
EXPERIENCE WITH PLATELIA ASPERGILLUS GALACTOMANNAN TESTING AT MIRAVISTA DIAGNOSTICS

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Invasive aspergillosis is a serious life-threatening infection resulting in 55-100% mortality in bone marrow and solid organ transplant recipients, in part because of delayed diagnosis. In 2003 the Platelia aspergillus galactomannan assay was FDA cleared for use in the US. To date, MiraVista Diagnostics has had the greatest experience with this kit since FDA approval. From July to December 2003, MiraVista performed 115 assays, testing 1018 unique samples; 132 of 1018 (13%) were positive. Of the positive samples, 42 (32%) were positive with results between 0.5 and 0.99, while 90 (68%) had results ≥ 1.0 . At MiraVista, while all positive results are verified by retesting the following day, negative results (<0.5) and high positives ≥ 1.0 are reported following initial testing to assure prompt availability to the ordering physician. Low positive results between 0.5 and 0.99 are reported after verification the next day. In support of our policy to report high positives on the initial day of testing, results ≥ 1.0 were reproducible in 73/76 (96%) cases, compared to 44/51 samples (86%) for low positives. The package insert suggests that all positive results should be verified by testing a second sample upon notification of the initial positive result. To date early follow up of positive results has occurred in $< 15\%$ of cases. Our experience also supports use of the in monitoring response to therapy. In conclusion the test has performed very well in clinical testing at a reference laboratory that specializes in rapid diagnosis of serious mycoses by antigen testing.