

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

A. 510(k) Number:

k150226

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for blood gases

D. Type of Test:

Not Applicable

E. Applicant:

Radiometer Medical ApS

F. Proprietary and Established Names:

Hematocrit and Metabolite QUALICHECK

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJS

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use

2. Indication(s) for use:

This Hematocrit and Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are: cGlucose, cLactate, Hct

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Not applicable

I. Device Description:

The Hematocrit and Metabolite QUALICHECK is a two-level quality control system, which can be used for quality control of the ABL77, ABL555, ABL 605/615/625, ABL 80 FLEX, ABL 80 Basic, and EML 105. The system consists of 30 ampoules per box. Each ampoule contains 2 mL of solution. Two levels of different concentrations of analytes for glucose, lactate, and hematocrit are provided. The quality control is an aqueous solution containing an organic buffer, acid salts, metabolites, and a preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Radiometer QUALICHECK5+

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

k980135

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device
	Radiometer Hematocrit and Metabolite QUALICHECK (Candidate Device)	Radiometer QUALICHECK5+ k980135 (Predicate Device)
Intended Use	The Hematocrit and Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.	Same
Form	Liquid	Same
Matrix	Aqueous solution	Same

Differences		
Item	Candidate Device	Predicate Device
	Radiometer Hematocrit and Metabolite QUALICHECK (Candidate Device)	Radiometer QUALICHECK5+ k980135 (Predicate Device)
Analytes	cGlucose, cLactate, Hct	pH, pCO ₂ , pO ₂ , cNa ⁺ , cK ⁺ , cCa ²⁺ , cCl ⁻ , cGlucose, cLatate, ctHb, sO ₂ , FO2Hb, FCOHb, FMetHb, FHbF, ctBil
Storage	2 °C to 25 °C for 2 years	2 °C to 25 °C until expiration date including up to 15 days at up to 32 °C
Levels	Two levels	Four levels

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

None was referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability:

The materials are traceable to the following standard materials:

Analyte	Unit	Traceable to
cGlucose	mmol/L	NIST Standard Reference Material (SRM) 917b
cLactate	mmol/L	L-Lactic Acid Lithium Salt (commercial source)
Hematocrit (Hct)	g/dL	Conductivity

Stability:

The shelf-life stability (real time testing) was conducted with three lots of Hematocrit and Metabolite QUALICHECK Level 1 and 2 at 32 °C for 3 months followed by 25 °C for a total of 25 months. Multiple time points were tested, with six replicates at each test point. The real-time stability study protocol and acceptance criteria have been reviewed and found to be adequate. The data indicated that the control solutions are stable for 24 months at 2 – 25 °C. There is no open-vial (in use) stability claim since the controls can only be used once. The contents should be used immediately after opening.

Expected Values/Value assignment

Assigned values and control ranges are established based on the true values and pre-determined specifications according to the internal procedure. The sponsor provided assigned values and control ranges for each analyte on each of the 3 different analyzers. To determine the assigned values and control ranges for the Hematocrit and Metabolite QUALICHECK, six trays of 1000 ampoules are sampled randomly from the Hematocrit and Metabolite QUALICHECK batch. Five ampoules are sampled from each of the 6 trays and 30 ampoules are sampled from the reference batch. The samples are conditioned and shaken at 25 °C in a water bath for 6 hours. Measurements of each parameter is performed alternately on the reference ampoules and the sample ampoules and repeated 5 times on one analyzer platform.

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:

Expected values for the representative analyzers are provided in the labeling for each specific lot. The labeling indicates each laboratory should establish its own acceptable ranges and use those provided only as a guide.

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.