



NICHE
DIAGNOSTICS, LLC



Niche Diagnostics, LLC is a biotechnology company that develops specialty tests for the detection of human diseases. The company capitalizes on the many years' experience of the management team in unique, reagent isolation, assay development and specialty laboratory testing.

Because many tests currently offered in the marketplace require increased specificity or sensitivity, the initial focus of our research is on the improvement of some of these tests. In addition, Niche seeks to develop new tests for undeveloped diagnostic opportunities. All testing services are offered through a fully licensed, clinical laboratory in Maine.

The first test offered by Niche Diagnostics for laboratory testing is a Histoplasmosis Urinary Antigen Enzyme Immunoassay (EIA). Future goals include further development and expansion of laboratory services.

OUR TEST

HISTOPLASMOSIS URINARY ANTIGEN ENZYME IMMUNOASSAY (EIA)

Histoplasma capsulatum and *Blastomycosis dermatidites* are fungal organisms that cause respiratory infections in immune-compromised patients, the elderly, Aids and transplant patients. Current tests in the marketplace lack specificity and are plagued by false positive results for infection with these two organisms. Niche has developed unique and highly specific monoclonal antibodies that capture and detect the presence of Histoplasmosis antigens in the urine of infected patients and overcome these false positive test results.

GENERAL INFORMATION

The Niche Histoplasmosis Urinary Antigen EIA is intended for the *invitro* evaluation of antigenuria in patients with Histoplasmosis. It is a solid phase, sandwich Enzyme Linked-Immuno-Sorbent Assay (ELISA). The test is used for the qualitative detection of Histoplasmosis polysaccharide antigens (HPA) in the urine of patients infected with *Histoplasma capsulatum*.



SERVICES

The Niche Diagnostics clinical laboratory provides specialty services in a fully licensed, CLIA approved facility in Scarborough, Maine. Our staff has many years' experience in providing quality testing results for our clients.

We are pleased to offer the Histoplasmosis Urinary Antigen (EIA) as the first test in a line of fungal tests currently under development. Two monoclonal antibodies specific for HPA that are used in this test were developed using a proprietary screening assay with patient urines.

Our goal is to continue to offer improved test results while also developing new reagents and assays for unmet diagnostic opportunities. Niche Diagnostics' exceptional combination of assay development skills coupled with rapid laboratory testing services offer a unique diagnostic testing opportunity for health care professionals and clinical testing facilities who seek to offer improved disease detection to their clients and patients.

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