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

A. 510(k) Number:

k130415

B. Purpose for Submission:

New device

C. Measurand:

Quality control material

D. Type of Test:

Not applicable

E. Applicant:

Radiometer Medical ApS

F. Proprietary and Established Names:

High Metabolite QUALICHECK

G. Regulatory Information:

1. Regulation section:

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

2. Classification:

   Class I, reserved

3. Product code:

   JJS, Controls for Blood Gases

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for use below.

2. Indication(s) for use:

   This High 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: pO2, ctHb, cGlucose and cLactate

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not applicable

I. Device Description:

The High Metabolite QUALICHECK is a single level quality control system consisting of thirty ampoules per box (each ampoule contains 2mL of solution). The quality control solution is an aqueous solution containing a biological buffer, salts, metabolites, and a preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   QUALICHECK5+

2. Predicate 510(k) number(s):
   k980135

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device
Indication for Use	This High 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
Base matrix	Aqueous solution	Same
Blood Gas Measurement	*p*O_2	Same
Oximetry Measurement	*c*tHb	Same
Metabolite Measurement	*c*Glucose, *c*Lactate	Same

Differences		
Item	Candidate Device	Predicate Device
Storage	2°C to 8°C until expiration date	2°C to 25°C until expiration date, including up to a total of 15 days at 32°C
Open Vial Claim	High Metabolite QUALICHECK solutions are light and heat sensitive. Avoid storage in direct sunlight. Use immediately after opening the ampoule	Ampoules should be conditioned for at least five hours at a constant temperature between 18 °C and 32 °C before use. To maintain the reliability of the blood gas parameters, you must use the contents of the ampoule immediately after opening and according to the instructions in the operator's manual for the relevant analyzer.
Preservatives	Germall II, Kathon	ProClin 950
Levels	One level	Four levels

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

Not applicable

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:

Parameter	Unit	Traceable to
pO_2	mmHg	NIST Standard Reference Material (SRM) gas 2658a and NIST 2659a
*c*Glucose	mmol/L (37°C)	NIST Standard Reference Material (SRM) 917b
*c*Lactate	mmol/L (37°C)	L-Lactic Acid Lithium Salt. SIGMA L2250
*ct*Hb	g/dL	NIST SRM (absorbance, wavelength). Hemoglobin-cyanide standard. J.T. Baker (Product No. 3061)

Stability

Shelf life study was conducted on one lot of High Metabolite QUALICHECK at temperatures: 32°C for 12 days followed by 8°C for a total of 25 months. Six replicates at each test point (0, 3, 6, 9, 12, 18, and 25 months) were tested by measurements on an ABL725. To prevent carryover, an additional rinse was performed between each measurement. Real-time stability study protocols and acceptance criteria have been reviewed and found to be adequate. The data indicated that the control solutions are stable for 2 years at 2-8°C. There is no open-vial (in-use) stability claim since the control can be used only once. The contents should be used immediately after opening.

Expected Values/Value assignment

The sponsor provided assigned values and control ranges for each analyte on each of

6 different analyzers. To determine the assigned values and control ranges for the High Metabolite QUALICHECK, six (6) trays of 1000 ampoules are sampled randomly from the High Metabolite QUALICHECK batch. Twelve ampoules are sampled from each of the trays and 72 ampoules are sampled from each batch. The samples were conditioned and shaken at 25°C in a water bath for 6 hours. Measurements are performed on a minimum of 3 validated ABL7xx devices with data collection. Measurement of each parameter is performed alternately on the reference ampoule and the sample ampoule and repeated 12 times on each ABL-7xx for a total of 144 measurements. Target ranges are calculated based on the mean ±2SD.

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:

   A representative target value for the control solution is provided in the labeling.

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.