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

A. 510(k) Number:

k130236

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:

Range+ QUALICHECK, Level 1

Range+ QUALICHECK, Level 2

Range+ QUALICHECK, Level 3

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, Controls for Blood-Gases

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for use.

2. Indication(s) for use:

   For In Vitro Diagnostic Use. This Range+ 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: pH, pCO2, pO2, ctHb, sO2, FO2Hb, FCOHb, FMetHb, FHbF , cK+, cNa+, cCa2+, cCl–, cGlu, cLac, ctBil

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not applicable

I. Device Description:

The Range+ QUALICHECK is an assayed quality control system, which can be used for quality control of the ABL700 Series, ABL800/8x7, ABL77, ABL80 and ABL90 analyzers from Radiometer. The Range+ QUALICHECK is a three level quality control system. Each level consists of 30 2mL ampoules of solution per box. The quality control solution is an aqueous solution containing a biological buffer, salts, glucose, lactate, dyes and a preservative, and it is equilibrated with carbon dioxide and oxygen. Range + QUALICHECK measures the following parameters: pH, *p*CO2, *p*O2, *c*tHb, *s*O2, *F*O2Hb, *F*COHb, *F*MetHb, *F*HbF , *c*K+, *c*Na+, *c*Ca2+, *c*Cl–, *c*Glu, *c*Lac, *c*tBil.

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
Indications for Use	For In Vitro Diagnostic Use. It is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.	Same
Matrix	Aqueous solution	Same
Blood gas measurement	pH, pO_2, pCO_2	Same
Oximetry Measurement	ctHb, sO_2, FO_2Hb, $FCOHb$, $FMetHb$	Same
Electrolyte Measurement	cK^+, cNa^+, cCa^{2+}, cCl^-	Same
Metabolite Measurement	*c*Glucose, *c*Lactate	Same
Hemoglobin Measurement	ctBil	Same
Compatible analyzers	•ABL700/705/710/715/720/725/730/735 • ABL805/810/815/820/825/830/835 • ABL80 - OSM SW • ABL90 FLEX	Same

Differences		
Item	Candidate Device	Predicate Device
Storage	2°C to 8°C until expiration date 5 hours between 18-32°C	2°C to 25°C until expiration date, including up to a total of 15 days at up to 32°C
Oximetry Measurement	*F*Hbf in Level 1	*F*Hbf in all four levels
Levels	Three levels	Four levels

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

None

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
pH	-	The IUPAC pH scale. Primary pH standards are certified by the Danish Primary Laboratory for Electrochemistry (DPLEC) at the Danish Institute of Fundamental Metrology (DFM) under DANAK accreditation no. 255. The system is validated by comparison with SRM produced by National Institute of Standards and Technology (NIST)
pCO_2	mmHg	NIST Standard Reference Material (SRM) gas 1674b and SRM 2625a
pO_2	mmHg	NIST Standard Reference Material (SRM) gas 2658a and NIST 2659a
cK^+	mmol/L (37°C)	NIST Standard Reference Material (SRM) 999b
cNa^+	mmol/L (37°C)	NIST Standard Reference Material (SRM) 919b
cCa^{2+}	mmol/L (37°C)	NIST Standard Reference Material (SRM) 915
cCl^-	mmol/L (37°C)	NIST Standard Reference Material (SRM) 999b
*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)
sO_2	%	NIST SRM (absorbance, wavelength). NIST SRM gas, whole blood, pH=7.4, ctHb=15 g%, sO2=100%

Stability:

Shelf-life characteristics for the Range+ QUALICHECK control solutions were determined using three different lots of each level at 32°C for 10 days followed by 8°C for 36 months. The products were placed at 32°C for 10 days to assess the potential short term temperature deviations during transportation and handling. Shelf-life and in-use stability was tested by measurements on 2 ABL735 analyzers, 6 replicates at each time point (0, 12, 25, and 36 months). Protocols and acceptance criteria have been reviewed and found to be adequate.

The control solutions are stable for 2 years at 2-8°C.

In-use Stability: Ampoules should be conditioned for at least 5 hours at a constant temperature between 18°C-32°C before use. The contents should be used immediately after opening.

Value Assignment

The sponsor provided assigned values and control ranges for each level. To determine the assigned values and control ranges for Range+ QUALICHECK, six (6) trays of 1000 ampoules are sampled randomly from the Range+ QUALICHECK batch. Twelve ampoules are sampled from each of the trays and 72 ampoules are sampled from the reference batch. The samples are conditioned and shaken at 25°C in a water bath for 6 hours. Measurements are performed on a minimum of 3 validated ABL7xx series 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 ABL7xx 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:

Representative target values for the control solutions have been 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.