

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

A. 510(k) Number:

k051447

B. Purpose for Submission:

New device

C. Measurand:

Pancreatic Amylase

D. Type of Test:

Quantitative, Enzymatic, Colorimetric

E. Applicant:

Sentinel CH. S.r.l.

F. Proprietary and Established Names:

Pancreatic Amylase

G. Regulatory Information:

1. Regulation section:

21CFR §862.1070

2. Classification:

Class II

3. Product code:

JFJ Catalytic Methods, Amylase

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Sentinel Pancreatic Amylase test is used for the quantitation of pancreatic amylase levels in human serum or plasma. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). For *In Vitro* use only.

3. Special conditions for use statement(s):

For Prescription use only

4. Special instrument requirements:

Abbott Aeroset and Abbott Architect c8000 Systems

I. Device Description:

The Sentinel Pancreatic Amylase reagent is used for the quantitative analysis of pancreatic amylase in serum and plasma on the Abbott Aeroset and Abbott Architect c8000 systems. Two ready-to-use, liquid reagents are supplied with the kit.

Reagent 1: 2X40 mL HEPES* buffer 52.5 mmol/L (pH 7.15), sodium chloride 87 mmol/L, magnesium chloride 12.6 mmol/L, α -glucosidase ≥ 4 kU/L, mouse antibodies to salivary α -amylase ≥ 30 mg/L, and sodium azide $<0.1\%$

Reagent 2: 2X11 mL HEPES* buffer 52.5 mmol/L (pH 7.15), 4, 6-ethylidene-G7pNP ≥ 4 mmol/L, sodium azide $<0.1\%$

*HEPES: 2-[4-(2-hydroxyethyl)-1-piperazinyl]-ethane sulfonic acid.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Pancreatic Amylase on the Hitachi 911 Analyzer

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

k895880

3. Comparison with the predicate:

Similarities		
Characteristic	Device	Predicate
Intended Use	Quantitative determination of alpha-amylase in serum and plasma	Quantitative determination of alpha-amylase in serum, plasma and urine
Measurement method	Colorimetric, enzyme-based	Same
Analytical Range	1-2200 U/L	3-1500 U/L
Shelf Life Stability	2-8 °C until expiration date on label	Same
On Board	30 days on analyzer	28 days on analyzer

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

None referenced

L. Test Principle:

This is an enzymatic, colorimetric two step assay. In the incubation step, the activity of the human salivary α -amylase is inhibited by two different monoclonal antibodies without affecting the pancreatic α -amylase. In the reaction step, defined oligosaccharides such as 4, 6-ethylidene (G7) p-nitrophenyl-pNP (G1) α , D-maltoheptoside (ethylidene-G₇PNP) are cleaved under the catalytic action of α -pancreatic amylases. The G₂PNP, G₃PNP and G₄PNP fragments that are formed are completely hydrolyzed to p-nitrophenol (pNP) and glucose by α -glucosidase. The increase of absorbance due to pNP formation is proportional to the pancreatic α -amylase activity in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Intra-assay precision on the Aeroset was assessed by assaying three control samples twenty times in one run. Intra-assay precision on the c8000 was assessed by assaying two control samples twenty times in one run. The sponsor states the acceptance criterion for the precision studies is: CV <6%. The results are presented in the tables below.

Intra Assay Precision Aeroset

	Level 1	Level 2	Level 3
Mean (U/L)	30.2	121.2	292.0
SD	0.67	0.67	0.79

%CV	2.22	0.55	0.27
------------	------	------	------

Intra Assay Precision c8000

	Level 1	Level 2
Mean (U/L)	33.4	89.1
SD	0.49	0.45
%CV	1.47	0.50

Inter-Assay Precision was assessed on the Aeroset by assaying three levels of control in duplicate in 2 runs for 14 days.

Inter-Assay Precision was assessed on the c8000 by assaying two levels of control in duplicate, one run, for 15 days.

The results are presented in the table below.

Inter Assay Precision Aeroset

Level	Mean	Within Run		Run to Run		Total	
		U/L	SD	CV%	SD	CV%	SD
1	30.1	0.42	1.40	0.58	1.92	1.20	3.99
2	121.8	0.48	0.40	1.64	1.34	1.99	1.64
3	291.9	0.89	0.31	2.56	0.88	3.25	1.11

Inter Assay Precision c8000

Level	Mean	Within Run		Run to Run		Total	
		U/L	SD	CV%	SD	CV%	SD
1	33.6	0.32	0.90	0.40	1.20	0.51	1.50
2	89.4	0.32	0.40	0.40	0.40	0.50	0.60

b. Linearity/assay reportable range:

The linearity was assessed by testing serial dilutions. The High Standard was prepared by adding a commercially marketed pure enzyme to an albumin matrix. Eight amylase linearity solutions were prepared by quantitatively diluting this stabilized stock standard. Linearity was assessed from duplicate testing of these solutions on the Aeroset system. The sponsor's studies show that the assay is linear to 2200 IU/L.

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

The sponsor verifies the traceability of the assay using an internal standard.

The sponsor establishes the reagent shelf life by performing real-time performance studies that support the 18 months stability claim.

The sponsor establishes reagent “on board” stability through real-time measurement of five control materials that are tested in triplicate at time 0 and 30 days. The studies support the 30 day stability claim of the reagent “on board” the analyzers.

d. Detection limit:

The sensitivity of the assay is 1 U/L. The sensitivity is determined on twenty replicates of normal saline and represents the lowest pancreatic α -amylase activity that can be distinguished from zero. It is calculated as 3 SD of the twenty replicates. The company also performed a precision study with a sample value of approximately 1 U/L. The sample was run ten times and has a %CV of 16.1%.

e. Analytical specificity:

Studies were performed to assess common or known substances that could interfere with the method. A summary is presented in the table below:

Compound	Concentration-No Interference
Hemoglobin	500 mg/dL
Bilirubin	40 mg/dL
Triglycerides	1500 mg/dL

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The Aeraset Pancreatic Amylase test (y) was compared with a commercially marketed method (x). A total of 72 serum samples ranging from 5-2428 U/L were tested. The results are as follows:

$$n = 72, r = 0.9994, y = 0.965x + 3.843$$

The c8000 Pancreatic Amylase test (y) was compared with the Aeraset method (x). A total of 56 serum samples ranging from 4-2290 U/L were tested.

The results are as follows:

$$n = 56, r = 0.9998, y = 1.011x - 0.796$$

- 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):
- 4. Clinical cut-off:
Not applicable.
- 5. Expected values/Reference range:

The following literature reference values are provided:

Serum-plasma 8-53 U/L

Junge W, Waldenstrom J, Bouman, A et al. Evaluation of the Assays for Total and Pancreatic α -Amylase based on 100% Cleavage of Et-G7-PNP at 6 European Clinical Centers (Poster Medlab 97) Basel, Switzerland: 12th IFCC European Congress of Clinical Chemistry, August 17-22, 1997.

The package insert recommends that each laboratory establish its own expected range.

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.