

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

A. 510(k) Number:

K050709

B. Purpose for Submission:

Seek clearance for a modification to a currently cleared device (K840011)

C. Measurand:

Normal and abnormal hemoglobin

D. Type of Test:

Semi-Quantitative isoelectric focusing assay

E. Applicant:

Wallac Oy

F. Proprietary and Established Names:

Resolve Hemoglobin Kit

JB-2 Staining System

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7415

2. Classification:

Class II

3. Product code:

GKA

4. Panel:

H. Intended Use:

1. Intended use(s):

The RESOLVE Systems Hemoglobin kit is designed to separate whole blood, cord blood or dried blood spot specimen for detection of normal and variant hemoglobins by isoelectric focusing.

2. Indication(s) for use:

The assay is intended for use as an aid in the diagnosis of neonatal and adult hemoglobinopathies.

3. Special conditions for use statement(s):

4. Special instrument requirements:

The kit is designed to be run on a flat-bed electrofocusing unit.

I. Device Description:

The RESOLVE Hemoglobin kit is available in 3 configurations (120 tests, 360 tests, 3600 tests). Each kit contains:

Component	135 Tests	360 tests	3600tests
Agarose IEF Gel	5	5	50
Anode Solution	30 ml	120 ml	480ml
Cathode Solution	30 ml	60 ml	240 ml
HB Elution Solution	30 ml	30 ml	240 ml
IEF Electrode Wicks	12	15	2 X 80
Blotting Papers	6	6	60
Blotting Strips	6	-	-
Sample Application Templates	5	Order separately	Order separately

J. Substantial Equivalence Information:

1. Predicate device name(s):

BioRad VARIANT Sickle Cell Short Program

BioRad Variant nbs Sickle Cell Program

2. Predicate 510(k) number(s):

K924813

K051072

3. Comparison with predicate:

Similarities			
Item	Device	VARIANT Sickle Cell Short Program	VARIANT nbs Sickle Cell Program
Intended Use	To separate whole blood, cord blood or dried blood spot specimen for detection of normal and variant hemoglobins	Qualitative screen for the presence of hemoglobin's F, A, S, D, C and E in eluates of neonatal blood collected on filter paper	Qualitative screen for the presence of hemoglobins F, A, S, D, C and E in eluates of neonatal blood collected on filter paper
Analytes identified	Hemoglobins F,A,E,D,S,C. In addition G and α - and β -thalassemia	Hemoglobins F,A,E,S,S and C	Hemoglobins F,A,E,D,S and C

Differences			
Item	Device	VARIANT Sickle Cell Short Program	VARIANT nbs Sickle Cell Program
Sample	Neonatal dried blood spots, whole blood and cord blood	Dried blood spots	Dried blood spots
Target Population	Neonates and adults	Neonates	Neonates

Differences			
Item	Device	VARIANT Sickle Cell Short Program	VARIANT nbs Sickle Cell Program
Principle	IEF	HPLC	HPLC

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

L. Test Principle:

Whole blood or cord blood, on a filter spot or collected into an EDTA or heparinized tube, is treated with a Hb Elution Solution to inhibit methemoglobin formation. The solution is then placed on an agarose gel containing RESOLVE Ampholytes pH 6-8, and the gel is placed on the electrofocusing unit.

When an electrical current is applied to the gel, the hemoglobin variants possessing individual isoelectric points (pI's), migrate through the gel. When an individual variant's pI equals the pH in the gel, it ceases migration and forms a discrete band. When all hemoglobin bands have focused, the gel is fixed in trichloroacetic acid.

Hemoglobin bands can be visualized by using the JB-2 Staining System. Stained or unstained gels can be scanned by a densitometer to estimate the percentages of normal and variant hemoglobins.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Variation was estimated by measuring the distance of certain Hb bands of FASC controls used in the comparison studies. The analysis of variance was used to calculate the following:

	n	Average distance (mm)	Within-gel precision (CV%)	Between-gel Precision (%CV)	Total precision Within laboratory (%CV)
HbA _{1c} vs. Hb C	216	17.8	2.2	1.8	2.8

Hb A vs. Hb F	223	2.1	3.3	2.9	4.4
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- b. *Linearity/assay reportable range:*
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
 - d. *Detection limit:*
 - e. *Analytical specificity:*
 - f. *Assay cut-off:*
2. Comparison studies:

- a. *Method comparison with predicate device:*

The RESOLVE Hemoglobin system was compared to HPLC. Samples included 60% from normal patients, 20% from hemoglobin combinations having Hb S and 20% from other hemoglobin variants to include Hb C, D, E, G-Philadelphia, α -thalassemia and β -thalassemia.

	n	HPLC	% Agreement	Lower 95% CI
Site 1	850	1	99.8	99.2
Site 2	837	2	97.7	96.7
Site 3	1031	1	99.1	98.4

- b. *Matrix comparison:*
3. Clinical studies:
- a. *Clinical Sensitivity:*

b. Clinical specificity:

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

4. Clinical cut-off:

5. Expected values/Reference range:

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.