

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k042169

B. Purpose for Submission:

New 510(k) for instrument – instrument performance was established with previously 510(k) cleared assays (see k011900, k831863 and k831858).

C. Measurand:

Glucose

Cholesterol

Triglycerides

D. Type of Test:

Quantitative Photometric

E. Applicant:

Stanbio Laboratory

F. Proprietary and Established Names:

Stanbio Laboratory Sirrus® Clinical Chemistry Analyzer

G. Regulatory Information:

1. Regulation section:

21CFR Sec - 862.1345 - Glucose test system

21CFR Sec - 862.1175 - Cholesterol (total) test system

21CFR Sec - 862.1705 - Triglyceride test system

21CFR Sec.-862.2160 - Discrete photometric chemistry analyzer for clinical use

2. Classification:

Class 2

3. Product code:

CGA - Glucose oxidase, glucose

CHH - Enzymatic esterase--oxidase, cholesterol

CDT - Lipase hydrolysis/glycerol kinase enzyme, triglycerides

JJE - Analyzer, chemistry (photometric, discrete), for clinical use

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indication(s) for use below

2. Indication(s) for use:

The Sirrus® Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by automatically various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes to include Glucose, Cholesterol, and Triglycerides.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Stanbio Laboratory Sirrus® Clinical Chemistry Analyzer

I. Device Description:

The system is composed of the following units. They are sampler, sample delivery, reagent tray, reagent delivery, reaction tray, mixing units, cuvette washing unit, spectrophotometer, etc. A complete list is present in the operator's manual.

The sample cups/tubes with the sample in it are set in the sample tray, and the reagent bottles are set in the reagent tray. Test orders for these samples are entered in the Order Entry screen. When the start button is clicked the cuvette washing unit starts cleaning from the No.1 cuvette. Before the last step of cuvette cleaning, water blank is measured. When the reaction tray rotates and the cuvette passes the optical measurement position, light absorption data of 1 or 2 wavelengths are measured. These data are the basis of optical absorption (Absorption = 0) to the following optical absorption measurement. After the water blank measurement, de-ionized water is aspirated out and the inside of cuvette is wiped out. When No.1 cuvette advances to one step before the R1 dispensation position, the reagent tray rotates and transports the reagent bottle to the reagent aspiration position.

Next, R1 probe moves to the aspiration position, above the reagent bottle, then moves down to the reagent level. This probe has a level sensing function and it stops when the probe tip touches the reagent. The designated amount of reagent is aspirated by the reagent pump. Next, R1 probe goes up and moves to the R1 dispensation position and waits for the cuvette coming to the dispensation position. When the cuvette comes to the position, R1 probe goes down to the designated level and dispenses the reagent. Then, R1 probe moves to the probe washing pot and both inside and outside are washed by de-ionized water there. After that, the residual water droplets are wiped out. At the 5th cycle after the R1 dispensation, the sample tray rotates to transfer No.1 sample cup/tube to the sampling position. The sample probe moves above the sample cup then goes down. The sample probe also has a level sensing function, and stops at the sample level. The designated amount of sample is aspirated

by the sample pump. Then the sample probe moves above No.1 cuvettes and goes down to the R1 reagent level in the cuvette, and dispenses the sample. After dispensation, the probe goes up. At the next cycle, the cuvette is moved to the mixing station-1, where R1 and the sample are mixed by MU-1, the mixing unit. This mixing is repeated in the next cycle, two times in total. The sample probe moves to the probe washing pot and both inside and outside are washed with de-ionized water, there. After that, the residual water droplets are wiped out. After R1 and the sample are mixed, optical measurement starts. When the reaction tray rotates and the cuvette passes the optical measurement position, light absorption data of 12 wavelengths are measured. After 5 minutes of R1 dispensation, the cuvette moves to R2 dispensation position, the same position as R1 dispensation, and then R2 is dispensed by R2 probe, which has the same function as R1 probe. After dispensation, R2 probe goes up. At the next cycle, the cuvette is moved to the mixing station-1, where R2 and the reaction liquid are mixed by MU-1. This mixing is repeated in the next cycle, two times in total. R2 probe moves to the probe washing pot and both inside and outside are washed with de-ionized water. After that, the residual water droplets are removed. After 4 minutes of R2 dispensation, the cuvette comes to the mixing station-2, where the particles in the reaction liquid are dispersed again by MU-2. (Mixing before the measurement is done by request.) After 10.7 minutes of sample dispensation, the reaction liquid in the cuvette is aspirated out by the No.1 nozzle of the cuvette washing unit and transferred to the drainage reservoir, out side of the system.

As the last step of the measurement for the 1st test of No. 1 sample, optical absorption data are converted into concentration or activity data using calibration curve. But the test results will not be printed out till the whole test results of No.1 sample are obtained. The same process is repeated for the 2nd, 3rd... test items, and the 2nd, 3rd... sample.

An optional ISE component is available and was cleared under 510(k), k040958.

See k011900, k831863 and k831858 for a description of the assays.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Cobas Mira Plus®
2. Predicate 510(k) number(s):
k920402

3. Comparison with predicate:

	Sirrus®	Cobas Mira Plus®
General		
System Principle	Discrete, single line random access, multi-test analysis	Random access, sample selective analysis
Throughput	240 tests per hour	132 tests per hour
Configuration	Analytical unit, Control Unit	Self contained analytical unit and control unit
Optical Measurement Unit		
Measurement Modes	Absorbance	Absorbance
Detector	Photo-diode	Filter photometer
Optical System	Wavelength range of 340 to 800 nm	Wavelength range of 340 to 600 nm
Filters	340,380,405,450,505,546,570,600,660,700, 750, and 800 nm	340, 405, 500, 550, and 600 nm
Linear absorbance range	0 – 2.5 A at 340 nm	0 – 2.4 A at 340 nm
Light Source	Tungsten halogen lamp	Xenon flash tube
Data Processing		
Calibration curve	Factor, Linear, Logit-log 1, Logit-log 2, Spline, Exponential, Polynomial	Factor, Linear, Polynomial
Reaction Unit		
Cuvettes	Plastics, semi disposable (Replace at 6 months, machine notification)	Plastics, disposable
Number of cuvettes	60 (Washed between tests)	72 (Disposable)
Cuvette washing	Automatic washing system in 10 operating steps. Reaction waste is aspirated out (1 step), cuvette is washed repeatedly (7 steps, (1 alkaline wash, 1 acidic wash, 5 deionized water washes)), and then residual liquid is removed (2 steps).	N/A
Path length	8 mm	6 mm
Volume	840 µL	600 µL
Reagent Volume	400 µL max	600 µL max
Sample/Reagent Delivery		
Pipetting System	Plunger driven by stepping motor	XYZ pipetting system
Sample Dispense	Sample volume: 3 – 30 µL; 0.5 µL step	Sample volume: 2 – 95 µL; 0.1 µL step
Reagent Dispense	Reagent volume: 20 – 350 µL, 5 µL step	Reagent volume: 100 – 600 µL; 1 µL step

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

NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices;
Approved Guideline

FDA guidance document “Guide for the Content of Premarket Submission for Software Contained in Medical Devices.”

L. Test Principle:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was performed according to NCCLS EP-5A. Two levels of control were tested.

Within Run:

Assay (Sample #)	Mean	Standard Deviation	% CV
Glucose (#1)	94 mg/dL	1.57	1.67 %
Glucose (#2)	270 mg/dL	2.61	0.97 %
Cholesterol (#1)	143 mg/dL	1.50	1.05 %
Cholesterol (#2)	242 mg/dL	2.68	1.11 %
Triglycerides (#1)	78 mg/dL	1.35	1.73 %
Triglycerides (#2)	183 mg/dL	1.79	0.98 %

Between Run:

Assay (Sample #)	Mean	Standard Deviation	% CV
Glucose (#1)	100 mg/dL	2.23	2.22 %
Glucose (#2)	302 mg/dL	4.86	1.61
Cholesterol (#1)	154 mg/dL	6.15	3.99 %
Cholesterol (#2)	263 mg/dL	4.17	1.58 %
Triglycerides (#1)	86 mg/dL	2.86	3.30 %
Triglycerides (#2)	208 mg/dL	5.56	2.67 %

b. Linearity/assay reportable range:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

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

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

d. Detection limit:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

e. Analytical specificity:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

f. Assay cut-off:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

2. Comparison studies:

a. *Method comparison with predicate device:*

To demonstrate substantial equivalence between the Sirus and the predicate device, Cobas Mira Plus®, three reagents (glucose, cholesterol, and triglyceride) with a finding of substantial equivalence (previous submissions) were tested on both instruments. A comparison was performed between the Stanbio Laboratory Sirus® Chemistry Analyzer and the Roche Cobas Mira Plus®. A total of 53 patient samples were assayed on both instruments. The results are reported in the following table.

Assay	Correlation Coefficient	Slope	Y-axis intercept	R Squared	Correlation Equation
Glucose	0.9971	0.887	16.17 mg/dL	0.9942	$y = 0.887x + 16.17$
Cholesterol	0.9894	1.126	-24.90 mg/dL	0.9789	$y = 1.126x - 24.90$
Triglycerides	0.9978	0.972	-5.03 mg/dL	0.9955	$y = 0.972x - 5.03$

b. *Matrix comparison:*

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

3. Clinical studies:

a. *Clinical Sensitivity:*

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

b. *Clinical specificity:*

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

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

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

4. Clinical cut-off:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

5. Expected values/Reference range:

See k011900 (Glucose), k831863 (Cholesterol), and k831858 (Triglycerides)

N. Instrument Name:

Sirus® Clinical Chemistry Analyzer

O. System Descriptions:

1. Modes of Operation:

Discrete, single line random access, multi-test analysis

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:
Bar Code ID codes 39 and 128 format
4. Specimen Sampling and Handling:
Direct sample collection tube or sample aliquot tub
5. Calibration:
Factor, Linear, Logit-log 1, Logit-log 2, Spline, Exponential, Polynomial
6. Quality Control:
Levy-Jennings Plot, Bar Charts, Westgard Multi-Rule Chart XB-R

**~~P. Other Supportive Instrument Performance Characteristics Data Not Covered In~~
The “Performance Characteristics” Section above:**

The software documentation was prepared in accordance with the FDA guidance document “Guide for the Content of Premarket Submission for Software Contained in Medical Devices.”

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.