

HC

Histoplasma

Co-Testing Serum & Urine Antigen is Key to Histoplasmosis Diagnosis

MVista® Quantitative Ag EIA

CASE REPORT: A patient with ulcerative colitis treated with TNF blocker therapy presented with respiratory symptoms but denied fever or weight loss. CT chest scans showed numerous parenchymal and pleural-based nodules with extensive mediastinal and bilateral hilar adenopathy. The urine tested negative for histoplasma antigen, but the serum antigen tested positive (2.89 µg/mL) using the MVista Histoplasma Galactomannan Antigen.

Test developed by & performed at MiraVista Diagnostics.

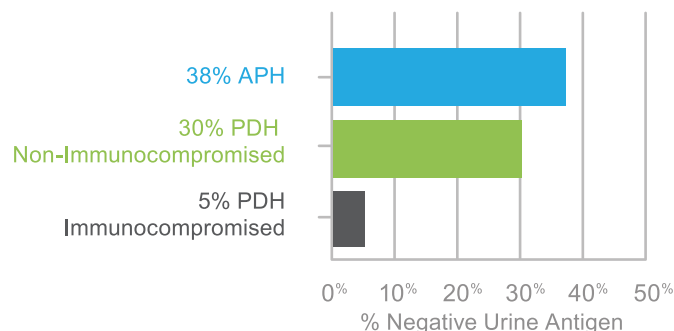
Combined Serum & Urine Antigen Testing is More Effective Than Urine Testing Alone

Antigen testing for both serum AND urine provides the highest sensitivity for histoplasmosis diagnosis. Urine can be antigen negative in patients with disseminated or diffuse pulmonary histoplasmosis.

- ~40% of Acute Pulmonary Histoplasmosis (APH) cases will be missed if only urine is tested
- 5-10% Progressive Disseminated Histoplasmosis (PDH)
- (PDH) cases will be missed if only urine is tested

ALERT: Antigen May Be Negative in Confirmed Histoplasmosis Cases

Urine may test negative for histoplasma antigen, and serum may be positive.



Be Aware of Complicating Factors That Impact Accurate & Timely Histoplasmosis Diagnosis

ANTIBODIES MAY BE NEGATIVE

for up to 8 weeks after exposure.

ANTIBODIES CAN REMAIN POSITIVE

for up to 5 years after infection.

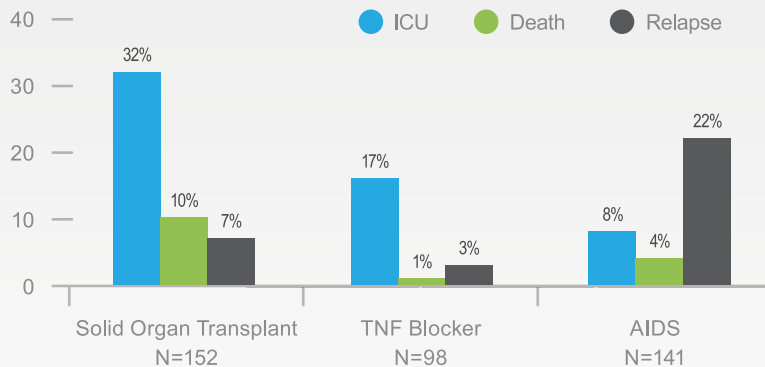
URINE ANTIGEN MAY BE NEGATIVE

and serum may be positive.

INITIAL ANTIGEN & ANTIBODY MAY BE NEGATIVE,

while subsequent tests are positive.
Re-testing may be required to establish accurate diagnosis.

KNOW THE RISKS: Clinical Outcomes of Histoplasmosis in Immunocompromised Patients



ACCURATE DIAGNOSIS AND TREATMENT ARE CRITICAL TO PREVENT HOSPITALIZATION AND MORTALITY ESPECIALLY IN IMMUNOCOMPROMISED PATIENTS

MVista Quantitative Ag EIA by MiraVista Diagnostics

TEST CODE: 310

METHODOLOGY:

- Quantitative Sandwich Enzyme Immunoassay (EIA)
- Serum and CSF are pre-treated to improve sensitivity

TURNAROUND: Testing is performed Monday-Friday

- Urine/BAL:** Same day
- Serum/Plasma/CSF:** 1 day
**New positives may require confirmation*

LIMITATIONS: The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

- Cross-reactions are seen with blastomycosis, paracoccidiomycosis, penicilliosis, less frequently in coccidioidomycosis, rarely in aspergillosis and possibly sporotrichosis.
- Sputolysin, sodium hydroxide and potassium hydroxide treatment degrade the antigen detected in the assay.

INTERPRETIVE INFORMATION:

- Positive Below the Limit of Quantification:** Results above the cutoff for positivity, but below 0.4 µg/mL fall outside the linear range of the assay. These results are positive, but not accurately quantifiable.
- Positive:** 0.4-19.0 µg/mL
- Positive Above the Limit of Quantification:** Results greater than 19.0 µg/mL fall outside the linear range of the assay.

CLINICAL SIGNIFICANCE: The MVista Histoplasma quantitative antigen test aids the diagnosis of histoplasmosis. Monitoring the antigen concentration helps determine when treatment can be stopped and to diagnose relapse.

SPECIMEN REQUIREMENTS:

- Serum/Plasma:** 1.2 mL
- CSF:** 0.8 mL
- Urine/BAL/Other Body Fluid:** 0.5 mL

SPECIMEN COLLECTION:

- Serum:** Collect serum specimens in serum separator or red top tube. Allow blood to clot for 30 minutes, then centrifuge. Pipette serum into a plastic screw cap vial.
- Plasma:** Collect plasma specimens in an EDTA, heparin or sodium citrate tube. Centrifuge for 15 minutes and pipette plasma into a plastic screw cap vial.
- Urine/CSF/BAL/Other Body Fluids:** Submit urine, CSF, BAL or other body fluids in a sterile screw cap container.

SPECIMEN STABILITY:

- Room Temperature:** 2 weeks
- Refrigerated:** 2 weeks
- Frozen:** Indefinitely

SPECIMEN REJECTION:

- If specimen is too viscous to pipette.
- Tissue, sputum, bronchial brushings, stool, FNA, biopsy, tracheal or bone marrow aspirate
- Stored in transport media, fixative or isolator tubes

TRANSPORT TEMPERATURE:

Refrigerated/Frozen/Room Temperature

SHIPPING INSTRUCTIONS:

Ship next day delivery: Monday - Friday.