

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K032862

B. Analyte:

Hemoglobin Fractions

C. Type of Test:

Qualitative, Hemoglobin Electrophoresis

D. Applicant:

InterLab Scientific Instruments, srl
Via Rina Monti NN 26 C.A.P. 00155
Rome, ITALY

E. Proprietary and Established Names:

InterLab Alkaline Electrophoresis Test System

F. Regulatory Information:

1. Regulation section:
21 CFR 864.7440
2. Classification:
Class II
3. Product Code:
JBD
4. Panel:
Hematology (81)

G. Intended Use:

1. Intended use:
The Interlab Alkaline hemoglobin Electrophoresis test system is intended for the separation of normal hemoglobins (A1, A2 and F) as well as certain abnormal or variant hemoglobins (S or D and C or E) using cellulose acetate supported on Mylar®. The test is a screening method for in vitro diagnostic use on the Microtech 672 PC and the Microtech 648 ISO fully automated analyzers. To distinguish hemoglobin S from D and C from E an alternate confirmatory test such as acid hemoglobin electrophoresis is necessary.

2. Indication for use:

The Interlab Alkaline hemoglobin Electrophoresis test system is intended for the separation of normal hemoglobins (A1, A2 and F) as well as certain abnormal or variant hemoglobins (S or D and C or E) using cellulose acetate supported on Mylar®. The test is a screening method for in vitro diagnostic use on the Microtech 672 PC and the Microtech 648 ISO fully automated analyzers. To distinguish hemoglobin S from D and C from E an alternate confirmatory test such as acid hemoglobin electrophoresis is necessary.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

The Cellulose Acetate supported on Mylar® strips are for use on the Microtech 672 PC and the Microtech 648 ISO instruments. These instruments employ the use of a robotic arm that moves the strip to the different stations. The instruments are offered as “open systems” and are considered Class I Exempt based on 21 CFR 862.2485, product code JJN.

H. Device Description:

The InterLab Alkaline Electrophoresis Test System provides identification of normal and certain abnormal and variant hemoglobins visually by staining of the separate fractions. The kit contains materials for 24 runs. There are two kits available (SRE205K and SRE157K) providing the ability to run 192 or 288 tests. Each kit contains the following: strips, running and soaking buffer, staining solution, destaining solution, and clearing solution. All reagents are ready to use.

I. Substantial Equivalence Information:

1. Predicate device name(s):

Sebia Hydragel 15 Hemoglobin

2. Predicate K number(s):

K991362

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>InterLab Alkaline Electrophoresis Test System</i>	<i>Hydragel 15 Hemoglobin</i>
Intended Use	Separation of normal hemoglobins as well as certain abnormal or variant hemoglobins.	Same
Method	Electrophoresis	Same
Sample	Hemolyzed separated red blood cells using distilled water	Hemolyzed separated red blood cells using hemolyzing solution
Sample application	Pipetting Station	Pipetting Station or manual
Results	Visual or relative percentages of fractions	Same
Normal Values	Hemoglobin A1: 95.5-98.5% Hemoglobin A2: 1.5-3.5% Hemoglobin F: <2.0%	Hemoglobin A1: $\geq 96.5\%$ Hemoglobin A2: $\leq 3.5\%$ Hemoglobin F: <2.0%
Differences		
Item	Device	Predicate
Support Medium	Cellulose Acetate on Mylar	Agarose Gel
Reagents	Running Buffer Staining Solution (Ponceau red) Destaining Solution Clearing Solution	Buffered Strips Amidoblack Stain Solution Hemolyzing Solution Destaining Solution Wash Solution Saline
Equipment	Microtech 684 ISO System Microtech 672 PC System	Hydrasys System Micropipettor

J. Standard/Guidance Document Referenced (if applicable):

EP5A *Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline*, NCCLS

K. Test Principle:

The principle of hemoglobin electrophoresis is based on the fact hemoglobin molecules in an alkaline solution have a net negative charge and move toward the anode in an electrophoretic system. The pattern of a normal adult displays predominantly Hemoglobin (Hb) A1, along with HbF, and HbA2, when the concentrations fall within normal ranges. The presence of abnormal bands is indicative of variant hemoglobins in the blood sample.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*Intra-assay

The intra-assay precision was measured using an abnormal control and three different patient samples run in replicate (4-6) on 8 cellulose acetate strips. The patterns were visually inspected and found to be qualitatively identical. Relative percentages of the fractions resulted in CV ranges from 0.9-3.98%.

Inter-assay

Inter-assay precision was measured using one abnormal control and three different patients run in replicates (4-6) on one cellulose acetate strip over ten days. The patterns were visually inspected and found qualitatively identical. Relative percentages of the fractions resulted in CV ranges from 1.58 – 5.34%

b. *Linearity/assay reportable range:*

An abnormal patient sample was serially diluted to 1:22.

Hemoglobin A1 and A2 were evaluated assess the lowest concentration that can be detected.

Linearity ranges for HbA2 in hemolyzed sample for both size kits were:

Microtech 672 PC .44-2.1 g/L

Microtech 548 ISO 0.5-1.7 g/L

c. *Traceability (controls, calibrators, or method):*

Not applicable

d. *Detection limit:*

The limit of detection was determined to be concentrations greater than 0.40 mg/ml with the exception of Hemoglobin S (HbS). The system will detect HbS concentrations greater than 0.47mg/ml.

e. *Analytical specificity:*

Ineffective centrifugation and/or RBC washing with saline solution will not yield a clear hemolysate. This may result in the presence of a red line at the application point, which is indicative of a poor quality electrophoretic patter. Frozen samples may produce an artifact band near HbA1. The point of sample application should not be visible in the pattern. If the application point is present as a line strongly stained, expect a smeared pattern, with poor resolution and substandard focusing of the bands. Deviation from the recommended test procedure may affect the results.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:*a. Method comparison with predicate device:*

A comparison study was performed using 93 samples from both normal and suspected pathological patients. The samples were run using both sample size kits. This study resulted in correlation coefficients greater than 0.99 and yielded a 100% agreement to the reference method for observed bands.

b. Matrix comparison:

Not Applicable

3. Clinical studies:*a. Clinical sensitivity:*

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a and b are not applicable):

Not Applicable

4. Clinical cut-off:

NA

5. Expected values/Reference range:

Reference Ranges

HbA1 96-98

HbA2 1.5-3.5

HbF ≤ 2

These ranges are based on ranges published in Clinical Laboratory Methods, John D. Bauer, MD (9th Edition, the C.V. Mosby Company (1982).

M. Conclusion:

Based on the review of the information provided, the InterLab Alkaline Electrophoresis Test System appears to be substantially equivalent (SE) to devices regulated under 21 CFR 864.7440, electrophoretic hemoglobin analysis system, product code JBD.