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Performance Characteristics of Diagnostic Assays for *Schistosoma* spp. from 2014 to 2017 in Ontario, Canada

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Background:

Differentiating between previous and current schistosomiasis infection in migrants and returned travelers often poses a diagnostic challenge. We evaluated the performance of real-time PCR assays compared to microscopy and serology for the diagnosis of schistosomiasis at our reference laboratory.

Methods: This study included all specimens submitted to our clinical reference laboratory for pan-*Schistosoma* serology and stool specimens for ova and parasite microscopy between April 1, 2014 and December 31, 2017. A random subset of 100 serum samples with corresponding stool sample submission were evaluated by real-time PCR assays for *Schistosoma mansoni* and *Schistosoma haematobium*.

Results: There were 8168 *Schistosoma* serology submission and 156, 771 stool specimens submitted to our reference laboratory during the inclusion period. Of the serum samples, 638 (7.8%) were serologically positive for pan-*Schistosoma*, 825 (10.1%) were indeterminate, and 6705 (82.1%) negatives. There were 46 stool samples from 29 patients positive for *S. mansoni*, and 1422 (17.4%) serology samples had a co-submission of stool sample within one year prior to or post-submission of serum samples. Using a composite reference standard of serology and stool microscopy, the combined PCR assays for *S. mansoni* had a sensitivity and specificity of 29.1% and 100% respectively with positive predictive value of 100% and negative predictive value of 27.3%. No *S. haematobium* was detected by PCR in the serum samples. There was no cross reactivity of the *S. mansoni* PCR assays to *S. haematobium*, *Plasmodium falciparum*, *Plasmodium vivax*, *Babesia*, or human DNA. Stool positivity was correlated to higher *Schistosoma* serology OD values with a mean of 1.80 (range 0.55-2.9) compared to 0.98 (range 0-3.78) in stool negatives ($p=0.0026$). Similarly, PCR positivity had higher serologic OD values with mean of 1.67 (range 0.65-2.9) compared to 0.90 (range 0-3.78) in PCR negatives ($p=0.0002$).

Conclusion:

We reiterate that serology is the most sensitive diagnostic test for schistosomiasis in our population. Serum PCR offered no greater performance than stool microscopy, however, its role in diagnostic parasitology should continue to be evaluated due to its high-throughput and operator-independent nature.