Evaluation of the LEUKO EZ VUE™ for Measuring Fecal Lactoferrin as a Marker of Intestinal Inflammation

C. Pennington*, J. H. Boone and D. M. Lyerly, TECHLAB®, Inc., Blacksburg, VA 24060

Infectious diarrheal diseases represent one of the primary causes of morbidity throughout the world. Inflammatory infections like *C. difficile* disease often involve tissue damage and dissemination, requiring immediate medical attention. Noninflammatory cases, on the other hand, do not cause extensive mucosal damage and tend to be more self-limiting; although in some instances (e.g., giardiasis), treatment still is needed. The biomarker, fecal lactoferrin, is a stable glycoprotein that is expressed by neutrophils. During intestinal inflammation, the infiltration of leukocytes into the lumen increases levels of fecal lactoferrin over baseline. The aim of our study was to compare a new immunochromatographic assay (LEUKO EZ VUE™) for the detection of elevated fecal lactoferrin as an indicator of fecal leukocytes.

**METHODS**

In our study, we compared a new immunochromatographic test, LEUKO EZ VUE™, with the LEUKO-TEST, a latex agglutination test to measure elevated lactoferrin as a marker for fecal leukocytes and an indicator of intestinal inflammation. There were 234 fecal specimens submitted from patients suspected of intestinal diarrhea by immunoassay followed by resolution of discrepant results using microscopy for the presence of fecal leukocytes. Additional studies were done to assess stability of the marker, reproducibility of results and testing of potential interfering substances.

**RESULTS**

Table 1. Comparison of the LEUKO EZ VUE™ to the LEUKO-TEST

<table>
<thead>
<tr>
<th>N=234</th>
<th>LEUKO EZ VUE™ positive</th>
<th>LEUKO-TEST positive</th>
<th>LEUKO EZ VUE™ negative</th>
<th>LEUKO-TEST negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>43</td>
<td>35</td>
<td>3</td>
<td>153</td>
</tr>
</tbody>
</table>

A total of 234 fecal specimens submitted for fecal leukocyte testing were evaluated by the LEUKO EZ VUE™ and LEUKO-TEST assays. There were 28 specimens providing discrepant results that were further tested by microscopy.

Table 2. Comparison of the LEUKO EZ VUE™ to the LEUKO-TEST with resolution of discrepant results using microscopy for fecal leukocytes

<table>
<thead>
<tr>
<th>N=234</th>
<th>LEUKO EZ VUE™ positive</th>
<th>LEUKO-TEST positive</th>
<th>LEUKO EZ VUE™ negative</th>
<th>LEUKO-TEST negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>63</td>
<td>15</td>
<td>3</td>
<td>15</td>
</tr>
</tbody>
</table>

Of the 35 specimens that tested LEUKO EZ VUE™ positive and LEUKO-TEST negative, 28 were confirmed positive for fecal lactoferrin using microscopy. All 35 specimens showed a higher overall agreement when compared to the combined results generated by the LEUKO-TEST and microscopic examination. The majority of discrepant results were LEUKO-TEST negative and LEUKO EZ VUE™ positive that were confirmed positive by microscopy.

**CONCLUSIONS**

- The LEUKO EZ VUE™ is both highly sensitive and specific for elevated fecal lactoferrin as an indicator of intestinal inflammation.
- The 10-minute format allows for a rapid assessment for fecal leukocytes.
- Results are simple to interpret and reproducible.
- Lactoferrin is a stable biomarker for intestinal inflammation.
- The LEUKO EZ VUE™ outperformed the LEUKO-TEST and represents an improved assay for intestinal inflammation.

**REFERENCES CITED**


Email: cpennington@techlab.com