

K071712

**7.0 510(k) SUMMARY OF THE LEUKO EZ VUE™**

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DEC 04 2007

**Date Prepared** November 19, 2007

**Product and Trade Name** TECHLAB® LEUKO EZ VUE™

**Classification** Class I, 21 CFR 866.5570

**Predicate Devices**

- **TECHLAB® LEUKO-TEST (K931241/A1).** The *LEUKO-TEST* is a latex agglutination test for detecting elevated levels of fecal lactoferrin as a marker of fecal leukocytes and intestinal inflammation. The test is simple to use and rapid.
- **Methylene Blue stain and Gram stain along with microscopic observation.** This assay is exempt from 510(k), but serves as a predicate device because it was marketed prior to 1976 and continues to be legally marketed today. The procedure involves the staining of fecal smears from patients with diarrhea followed by microscopic observation for the presence of leukocytes. The analysis must be performed by qualified individuals who have experience in the microscopic identification of leukocytes in fecal specimens. In addition, the test must be performed as soon as possible after collection of the specimen because of the instability of fecal leukocytes.

**Intended Use**

The *LEUKO EZ VUE™* test is an immunochromatographic test for the qualitative detection of elevated levels of fecal lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The *LEUKO EZ VUE™* test detects lactoferrin in liquid, semi-solid, and solid fecal specimens. A positive test result indicates an increased level of fecal lactoferrin and warrants additional testing. **FOR IN VITRO DIAGNOSTIC USE.**

**Device Description**

The *LEUKO EZ VUE™* test is a 10 minute immunochromatographic device for the detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator

of intestinal inflammation. The test utilizes the same polyclonal antibodies against human lactoferrin as our previously cleared *LEUKO-TEST* assay. The polyclonal antibodies to human lactoferrin are immobilized on nitrocellulose and the conjugate consists of the same antibodies linked to colloidal gold particles. The membrane cassette contains two stripes of immobilized antibodies. One stripe contains anti-lactoferrin antibodies. The other, representing a control stripe, contains anti-IgG antibodies. The diluted sample and gold conjugate migrate by capillary action when the sample is added to the well. If elevated lactoferrin is present in the sample, gold conjugate-lactoferrin complexes form and are captured by the immobilized anti-lactoferrin antibodies in the stripe. The lactoferrin-conjugate-antibody complexes appear as a single red line in the test portion of the Results window. In the control stripe, conjugate binds to the immobilized anti-IgG antibodies, demonstrating correct migration of the sample and conjugate along the membrane. The conjugate-anti-IgG antibodies appear as a single red line in the control portion of the Results window.

#### Comparative information of equivalent devices

| Test   | Description  | Format  | Turn-around time | Limitations  |
|--|--|---|------------------|--|
| <i>LEUKO EZ VUE™</i>   | Intended for determining elevated levels of fecal lactoferrin as a marker for fecal leukocytes and an indicator of intestinal inflammation. A positive test result indicates an increased level of fecal <i>lactoferrin</i> and warrants additional testing. | Lateral flow  | 10 minutes       | Rapid test format as the <i>LEUKO-TEST</i> but overcomes inherent problems of latex agglutination, including difficult-to-read reactions |
| <i>LEUKO-TEST</i> (K931241/A1)                               | Intended for determining elevated levels of fecal lactoferrin as a marker for fecal leukocytes and an indicator of intestinal inflammation   | Latex agglutination                                     | 3 minutes        | Latex agglutination may give difficult-to-read reactions as well as other inherent problems  |
| Methylene Blue and Gram stain for observing fecal leukocytes | Intended for detecting fecal leukocytes in fecal smears  | Staining of fecal smears and examination for leukocytes | 30 to 60 minutes | Requires experience and test must be performed within minutes of collecting the fecal specimen due to instability of leukocytes          |

## Summary of Performance Data

TECHLAB<sup>®</sup>, Inc. has evaluated the *LEUKO EZ VUE™* test, which is a new lateral flow test for the detection of elevated levels of fecal lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The purpose of this study was to evaluate the performance of the *LEUKO EZ VUE™* test as an *in vitro* diagnostic aid to help identify patients with inflammatory diarrhea.

When comparing the *LEUKO EZ VUE™* to the *LEUKO-TEST* in clinical studies, the *LEUKO EZ VUE™* test had positive, negative, and overall agreements of 93%, 80%, and 83%, respectively. Individual results are shown in the table below.

| <i>LEUKO EZ VUE™</i> vs<br><i>LEUKO-TEST</i><br>(N=375) | <i>LEUKO-TEST</i><br>Positive | <i>LEUKO-TEST</i><br>Negative | Total |
|---|-------------------------------|-------------------------------|-------|
| <i>LEUKO EZ VUE™</i><br>Positive                        | 98                            | 55                            | 153   |
| <i>LEUKO EZ VUE™</i><br>Negative                        | 7                             | 215                           | 222   |
| Total   | 105                           | 270                           | 375   |

### 95% Confidence Intervals

|                            |     |          |
|----------------------------|-----|----------|
| Percent Positive Agreement | 93% | 86 – 97% |
| Percent Negative Agreement | 80% | 74 – 84% |
| Overall Percent Agreement  | 83% | 80 – 86% |

Additional studies including intra- and inter-assay variation showed the assay to be reproducible with all positive samples remaining positive and all negative samples remaining negative upon additional testing. Serial dilutions of highly purified human lactoferrin demonstrated acceptable assay sensitivity with a minimum detection limit  $\geq$  128 ng/mL.

The *LEUKO EZ VUE™* test is simple to perform, requiring minimal technical training. The procedure includes a single specimen dilution, the transfer of 4 drops of diluted specimen to the sample well of the membrane cassette and a visual reading following a 10-minute incubation.

Based on these findings, we believe the *LEUKO EZ VUE™* test is substantially equivalent to the *LEUKO TEST* now used to evaluate patients for elevated fecal leukocytes as an indicator of intestinal inflammation. Further, our results demonstrate that the *LEUKO EZ VUE™* test is suitable as an *in vitro* diagnostic aid to help identify patients with inflammatory diarrhea.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 04 2007

TECHLAB Inc.  
c/o Mr. Charles Pennington  
Director of Product Development  
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Re: k071712

Trade/Device Name: TECHLAB® *LEUKO EZ VUE*™  
Regulation Number: 21 CFR 866.5570  
Regulation Name: Lactoferrin, antigen, antiserum, control  
Regulatory Class: Class I  
Product Code: DEG  
Dated: November 19, 2007  
Received: November 21, 2007

Dear Mr. Pennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

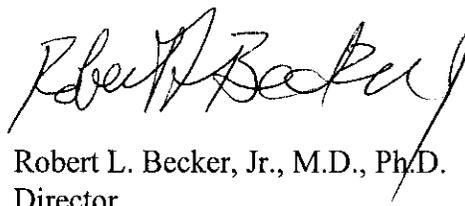
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

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FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", written in a cursive style.

Robert L. Becker, Jr., M.D., Ph.D.  
Director

Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

**2.0 STATEMENT OF INTENDED USE**

**Indications for Use**

510(k) Number (if known): K071712

Device Name: *LEUKO EZ VUE™*

The *LEUKO EZ VUE™* test is an immunochromatographic test for the qualitative detection of elevated levels of *fecal* lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The *LEUKO EZ VUE™* test detects lactoferrin in liquid, semi-solid, and solid fecal specimens. A positive test result indicates an increased level of fecal lactoferrin and warrants additional testing.  
FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

*Maria M Chan*  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K071712