been cleared or approved by the US Food and Drug Administration (US FDA). Treatment decisions should be made in consideration of all relevant clinical and laboratory findings.</p>				

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