MiraVista DIAGNOSTICS
Rapid Fungal Testing. Accurate Results.

Histoplasma Urine Antigen LFA

MiraVista Diagnostics developed a highly accurate ***Histoplasma* Urine Antigen LFA** to meet the diagnostic challenges for any location or clinical setting.

Accurate and Timely Diagnosis Matters

MiraVista Diagnostics' dedication to innovation and improved accessibility to high quality fungal diagnostics has created a CE Marked *Histoplasma* Urine Antigen LFA – making patient evaluation and results simple. The *Histoplasma* Urine Antigen LFA is a rapid, non-invasive test with a proven clinical sensitivity of 93.18% and 96.96% specificity relative to culture proven cases, can be operated in low complexity clinical settings and requires no complex laboratory equipment. Patient evaluation and results can be provided in approximately 40 minutes in a single visit.

Early Detection

Histoplasmosis is a systemic infection caused by the dimorphic fungus *Histoplasma capsulatum*. Rapid diagnosis is important for early initiation of treatment in progressive disseminated and acute pulmonary histoplasmosis cases. Antigen detection has been proven useful for rapid diagnosis.

- **50 – 75% of AIDS patients might have the first manifestation of AIDS present as progressive disseminated histoplasmosis**
- **Missed or delayed diagnosis can result in poor patient outcomes**
- **Rapid methods to diagnose histoplasmosis could dramatically decrease the time to initiate treatment, resulting in reduced mortality[1]**
- **Late detection of histoplasmosis is a major cause of mortality in 30% of PLHIV**
- **There is a 90% survival rate if diagnosed and treated with liposomal amphotericin B or itraconazole**

Advantages of the MiraVista *Histoplasma* Urine Antigen LFA

- **Rapid 3 step process**
- **Quick turnaround time allows for timely diagnosis and treatment**
- **No complex equipment required**
- **Can be performed in low complexity clinical settings**
- **Results are ready in approximately 40 minutes**
- **Non-invasive specimen collection**
- **CE Marked product**

HEADQUARTERS
4705 Decatur Blvd. | Indianapolis, Indiana 46241 USA

866.647.2847

Version 2 | January 2023

miravistalabs.com/devices

MiraVista DIAGNOSTICS
Rapid Fungal Testing. Accurate Results.

Study Results

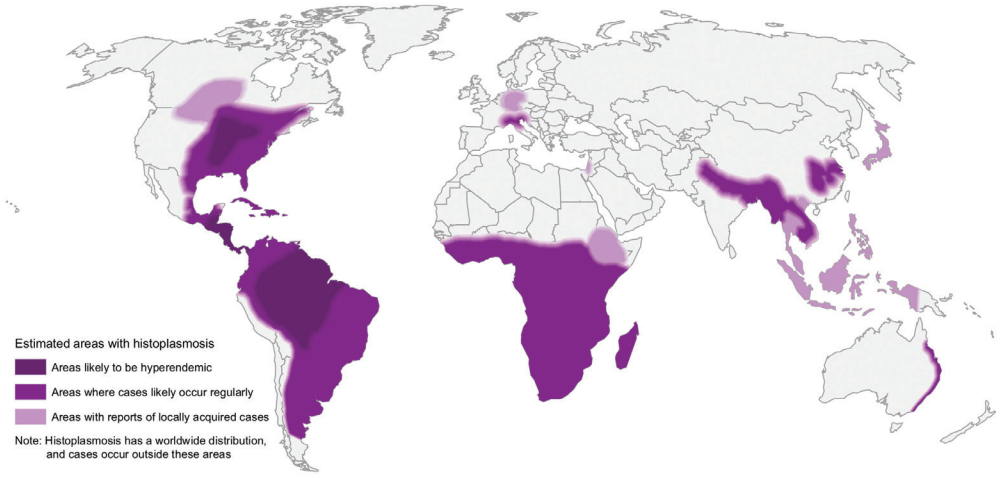
> Sensitivity and specificity of the MVD LFA was 96%, compared with 96% sensitivity and 77% specificity of the MVD EIA. Concordance analysis between MVD LFA and the MVD EIA displayed an 84% agreement, and a Kappa of 0.656.[2]

> The MVD LFA evaluated in this study has several advantages, including a turnaround time for results of approximately 40 min, no need for complex laboratory infrastructure or highly trained laboratory personnel, use of urine specimens, and ease of performing.[2]

> A Multicenter, prospective, double-blinded study conducted in ten Mexican hospitals determined the MiraVista *Histoplasma* Urine Antigen LFA had a sensitivity of 90.4% and specificity of 92.3% in PLVHIV that had *H. capsulatum* in blood, bone marrow or tissue culture or histopathological compatible exam.[1]

Study	LFA Sensitivity	LFA Specificity	EIA Sensitivity	EIA Specificity
US LFA study (IDSA)	78.8%	99.3%	95.5%	99.7%
Columbia LFA Study (J.Fungi)	96%	96%	96%	77%
Mexico LFA/Immy EIA study, (PLOS)	90.4%	92.3%	NA*	NA*

*MVista *Histoplasma* Antigen EIA not evaluated.



Global Impact of Histoplasmosis

The global burden of histoplasmosis is not known and is under-estimated. A recent modelling study in Latin America, estimated 6,710 to 15,657 HIV-associated cases of disseminated histoplasmosis each year. In Guatemala, disseminated histoplasmosis is more common than TB as the presenting opportunistic infection in advanced HIV disease.[3]

REFERENCES:

1. Martinez-Gamboa A., Niembro-Ortega MD, Torres-Gonzalez T. Diagnostic accuracy of antigen detection in urine and molecular assays testing in different clinical samples for the diagnosis of progressive disseminated histoplasmosis in patients living with HIV/AIDS: A prospective multicenter study. PLOS Neg Trop Dis. March 2021.
2. Cáceres, D.H.; Gómez, B.L.; Tobón, Á.M.; Minderman, M.; Bridges, N.; Chiller, T.; Lindsley, M.D. Validation and concordance analysis of a new lateral flow assay for detection of *histoplasma* antigen in urine. J. Fungi 2021, 7, 799.
3. Colombo, AL. GAFFI Fact Sheet Histoplasmosis. August 2020.

MiraVista *Histoplasma* Urine Antigen Lateral Flow Assay is a CE Marked product. Not FDA cleared. Not available in the U.S.

HEADQUARTERS
4705 Decatur Blvd. | Indianapolis, Indiana 46241, USA

866.647.2847

miravistalabs.com/devices

Version 2 | January 2023