

**SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k112955

B. Purpose for Submission:

Modification of the previously cleared device (k100602) - extend the lower end of the measuring range from 0.7 mmol/L to 0.3 mmol/L.

C. Measurand:

Whole venous and arterial blood for lactate

D. Type of Test:

Quantitative, Electromechanical Biosensor using lactate oxidase

E. Applicant:

Nova Biomedical

F. Proprietary and Established Names:

Nova StatStrip Lactate Hospital Meter System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1450; Lactic acid test system
21 CFR 862.1660; Quality control material (assayed and unassayed)

2. Classification:

Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)
Class I, reserved

3. Product code:

KHP, acid, lactic, enzymatic method
JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication for use below

2. Indication(s) for use:

Meter:

The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.

Test Strips:

Nova StatStrip Lactate Test Strips are intended for use only with the Nova StatStrip Lactate Hospital Meter for quantitative determination of lactate in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. The performance characteristics of the device for lactate measurements on capillary specimens have not been established. Nova StatStrip Lactate Test Strips are for testing outside the body (in vitro diagnostic use only).

Control and Linearity Solution:

Nova StatStrip Lactate Control Solutions are intended for use only with the Nova StatStrip Lactate Hospital Meter and Nova StatStrip Lactate Test Strips as a quality control check to verify the accuracy of blood lactate test results. There are two levels of controls (Level 1 and Level 2).

Nova StatStrip Lactate Linearity Kit solutions are used to check the linearity of the Nova StatStrip Lactate Hospital Meter. There are 4 levels of lactate linearity solutions: Level 1, Level 2, Level 3, and Level 4.

3. Special conditions for use statement(s):

- Fluoride or EDTA should not be used as preservatives for Whole Blood specimens.

- Not for use with serum, plasma or capillary whole blood
- Not for testing on neonates
- Inaccurate results may be obtained when operating relative humidity exceeds 90%.
- No studies were conducted with patients suspected of having sepsis

4. Special instrument requirements:

Nova StatStrip Lactate Hospital Meter

I. Device Description:

The Nova StatStrip Lactate Hospital Meter System contains a blood lactate meter, test strips, 2 levels of ready-to-use liquid control solutions (0.3-0.8 mmol/L and 1.3-2.1mmol/L, 4 levels of ready-to-use liquid linearity solutions (0.3-0.8mmol/L, 1.3-2.1mmol/L, 5.0-7.0 mmol/L, 8.5-12.0mmol/L and 14-18.5mmol/L) and a meter docking station.

The Lactate Test Strips, the Control and Linearity solutions are identical to those cleared in 510(k) k100602.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Nova StatStrip Lactate Hospital Meter System

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

k100602

3. Comparison with predicate:

Similarities and Differences		
Characteristics	Predicate k100602 Nova StatStrip Lactate Hospital Meter System	Proposed k112955 Nova StatStrip Lactate Hospital Meter System
Intended Use /Indications for use	The device is intended for in vitro diagnostic use by healthcare professionals for multiple patient uses in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of	Same

	<p>patients suspected of having lactic acidosis.</p> <p>Nova StatStrip Lactate Test Strips are intended for use only with the Nova StatStrip Lactate Hospital Meter for quantitative determination of lactate in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. The performance characteristics of the device for lactate measurements on capillary specimens have not been established. Nova StatStrip Lactate Test Strips are for testing in vitro diagnostic use only.</p> <p>Nova StatStrip Lactate Control Solutions are intended for use only with the Nova StatStrip Lactate Hospital Meter and Nova StatStrip Lactate Test Strips as a quality control check to verify the accuracy of blood lactate test results. There are two levels of controls (Level 1 and Level 2).</p> <p>Nova StatStrip Lactate Linearity Kit solutions are used to check the linearity of the Nova StatStrip Lactate Hospital Meter. There are 4 levels of lactate linearity solutions: Level 1, Level 2, Level 3, and Level 4.</p>	
Measuring Ranges	0.7 ~ 20.0 mmol/L	0.3 ~ 20.0 mmol/L
Levels of Linearity Set	4	Same
Operating Principle	Electromechanical Biosensor Lactate oxidase	Same
Sample Type	Venous or arterial whole blood	Same
Sample volume	0.6 µL	Same
Sample application	Capillary Action	Same
Handheld meter	Yes	Same

Test time	13 seconds	Same
Calibration	Automatic	Same
Data storage	1000 patient tests 200 QC tests 4000 Operators	Same
Weight	360 grams	Same

K. Standard/Guidance Document Referenced :

None were referenced.

L. Test Principle:

The Nova StatStrip Lactate Test Strips have an electrode that measures lactate. Lactate in the blood sample mixes with the reagent on the test strip to produce an electric current. The amount of current produced is proportional to the amount of lactate in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The Nova StatStrip Lactate Hospital Meter System is physically identical to the predicate Nova StatStrip Lactate Hospital Meter System cleared in k100602 except for the extended lactate measurement range (0.3 ~ 20.0 mM vs 0.7 ~ 20.0 mM). The software has been modified to accommodate the extended measurement range. Other than the differences mentioned above the performance characteristics of this device are the same as the predicate.

a. Precision/Reproducibility:

Previously established in k100602

b. Linearity/assay reportable range:

A linearity study was performed using adjusted whole blood samples with 9 different lactate concentrations ranging from 0.2 to 21 mM with the following target concentrations: 0.2-0.6, 1.0- 2.0, 3.0-4.0, 5.0-7.0, 8.0-9.0, 10-12, 13-15, 16-18, and 19-21 mM, respectively. Three lots of test strips were used with five StatStrip Lactate hospital test meters for this study. Two measurements were taken on each meter for each sample solution. The result of each lot of test strip was plotted against the paired results from the CCX laboratory analyzer (as reference measurement). Results of the regression analysis are summarized below:

	Slope	Y-Intercept	R ²
Lot 1	0.9937	0.0415	0.997

Lot 2	0.9809	0.0588	0.9981
Lot 3	0.9909	0.0061	0.9979

Based on the linearity study results, the sponsor claimed that the measuring range of the device is 0.3 to 20 mmol/L.

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

Close vial and open vial stability for Lactate Control Solution and Lactate Linearity Solution and value assignment of the Lactate Control Solution were established and cleared in submission k100602. Please refer to k100602 for information.

d. Detection limit:

LoQ previously established as 0.3 mmol/L in k100602.

e. Analytical specificity:

Previously established in k100602

f. Assay cut-off:

Not applicable

g. Cleaning and Disinfection

Previously established in k100602

2. Comparison studies:

a. Method comparison with predicate device:

Since this candidate device is identical to the predicate device, only an in-house method comparison was performed.

A total of 105 whole blood specimens, with the concentrations distributed across the 0.3-20 mM reportable range were analyzed on the Nova Stat Profile CCX Analyzer (comparative method) and each of the three lots of test strips on the Nova StatStrip lactate meter (candidate method). The result of each test strip was plotted against the paired results from CCX. Results of the regression analysis are summarized below:

	Slope	Y-Intercept	R ²
Lot 1	0.9739	0.0855	0.9957
Lot 2	0.9897	0.0533	0.9971
Lot 3	0.9818	0.0653	0.9964

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:

Normal adult blood lactate range (referenced from Tietz Textbook of Clinical Chemistry) is 0.56 ~ 1.39 mmol/L for venous blood and 0.35 ~0.75 mmol/L for arterial blood.

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.