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Presentation Title: M-1693 - **An Evaluation of Four Commercial Assays for the Detection of Cryptococcal Antigen**

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Abstract: Background: Cryptococcus continues to be a common opportunistic infection in immunocompromised patients with a reported mortality rate of approximately 12% in the United States and 50 to 70% in undeveloped countries. The laboratory diagnosis of Cryptococcus is made by isolating Cryptococcus spp. from clinical specimens or by serology. Cryptococcal antigen (CrAg) detection by latex agglutination using serum or cerebrospinal fluid (CSF) has been reported to have sensitivity as high as 99%. Methods: Prospective serum samples (n=632) submitted to our laboratory for routine CrAg testing by the Meridian Premier™ Cryptococcal EIA (Meridian Bioscience, Inc., Cincinnati, Ohio) were tested in parallel by the IMMY CrAg Lateral Flow Assay (LFA) (Immuno-Mycologics, Inc., Norman, OK), the IMMY ALPHA CrAg EIA, and the Meridian CrAg latex agglutination system (CALAS®). The results of latex agglutination were considered the reference standard and titers of ≥1:2 were considered positive. Positive samples were titered to an endpoint by the LFA and latex assays. Specimens showing discordant results after initial testing were repeated by all methods. Results: Following repeat testing, the Meridian EIA, IMMY LFA and IMMY EIA demonstrated agreements of 99.4% (628/632), 99.8% (631/632) and 99.7% (630/632), respectively. Compared to latex agglutination, the sensitivity and specificity of the assays was determined to be 42.9%/100%, 100%/99.8% and 100%/99.7%, respectively. Interestingly, there were 4 sera that were negative by the Meridian EIA but positive by the three other assays. Furthermore, one sample was positive by both the IMMY EIA and LFA assays, borderline reactive by the Meridian latex agglutination test, and negative by the Meridian EIA. Conclusions: These findings suggest that, compared to latex agglutination, the IMMY EIA and LFA assays are more sensitive than the Meridian EIA (100% versus 42.9%). The IMMY LFA is rapid and technically easy to perform; however, results are subjective and are not directly interfaced to the laboratory information system (LIS). In contrast, the IMMY and Meridian EIAs offer an objective screening result, can be automated, and are interfaceable with the LIS.
Presentation Abstract