



CLINICAL DIAGNOSIS

Why Should I Send My Fungal Tests to MiraVista Diagnostics?

Reliable Results = Confident Decision Making = Better Patient Outcome

As a clinician or laboratory director, you expect accurate and timely results when you submit a diagnostic test. The cost of a mistaken diagnosis, both monetarily and in patient suffering, outweighs the marginal difference in expense of the lowest priced versus highest priced diagnostic test. The outcome of a missed diagnosis is serious and can be life-threatening if advanced disease is suspected. Although this summary will only scratch-the-surface, some notable examples described below may help you make this decision.

Innovative Rapid and Reliable Diagnostic Tests

Many of the tests offered by MiraVista Diagnostics (MVD) were developed by MVD scientists and are only available from MVD. Each test development requires months of laboratory work to exceed the strict validation requirements set forth by CLIA (Clinical Laboratory Improvement Amendments), CAP (College of American Pathology), and other certifying programs.

Rapid results are essential to prompt decisions affecting treatment. We perform our antigen test 6 days per week, twice daily Tuesday through Friday and once on Monday and Saturday. Results are reported the same day we receive the specimen in 90% of cases, by the next day in 95%, and by the third day in 99% of cases. Turnaround time is longer if the specimen is routed through another laboratory. If you need results, you can contact Laboratory Support (labsupport@miravistalabs.com).

To expedite receipt of positive results above a certain threshold, 4.0 ng/mL for *Histoplasma* antigen for example, we report them the same day if they are received before 10-11 AM ET. To assure accuracy, positive results are repeated the next shift or day, and if the subsequent test does not repeat as positive and within 25% of the initial result, the submitting laboratory is contacted to inform them that a

third test will be conducted and the reported results will be amended if the difference is more than 25%. If the specimen was positive but below 4.0 ng/mL, the test is repeated before reporting, delaying the result by up to one day. Upon request of the laboratory, we may do an additional test.

Ensuring a test is clinically useful is also vital. MVD believes that clinical validation is as important as analytical validation. The diagnostic performance of tests offered at MiraVista are investigated in clinical settings and commonly described in peer-reviewed publications. For example, the *Histoplasma* antigen test has been used in over 60 published, peer-reviewed studies. Many of these manuscripts are available on our website (<https://miravistalabs.com/>) and others may be obtained by contacting Dr. Wheat (jwheat@miravistalabs.com).

Continual Test Improvement

MVD scientists strive to make our tests the “gold standard”. We modified our *Histoplasma* Antigen EIA in 2021 to reduce turnaround time and eliminate the “below the limit of quantification-BLQ” category to assure outstanding performance. To satisfy the College of American Pathologists (CAP) requirements, analytical sensitivity, specificity, repeatability, reproducibility, robustness (storage stability, free-thaw effects) and test reagent stability were all investigated.

Highest Quality Control Practices

Reliable test results not only require a well-designed assay but also need highly trained people to perform them. All testing at MiraVista is conducted by Medical Laboratory Scientists who have a bachelor’s or master’s degree in science (Clinical Laboratory Science, Biology, Chemistry,

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Health Sciences) from an accredited institution. In addition, most laboratory personnel are certified by the ASCP (American Society for Clinical Pathology) as Medical Laboratory Scientists. Training often requires at least 1 month per test for each employee. Training includes “hands-on” practice and each scientist is only able to perform a test after demonstrating competency on blinded evaluation. Proficiency testing is also conducted at the laboratory level, as MVD undergoes semi-annual blinded third-party CAP proficiency testing. For analytes that are not available through a third-party program, internal testing is performed.

Expert Clinical Consultation and Laboratory Support

MiraVista has a team of infectious disease, diagnostic medicine, and laboratory scientists available to answer your questions. We are available by phone or email M – F (8 AM – 5 PM, EST). **We want to hear your concerns and suggestions for how to better meet your needs.**

Contact Information

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Laboratory Support Needs

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