

DETECTION OF *ASPERGILLUS* GALACTOMANNAN ANTIGEN IN PEDIATRIC SERUM SAMPLES: A PERFORMANCE EVALUATION OF THE BIO-RAD PLATELIA™ *ASPERGILLUS* EIA

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Background: Invasive Aspergillosis (IA) is a life-threatening invasive fungal infection in severely immunocompromised pediatric patients. Establishing a definitive, early diagnosis can be difficult, as it requires invasive procedures; and the sensitivity of both microbiologic and histopathologic tests are often low. The Bio-Rad Laboratories Platelia™ *Aspergillus* EIA is a one-stage immunoenzymatic sandwich microplate assay that uses rat monoclonal antibody EBA-2 to detect circulating galactomannan (GM). We retrospectively evaluated the utility of the Platelia™ *Aspergillus* EIA for the detection of GM, using sera collected prospectively from immunocompromised pediatric patients with cancer, and pediatric recipients of hematopoietic stem cell transplants (HSCT) at high risk for IA. **Methods:** A total of 661 serum specimens, collected from 47 patients were analyzed. An investigator blinded to assay results used EORTC/IFICG and NIAID/MSG standardized criteria to define patients as having Proven (9 patients, 136 samples), Probable (5 patients, 31 samples), or no IA (33 control patients, 494 samples.) Serum samples were tested for GM with the Platelia™ EIA, utilizing the manufacturer's directions. Negative, positive, and 2 cut-off controls were run on each plate to validate the test results. A GM Index was calculated as the ratio of sample optical density relative to mean optical density of the 2 cut-off controls. **Results:** Utilizing a positive GM Index cut-off of ≥ 0.5 , 7 of 14 (50%) patients with either proven or probable IA were detected. Three of the seven patients in whom no GM antigen was detected had only specimens prior to IA diagnosis available for testing, and three had only 2 specimens available for testing. GM antigen was detected by Platelia™ *Aspergillus* EIA an average of 10.7 days prior to IA diagnosis using clinical criteria. Specificity was 98.4% (485/493 specimens) in the control population. **Conclusions:** Bio-Rad Platelia™ *Aspergillus* EIA demonstrated excellent specificity and the ability to significantly increase the speed with which some cases of IA are diagnosed. Sensitivity of 50% was lower than in previous studies possibly due to the inherent difficulty of specimen availability in a retrospective study, and to the concomitant use of multiple mold-active antifungal therapeutic agents.