

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

A. 510(k) Number:

k051928

B. Purpose for Submission:

New device (control)

C. Measurand:

Control for pH/Blood gases, co-oximetry, electrolytes, glucose, lactate and creatinine

D. Type of Test:

Control material

E. Applicant:

Radiometer Medical ApS

F. Proprietary and Established Names:

AutoCheck6+

G. Regulatory Information:

1. Regulation section:

21 CFR Section 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJY, control, Multi-analyte mixture

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

The AutoCheck6+ is a liquid four ampoule quality control system for checking the precision and accuracy of Radiometer Medical ApS analyzers for pH/Blood gases, co-oximetry, electrolytes, bilirubin, glucose, lactate, and creatinine.

2. Indication(s) for use:

The AutoCheck6+ is a liquid four ampoule quality control system for checking the precision and accuracy of Radiometer Medical ApS analyzers for pH/Blood gases, co-oximetry, electrolytes, bilirubin, glucose, lactate, and creatinine.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with Radiometer analyzers

I. Device Description:

The AutoCheck6+ quality control system includes control material at four different levels (Levels 1-4). The controls are aqueous and consist of a buffer with salts, metabolites, enzymes, dyes and preservatives, equilibrated with carbon dioxide and oxygen. The controls do not contain any animal or biological components.

The controls are supplied in 0.7 mL ampoules, 30 ampoules per box of each control level. The ampoules are used only once after being opened.

J. Substantial Equivalence Information:

1. Predicate device name(s):

AutoCheck5+

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

k992859

3. Comparison with predicate:

Similarities		
Item	AutoCheck6+	AutoCheck5+
Intended use	same	For use in checking the precision and accuracy of Radiometer analyzers.
Format	same	Liquid control contained in ampoules.

Differences		
Item	Device	Predicate
Test parameters	pH, pCO ₂ , pO ₂ , ctHb, sO ₂ , FO ₂ Hb, FCOHb, FMetHb, FHbF, cK ⁺ , cNa ⁺ , cCa ²⁺ , cCl ⁻ , cGlu, cLac, ctBil and the addition of cCrea (creatinine)	pH, pCO ₂ , pO ₂ , ctHb, sO ₂ , FO ₂ Hb, FCOHb, FMetHb, FHbF, cK ⁺ , cNa ⁺ , cCa ²⁺ , cCl ⁻ , cGlu, cLac, ctBil

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

N/A

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

N/A

b. Linearity/assay reportable range:

N/A

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

Traceability: The different parameters contained within AutoCheck6+ are traceable to various chemistry standards, with most parameters traceable to a NIST SRM. A Certificate of Traceability was provided for each level of control. The added parameter, creatinine, is traceable to NIST SRM 914.

The control ranges are determined by using an established protocol that includes performing runs on six different analyzers and with several different operators over a number of days. The final ranges for each level of the control are lot specific and found on the Control Ranges data sheets provided with the product. Additionally, the controls can only be used on the Radiometer analyzers listed on the data sheets.

Stability: The stability of the closed ampoules was established using both real-time and accelerated stability studies. Only closed container stability was performed since the control is used only one time after the ampoule is opened. Since the stability in the labeling is stated to be 24 months at 2-8°C, 4 weeks at up to 25°C, or 15 days for up to 32°C, several different stability studies are performed. These included storage at 6°C, 10°C, and 25°C for 103 weeks as well as storage at 32°C and 40°C for 39 weeks and 26 weeks respectively. Upon testing at the various time points, the measured results must fall within the preset acceptable performance limits for each parameter.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

N/A

b. *Clinical specificity:*

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

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 substantial equivalence decision.