



TECHNICAL NOTICE

THE MEDICAL FOUNDATION

Histoplasma Galactomannan Antigen, Quantitative EIA, Urine

Effective Date: September 1, 2016

Performing Department: Immunology

Clinical Significance:

This assay detects an antigen associated with *Histoplasma capsulatum* in urine (galactomannan) in patients with disseminated histoplasmosis. It is a rapid method to aid in the diagnosis of histoplasmosis. Measurement of antigen in urine offers the highest sensitivity for diagnosis of acute pulmonary or disseminated histoplasmosis. This test should not be used as the sole means of diagnosis, but can be used as an aid in the diagnosis of histoplasmosis. Clinical diagnosis should be made in conjunction with other diagnostic procedures including but not limited to radiographic examination, microbiological culture, and/or histologic examination of tissue biopsy samples.

Method: Quantitative Enzyme Immunoassay (EIA)

Reference Range: Not Detected

Interpretive Data: Less than 0.4 ng/mL = Not Detected
0.4-3.1 ng/mL = Detected (below the limit of quantification)
3.2-20.0 ng/mL = Detected
Greater than 20.0 ng/mL = Detected (above the limit of quantification)

The quantitative range of this assay is 3.2-20.0 ng/mL. Antigen concentrations between 0.4-3.1 or >20.0 ng/mL fall outside the linear range of the assay and cannot be accurately quantified.

This EIA test should be used in conjunction with other diagnostic procedures, including microbiological culture, histologic examination of biopsy samples, and/or radiographic evidence, to aid in the diagnosis of histoplasmosis.

This test was developed and its performance characteristics determined by The Medical Foundation Laboratory. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Specimen Requirements and Collection:

Specimen Type: Random Urine

Preferred Volume: 2 mL

Minimum Volume: 1 mL

Collection: Transfer 2 mL urine to a screw-capped plastic transport tube

Storage: Room temperature: Unacceptable Refrigerated: 2 weeks Frozen: 2 weeks (avoid repeated freeze/thaw cycles)

Transport: Refrigerated

Causes for Rejection: Specimens other than urine. Urine in boric acid

Testing Schedule: Monday and Wednesday **Reported:** 1-5 Business Days

Order: Test #: 45935 **CPT:** 87385 **Test Mnemonic:** HISTO AG U

Please direct any questions, or comments regarding this notice to Qing Li, Ph.D. (qli@sbfm.org) at (574) 234-4176 extension 1584, Amobi Ezenekwe, M.D. (aezenekwe@sbfm.org) at (574) 251-1734 or call The Medical Foundation, (574) 234-4176 or (800) 544-0925.

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