ASSESSMENT OF A NEW PARASITOLOGY SCREENING DIAGNOSTIC ELISA FOR THE DETECTION OF ANTIGENS OF GIARDIA SPP., CRYPTOSPORIDIUM SPP. AND ENTAMOEBA HISTOLYTICA IN FECAL SPECIMENS


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Study Focus and Goals:
- Evaluate the performance of a newly developed ELISA-type screen (The Tri-Combo parasite screen, TechLab®, Inc.) for the presence of Giardia spp., Cryptosporidium spp., and/or E. histolytica antigens in human stool samples under clinical laboratory conditions.
- The Tri-Combo parasite screen was compared to established ELISA-type tests on the market for the individual detection of Giardia spp., Cryptosporidium spp., or E. histolytica antigen in human stool samples.

Methods:
- A total of 618 clinical samples at three international sites:
  - 297 samples at the International Center for Diarrheal Disease Research, Dhaka, Bangladesh
  - 87 samples at the National Institutes of Infectious Disease, Tokyo, Japan
  - 234 samples at the Bernard Nocht Institute for Tropical Medicine, Hamburg, Germany

Results(1):
- All samples were run on the Tri-Combo test and the Giardia II, Cryptosporidium II, and E. histolytica II ELISA tests (TechLab®).
- Discrepant samples were re-run on the Tri-Combo and individual tests.

Results(2):
- Comparison of the TRI-COMBO parasite screen by study site:

<table>
<thead>
<tr>
<th>Study Site</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Positive Predictive Value (%)</th>
<th>Negative Predictive Value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tokyo, Japan</td>
<td>72.8</td>
<td>100</td>
<td>100</td>
<td>98.7</td>
</tr>
<tr>
<td>Dhaka, Bangladesh</td>
<td>100</td>
<td>94.25</td>
<td>92.48</td>
<td>100</td>
</tr>
<tr>
<td>Hamburg, Germany</td>
<td>94</td>
<td>90.6</td>
<td>94</td>
<td>98.4</td>
</tr>
<tr>
<td>Combined Positive</td>
<td>97.9</td>
<td>97.8</td>
<td>93.44</td>
<td>199.1</td>
</tr>
</tbody>
</table>

Results(3):
- Comparison of the TRI-COMBO parasite screen by organism:

<table>
<thead>
<tr>
<th>Reference ELISA</th>
<th>Test</th>
<th>No. of Specimens with result</th>
<th>Positive</th>
<th>True</th>
<th>False</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giardia</td>
<td>Positive</td>
<td>94</td>
<td>44</td>
<td>1</td>
<td>61</td>
<td>0</td>
</tr>
<tr>
<td>Cryptosporidium</td>
<td>Positive</td>
<td>47</td>
<td>42</td>
<td>5</td>
<td>1</td>
<td>413</td>
</tr>
<tr>
<td>E. histolytica</td>
<td>Positive</td>
<td>42</td>
<td>42</td>
<td>0</td>
<td>1</td>
<td>411</td>
</tr>
</tbody>
</table>

1False positive results from the entire panel of samples (a total of 13) were recorded as FP for all 3 parasites.

Conclusions:
- The Tri-Combo parasite screen effectively detected antigens from Giardia spp., Cryptosporidium spp., and E. histolytica parasites in clinical stool samples at three international sites as compared to three diagnostic tests specific for each individual organism.

References and Acknowledgments:
4. Nocht Institute for Tropical Medicine and Hygiene without benefit to Dr. Petri.
5. We thank TechLab®, Inc. for the contribution of the Tri-Combo parasite screen by organism.