1458. A Multi-center Laboratory Investigation of Coccidioidomycosis Enzyme Immunoassay Reproducibility in Patients with Confirmed Disease and Controls

Soofia Khan, MD[1,2]; Rebecca Sunenshine, MD[3,4]; Michael A. Saubolle, PhD[5]; Kelly Barbian, MT[5]; Megan Eguchi, MPH[3]; Ahmed Mohammed, BVSc, MSc, PhD[3]; Orion Mccotter, MPH[1]; Ken Komatsu, MPH[1]; Benjamin Park, MD[6]; Michael V Lancaster, PhD[7]; [1]Arizona Department of Health Services, Phoenix, AZ; [2]University of Arizona College of Medicine, Phoenix, AZ; [3]Disease Control Division, Maricopa County Department of Public Health, Phoenix, AZ; [4]Ophpr, Centers for Disease Control and Prevention, Phoenix, AZ; [5]Laboratory Sciences of Arizona/Banner Health, Tempe, AZ; [6]Mycotic Diseases Branch, Centers for Disease Control and Prevention, Atlanta, GA; [7]Kern County Public Health Laboratory, Bakersfield, CA

Session: 192. Fungal Infections
Saturday, October 11, 2014: 12:30 PM

Background. Coccidioidomycosis or Valley Fever (VF) is a respiratory fungal infection endemic to the southwestern United States (US) with rising reported incidence rates over the last decade causing public health concern. Arizona VF surveillance is based predominantly on laboratory testing, including enzyme immunoassay (EIA), making VF EIA reproducibility and validity critical for determining disease burden. To evaluate the laboratory reproducibility of VF EIA results, we compared EIA IgM and IgG results from two different manufacturers [Immuno-Mycologics, Inc. – Premier *Coccidioides* EIA (Immy) and Meridian Biosciences, Inc. – *Coccidioides* Antibody EIA (Meridian)] using sera from the same patients divided among three laboratories.

Methods. Serum samples from 150 patients with laboratory (immunodiffusion and/or complement fixation) and clinical evidence of VF and 50 de-identified serum specimens (controls) from healthy individuals without travel to endemic areas, (presumed negative for VF), were blinded and distributed frozen to three laboratories after retrospective selection by the Kern County Department of Public Health. **Results** were analyzed for concordance and percent agreement as a primary outcome. EIA sensitivity and specificity were calculated as secondary outcomes.

Results. Percent agreement for EIA IgM and IgG combined among the three labs was 85.5% for Immy (90% for IgM and 89% for IgG) and 70.5% for Meridian (67% for IgM and 81%, for IgG alone). Of note, Meridian IgM EIA results were positive for 13 of 50 controls in one laboratory. Sensitivity for EIA IgM and IgG combined was 68.5% for Immy and 72.4% for Meridian; specificity was 99.3% for Immy and 91.3% for Meridian.

Conclusion. Percent agreement of EIA IgM and IgG among laboratories varies depending on the brand of EIA test kit used. One laboratory appears to have an increase in false positive EIA IgM results with the Meridian EIA test kit, which might explain reports of decreased specificity associated with the Meridian EIA IgM test kit described in the literature. Further studies looking at differences between laboratory methods for both test kits at different laboratories, including the wash step, are needed to determine the etiology of the discordant results.

Disclosures. **All authors:** No reported disclosures.