510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

K182744

B. Purpose for Submission:

Clearance of control materials for the HemoCue Hb 301 System and HemoCue Hb 801 System

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative determination of hemoglobin

E. Applicant:

EUROTROL B.V.

F. Proprietary and Established Names:

HemoTrol WB - Low, HemoTrol WB - Normal, HemoTrol WB - High

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   GGM, Control, Hemoglobin

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   HemoTrol WB is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue Hb 301 and the HemoCue Hb 801 System. HemoTrol WB is intended for the quantitative determination of hemoglobin.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   HemoCue Hb 301 System and HemoCue Hb 801 System

I. Device Description:

HemoTrol WB is an assayed hemoglobin quality control material intended for professional use in the verification of the precision and accuracy of the HemoCue 301 and HemoCue 801 systems. HemoTrol WB contains bovine red blood cells with hemoglobin lysates in MetHb and additional stabilizers. For daily quality control, three physiologically relevant levels are available.

HemoTrol WB solutions are filled in reclosable plastic primary containers. Each bottle contains 1.1 g of HemoTrol WB solution. The primary containers are equipped with colored polypropylene caps. Cap color depends on the concentration of hemoglobin (Low: red cap; Normal: white cap; High: blue cap). Two bottles of the same level are placed in a plastic blister and packed in a product box together with the combined instructions for use (IFU) and value sheet. Both the primary containers and product box are labeled.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemoTrol WB - Low, HemoTrol WB - Normal, HemoTrol WB - High

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

   K964052

3. Comparison with predicate:

Similarities		
Item	Candidate HemoTrol WB - Low, HemoTrol WB - Normal, HemoTrol WB - High	Predicate Eurotrol HemoTrol K964052
Intended use	HemoTrol WB is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue Hb 301 and the HemoCue Hb 801 System. HemoTrol WB is intended for the quantitative determination of hemoglobin.	HemoCue HemoTrol is an assayed hematology control intended for use in the verification of the accuracy and precision of the HemoCue B-Hemoglobin and the HemoCue Hb 201 systems.
Analyte	Hemoglobin	Same
Fill volume	1 mL	Same
Number of Levels	3 levels: Low, Normal, High	Same
Open vial stability	31 days	Same
Primary Container	Reclosable plastic primary containers with polypropylene caps	Same
Procedure	Allow the vial to stand for 15 minutes at room temperature. Mix the vial before sampling. Do not fill the cuvette from the vial. Dispense a drop of the control material onto a hydrophobic surface. Fill the cuvette according to the manufacturer's instructions. Wipe any excess material from the vial and the cap with a clean tissue. Recap the vial tightly.	Same
Secondary Packaging	Two bottles of the same level are placed in a plastic blister and packed in a product box together with the combined instructions for use (IFU) and value sheet.	Same
Storage temperature	2–8˚C	Same
Where used	Point of care (POC) sites and clinical laboratory	Same

Differences		
Item	Device HemoTrol WB - Low, HemoTrol WB - Normal, HemoTrol WB - High	Predicate Eurotrol HemoTrol K964052
Analyte Concentration Range	95–160 g/L	80–160 g/L
Contents	Contains purified bovine red blood cells with hemoglobin lysate and preservatives	Contains purified bovine hemoglobin lysate but not stabilized bovine red blood cells or preservatives
Target analyzer	HemoCue Hb 301 System and HemoCue Hb 801 System	HemoCure B-Hemoglobin and HemoCue Hb 201 systems
Operations	The absorbance is measured by using a dual wavelength spectrophotometric technology. Measurements are performed at 506 nm and 880 nm.	The absorbance is measured by using a dual wavelength spectrophotometric technology. Measurements are performed at 570 nm and 880 nm.

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

- CLSI EP05-A3; Evaluation of Precision Performance of Qualitative Measurement Methods; Approved Guideline - Third Edition.
- CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

L. Test Principle:

The absorbance of hemoglobin in the control materials is measured by using a dual wavelength (506 nm and 880 nm) spectrophotometric technology in the HemoCue Hb 301 and HemoCue Hb 801 Systems.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   One lot of control material at three hemoglobin levels was tested on both analyzers - HemoCue Hb 301 System and HemoCue Hb 801 System. The samples were tested with five replicates per analyzer per day over five operating days. Total precision was within the defined acceptance criteria.

HemoCue Hb 301 System:

Hemoglobin level	Mean (g/L)	SD (g/L)	%CV
Low	103.20	1.13	1.10
Normal	139.90	1.57	1.12
High	171.90	1.90	1.10

HemoCue Hb 801 System:

Hemoglobin level	Mean (g/L)	SD (g/L)	%CV
Low	96.40	0.81	0.84
Normal	132.60	0.89	0.67
High	163.50	0.72	0.44

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Stability- Shelf Life

Shelf life stability at 2–8˚C was assessed using control materials of three hemoglobin levels. Three lots of each hemoglobin level were tested with 3–6 replicates per lot per time point. Eight time points between 0 to 127 days were tested on both analyzers - HemoCue Hb 301 System and HemoCue Hb 801 System. Shipping conditions with temperature ranges of either 22–30˚C or -10–3˚C were applied on Day 7–14. The study data supported the recommended stability claim of 108 days at 2–8˚C.

In-use stability

In-use stability at 2–8˚C was assessed using control materials of three hemoglobin levels. Five time points (0, 14, 21, 28, and 35 days) were tested on both analyzers - HemoCue Hb 301 System and HemoCue Hb 801 System. Each hemoglobin level was tested with 2–4 replicates per lot per time point. The study data supported the recommended stability claim of 31 days at 2–8˚C.

Expected Values

Three physiologically relevant levels are available:

HemoTrol WB Level	Target Total Hemoglobin (g/L)
Low	95
Normal	130
High	160

Value Assignment

Value assignment is performed for each new lot of HemoTrol WB. Three samples of control materials were evaluated on three HemoCue Hb 801 Systems, with three lots of microcuvettes. Each sample is measured once per microcuvette lot per analyzer, providing 27 replicates. If the 27 measurements are within the acceptance criteria (4% for Normal and 7% for Low and High), a value range is assigned to the lot as the mean value of these 27 measurements with ±4% for Normal and ±7% for Low and High.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

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:

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809.

O. Conclusion:

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