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

A. 510(k) Number:

K050423

B. Purpose for Submission: Notification of intent to manufacture and market the device: The Omni Analyzers (OMNI Modular, Omni C, and Omni S) for use in the measurement of pleural fluid pH

C. Measurand:

Pleural Fluid

D. Type of Test:

Ion Selective Electrode

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Proprietary Name: Roche Diagnostics pH electrode on the OMNI Modular, C, and S Analyzers.

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1120

2. Classification:

   Class II

3. Product code:

   CHL

4. Panel:

75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indication for below.

2. Indication(s) for use:

   Pleural Fluid

   The Omni (Modular, C, and S) can be used for the measurement of pH in pleural fluid, as long as care is taken to ensure that the specimen to be analyzed is clear of fibrin clots or other debris which may block the sample transport system.

   The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with paraneumonic effusions.

   Critical Values:

   pH>7.3 is measured in uncomplicated paraneumonic effusions. All pleural effusions with a pH of <7.3 are referred as complicated paraneumonic effusions; they are exudative in nature.

3. Special conditions for use statement(s):

   Pleural fluid pH on the Roche Omni (Modular, C, and S) is to be used only in the pH range of 7.0 – 7.5

4. Special instrument requirements:

   For professional use only.

I. Device Description:

The Omni (Modular, C, and S) pH electrode uses the Sorensen 1909 principle which is based on the measurement of hydrogen ion (H^+) concentration. The electrodes consist of a special H^+ glass membrane and an accompanying Ag/AgCL reference electrode. The pH electrode is a component of an array of Ion Selective electrodes used to measure specific ions in the blood.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AVL model 995-Hb pH/blood gas analyzer and the CIBA-Corning Model 288 blood gas analyzer.

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

   k895317, k872888

3. Comparison with predicate:

Feature/Claim	Omni Analyzers (Modular, C and S)	AVL Model 995-Hb	CIBA-Corning Model 288
Ph Measuring principle	Omni (Modular, C, and S) pH electrode uses the Sorensen 1909 principle which is based on the measurement of hydrogen ion (H^+) concentration.	SAME	SAME
Electrode Membrane	H^+ sensitive glass membrane	SAME	SAME
Reference Electrode	Ag/AgCl	Colomel	Ag/AgCl
Concentration of the KCL Reference Solution	1.2M	0.6M	4M

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

No guidcance or standard document referenced

L. Test Principle:

Ion Selective Electrode (ISE)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision/Reproducibility was established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Precision/Reproducibility of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

b. Linearity/assay reportable range:

Linearity/assay reportable range was established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Linearity/assay reportable range of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

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

Traceability, Stability, and Expected values (controls, calibrators, or methods) were established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Traceability, Stability, and Expected values (controls, calibrators, or methods) of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in

section P. - Other Supportive Device and Instrument Information.

d. *Detection limit:*

Detection limit was established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Detection limit of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

e. *Analytical specificity:*

Analytical specificity was established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Analytical specificity of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

f. *Assay cut-off:*

Assay cut-off was established in the initial submission of the OMNI Modular Analyzer (k990092), the OMNI C Analyzer (k013373) and the Omni S Analyzer (k032311) on whole blood.

Further studies of the Assay cut-off of pleural fluid pH were researched in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

2. <u>Comparison studies:</u>

a. *Method comparison with predicate device:*

Roche Diagnostics used regression analysis to determine the appropriate range for pleural fluid. The defined specification was a difference of no more than 0.7 pH units. 35 samples were used in the regression analysis. The correlation coefficient between the OMNI and

Roche 995 results was 0.998. The r-square for the linear model was 0.995.

N=35
Y=0.896x + 0.8
Correlation 0.998

Values below 7.0 can be expected to show differences greater than 0.7 variation establishing the functional range of pleural pH as 7.0 – 7.5

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:

Studies of the Expected values/Reference range of pleural fluid pH were researched and have been established in literature on the predicate device. These findings are referenced in section P. - Other Supportive Device and Instrument Information.

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.

P. Other Supportive Device and Instrument Information:

Is pH paper an acceptable, low-cost alternative to the blood gas analyzer for determining pleural fluid pH? Lesho EP, Roth BJ. Chest 1997; 112:1291 – 1292

Comparison of Pleural Fluid pH Values Obtained Using Blood Gas Machine, pH Meter, and pH Indicator Strip. Cheng DS, Rodriguez RM, Rogers J, Wagster M, Starnes DL, Light RW. Chest 1998; 114:1368 – 1372.

Comparison of the Use of Accuracy of Methods for Determining Pleural Fluid pH. Chandler TM, McCoskey EH, Byrd RP, Roy TM. Southern Medical Journal, February 1999; Volume 92, No. 2, pages 214 – 217.

Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Thomas L. 1st Ed. (TH-Books, English Edition 1998) p. 1363