Lactate Using Nova StatStrip Lactate Hospital Meter System

Purpose

This test procedure uses the Nova StatStrip Lactate Test Strips and Lactate Hospital Meter, a non-waived (moderately complex) test under CLIA, and is intended for measuring lactate level in fresh venous or arterial whole blood specimens.

Scope

This procedure may be performed by trained personnel approved to perform clinical laboratory tests as defined in Section 1206 of the California Business and Professional Code (Cal Bus & Prof Code) or per departmental policy (e.g., Registered Nurse - RN, Licensed Vocational Nurse - LVN, Medical Assistant - MA, Certified Registered Nurse Anesthetist - CRNA, Certified Nurse Midwife - CNM, Nurse Practitioner - NP, Medical Doctor - MD, Doctor of Osteopathy - DO, Physician Assistant - PA, Respiratory Care Practitioner - RCP, Perfusionist), whichever is more restrictive.

Policy

- Lactate testing on whole blood specimens using Nova StatStrip is for in vitro diagnostic quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens.
- Lactate measurements that are inconsistent with patient symptoms should be confirmed with a clinical laboratory test method.
- Positive patient identification must be made using two unique identifiers prior to patient testing.

Specimen Sources

- Venous whole blood
- Arterial whole blood
- Sample size: 0.6 µL

Specimen Collection

Collect venous or arterial blood by the standard venipuncture procedure, into a sodium or lithium heparin tube.

Specimen Storage

- Test freshly collected venous or arterial blood samples as soon as possible.
- It is not clinically appropriate to delay testing of freshly collected whole blood specimen for lactate levels.

Specimen Rejection

The following conditions will lead to cancelation of the test:

- Whole blood specimen collected in EDTA tube
- Whole blood collected in Fluoride (gray) top tube
- Specimens received with name or identification discrepancies
- Unlabeled specimens

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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Reagents and Materials Provided

- Nova Biomedical StatStrip Lactate Test Strips
- Nova Biomedical StatStrip Lactate Control Solutions –Level 1 and Level 2
- Nova Biomedical StatStrip Linearity Kit

Materials and Equipment Required but Not Provided

- Nova Biomedical StatStrip Lactate Hospital Meter.
- Phlebotomy supplies

Note:
When not in use, make sure to keep the meter fully charged by placing it into the Docking/Charging Station.

Storage and Stability

- Keep the Test Strip vial tightly closed when not in use and store only it its original vial.
- Store the Test Strips, Control Solutions and linearity Kit at room temperature (15-30°C).
- **Do not refrigerate or freeze** the reagents and materials

Expiration

- The expiration date is printed on the vials. Control Solutions, Linearity Solutions and Test Strip vials must be labeled with open and expiration dates.
- Once opened, reagents and materials stored as indicated will be stable for up to 90 days or until the expiration date, whichever comes first.

Safety Precautions

- Observe standard precautions when collecting blood. Follow blood collection protocols and procedures. Wear personal protective equipment, as required. Handle all specimens as if they contain infectious agents.
- Refer to the safety manual for additional information. Discard of used test reagent and materials in the biohazardous waste.

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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Cleaning and Disinfecting the Meter

Follow the local approved infection control policies.

- Wipe the external surface of the meter thoroughly between each patient and after controls, using the approved germicidal wipe (e.g., PDI Sani-cloth AF, Clorox wipes, or 70% isopropyl).
- Repeat the process at least three (3) times horizontally and three (3) times vertically.
- When using the PDI Sani-cloth AF, ensure that the meter surface stays wet for three (3) minutes; when using Clorox wipes make sure to allow the meter to air dry completely.

Note:

- ***Never re-use a previously soiled wipe.***
- ***Clorox wipes must be used for disinfecting the meters used on C. difficile isolation patients***

Warning!

- ***Avoid wiping the meter's barcode scanner and electrical connector (power cord).***
- ***Do not allow fluid to enter the test strip port or connector, or allow pooling of liquid on the touch screen. If liquid does get into the strip port or connector, immediately dry the components with a dry cloth or gauze.***
- ***Do not spray the meter directly with solutions as this could cause the solution to enter the case and damage the electronic components.***
- ***Do not immerse the meter or hold the meter under running water.***

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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Operator Login Procedure

Follow the steps below to login and access the StatStrip Lactate Hospital Meter.

Note:

- ***After the initial power or battery replacement, the Boot screen appears and is displayed while the software loads. The Welcome screen is displayed once the software has loaded.***
- ***The meter needs to be charged until the green light on the charging station lights up.***
- ***Make sure that the spare rechargeable battery is in place/ in the charging station.***

Warning!

- ***Do not stare into the Laser light or point it towards anyone's eyes while scanning a barcode.***

Step	Action
1	From the Home screen, press the Login soft key at the bottom of the middle of the screen or press OK/Enter button. The Enter Operator ID screen displays.
2	Enter the Operator's numeric ID. ***Note:*** ***When an invalid ID is entered, the screen displays the invalid ID number with a message "is not a valid ID Try again."***
3	Press the Accept soft key at the bottom of the screen.
4	After the Operator ID is accepted, the Patient Test screen displays. The meter is now ready to run Patient tests, Quality Control tests, Linearity tests, review results, set time, etc.

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Linearity Test Reagents and Materials

The following reagents, materials and instrument are required to perform the Linearity test procedure.

- Nova Biomedical StatStrip Linearity Kit/Solutions (4 vials – Levels 1 thru 4, 4 mL each)
- Nova StatStrip Lactate Hospital Meter
- Nova StatStrip Lactate Test Strips (Each strip is only used once. **Do not re-use.)**
- Nova StatStrip Lactate Linearity Kit

Linearity Test Procedure

Perform the Linearity Test procedure on the Nova StatStrip Lactate Hospital Meter System when indicated below:

- Every six months (a requirement for moderately complex tests)
- On any new Nova StatStrip Lactate Hospital Meter
- With each new lot of Nova StatStrip Lactate Test Strips

Note:

- ***When Linearity Testing is needed, perform Linearity Testing prior to performing the daily Quality Control and testing patient samples.***
- ***Refer to the instrument manual for detailed information and to the Operator Login Procedure header block.***

Warning!
Use a new Lactate Test Strip for each level of Linearity Solution vial and complete all the steps in the procedure below, one vial at a time, until all four Linearity levels (Level 1, Level 2, Level 3 and Level 4) have been successfully tested.

Step	Action
1	**Enter the Test Strip lot number as indicated below:** • From the Patient Test screen, press the Menu soft key. • From the Menu screen, press the Linearity soft key. • The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key. • Press the Accept soft key if the lot number is correct. *Note:* ***If the Strip Lot Number is invalid, the screen displays the invalid number with "is not a valid Strip Lot # Try again."***

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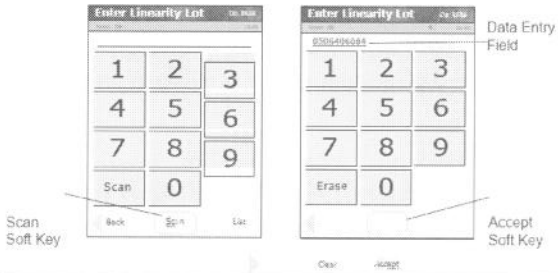
Linearity Test Procedure, continued

Step	Action
2	**Enter the Linearity Test Strip lot number as indicated below:** • The Enter Linearity Lot screen displays. • Enter the Linearity lot number, select from the Linearity Lot List screen (press the List soft button), or scan the barcode. (To scan the barcode, press the Scan soft key.) • Press the Accept soft key if the lot number is correct. ***Note:*** ***If the Linearity Lot Number is invalid, the screen displays the invalid number with "is not a valid Linearity Lot Try again."*** 
3	The Insert Strip screen displays. Insert a Test Strip as shown on the screen.  ***Note:*** ***With the test strip correctly inserted, the Apply Sample screen displays.***

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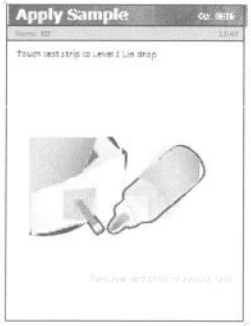
Linearity Test Procedure, continued

Step	*Action*
4	**Apply Linearity Solution to the Test Strip:** • Gently shake the Nova StatStrip Lactate Linearity Solution before each use. • Discard the first drop of linearity solution from the bottle to avoid contamination. • Place a drop of linearity solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter. 
5	**Linearity Result Screen:** • Recap the linearity solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock. • When the meter completes the test, the Linearity Result screen displays with the results in mmol/L. • To accept the linearity result, press the Accept soft key. *Note:* • ***The expected value range of each solution is printed on each solution vial.*** • ***The linearity results should fall within the range of results printed on the label.***

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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Linearity Test Procedure, continued

Step	Action
6	**Linearity results outside of the expected range** • If linearity solution test result is outside the expected range (either higher or lower), the meter and /or test strip may not be working correctly as a system. When this occurs, repeat the linearity check/test. • If the linearity repeat results are still outside of the expected range, contact the local Point of Care Coordinator for further instructions. • Document the results according to your local procedure. *Note:* ***An out of range StatStrip Linearity result may be caused by the following:*** • ***The test procedure may have not been followed properly. Retest and follow the step by step procedure carefully.*** • ***The Linearity Solution may have expired or have been contaminated. Check the expiration date of each vial.*** • ***Make sure that the vial is tightly closed after use.*** • ***The Test Strip may have expired. Check the expiration date on the Test Strip vial.*** • ***The Test Strip may have been damaged – i.e., by extreme temperatures or by leaving the Test Strip vial cap open. Retest using a new Test Strip.*** • ***The Lactate Hospital Meter may not be working properly.***
7	Repeat steps 1 through 6 until all four Linearity Solution vials (Levels 1 thru 4) have been successfully tested.

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Quality Controls

Nova Biomedical StatStrip Lactate Control Solutions –Level 1 and Level 2:

- The Lactate Control Solutions are used as a quality control check to make sure that the Meter and the Test Strips are working correctly.
- The control solution test is performed the same way that a blood test is performed, except that the control solution is used in place of a blood drop and the control feature of the meter is utilized.
- Testing of the control solutions confirms that the meter and test strips are working correctly. The control solution test results should fall within the range results printed on the vial label of the controls.
- Document the results according to your local procedure. If results are outside the expected range, the test must be repeated.
- If repeat testing still produce results that are outside the expected range, the system may not be performing correctly. Do NOT release patient results. Contact your local Point of Care Coordinator for further instructions.

Control Solutions are tested/run as follows (after Linearity Test, as required, and before testing patient samples):

- Before using the Nova StatStrip Lactate Hospital Meter for the first time
- Each day of use
- If the patient test has been repeated and the blood lactate results are still lower or higher the expected results
- If there are other indications that the system is not working properly
- If you drop the meter

Quality Control Procedure

- Follow and complete all steps below to perform Quality Control testing, using the Nova StatStrip Lactate Control Solutions Level 1 and Level 2 (**one Control Solution vial at a time**), and using a new Lactate Test Strip for each control level.
- Refer to the **Operator Login Procedure** header block.
- Two levels (Level 1 and Level 2) of Quality Controls must always be tested.

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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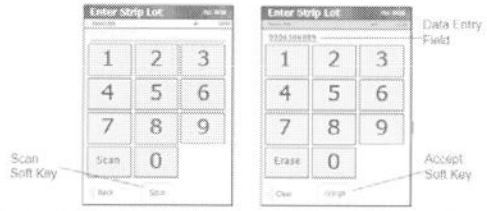
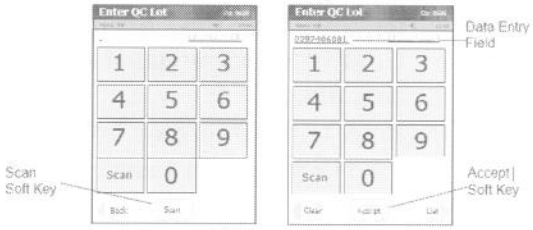
Quality Control Procedure, continued

Step	Action
1	**Enter Strip Lot Number as follows:** • From the Patient Test screen, press the QC soft key. • The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key. • Press the Accept soft key if the lot number is correct. ***Note:*** ***If the Strip Lot Number is invalid, the screen displays the invalid number with "is not a valid Strip Lot # Try again."*** 
2	**Enter the Quality Control Lot Number of the QC Levels** • The Enter QC Lot screen displays. Enter the QC lot number, select from the QC Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key. • Press the Accept soft key if the lot number is correct. ***Note:*** ***If the QC Lot Number is invalid, the screen displays the invalid number with "is not a valid QC Lot Try again."*** 

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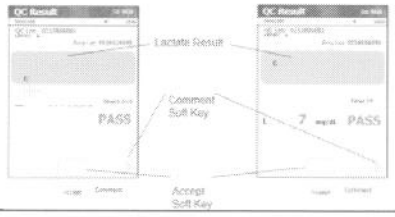
Lactate Using Nova StatStrip Lactate Hospital Meter System,
Continued

Quality Control Procedure, continued

Step	Action
3	**Insert a Test Strip as indicated:** • Insert Strip screen displays. Insert a Test Strip as shown on the screen. • With the test strip correctly inserted, the Apply Sample screen displays. • Gently shake the StatStrip Lactate Control Solution before each use. • Discard the first drop of control solution from the bottle to avoid contamination. • Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter. • Recap the control solution. 
4	**QC Result:** • The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock. • When the meter completes the test, the QC Result screen displays with the results in mmol/L. • To accept the result, press the Accept soft key. ***Warning!*** ***Do not test patient sample until a Control solution test result is within expected range.*** 

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
Continued

Quality Control Procedure, continued

Step	Action
5	**Acceptable results ranges** • Acceptable control assay ranges are printed on the Nova Lactate Control Solutions vial label. • An acceptable result within control assay ranges must be obtained for both Control levels (1 and 2) before testing patient samples. • If a QC test does not fall within the specified range, verify that the Nova Lactate Test Strips and Control Solutions are not past their expiration dates. • Repeat the test with a new strip. • If the second test fails, inspect the meter. • Repeat the test with a new control. • If the third test fails, contact the local Point of Care Coordinator. *Note:* ***A comment must be documented on the QC log for all failed QC results.***
6	Repeat steps 1 through 6 until both Control Levels 1 & 2 have been successfully tested.

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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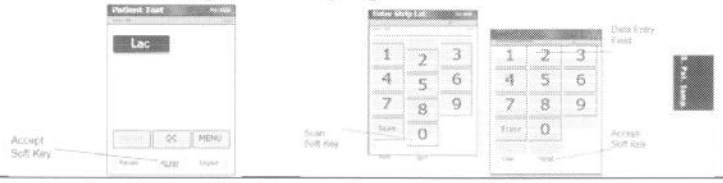
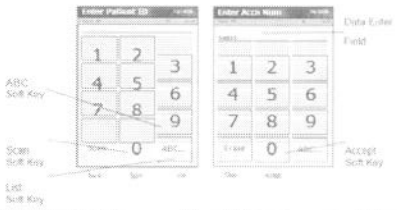
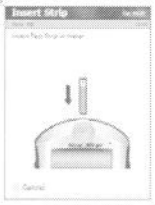
Patient Testing Procedure

- Follow these steps to perform lactate testing on patient specimens.
- Refer to the **Operator Login Procedure** header block.

Step	Action
1	**Enter Strip Lot Number:** • From the Patient Test screen, press the Accept soft key. • The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key. • Press the Accept soft key if the lot number is correct. ***Note:*** ***If the Strip Lot Number is invalid, the screen displays the invalid number with "is not a valid Strip Lot # Try again."*** 
2	**Enter the patient's medical record number (MRN):** • From the Enter Patient ID or Med Rec # (Accn Num) screen, use the numeric keypad or scan the armband barcode to enter the patient's MRN. • Press the Accept soft key. (The Insert Strip screen displays.) 
3	Insert a test strip as shown on the meter screen. 
4	The Apply Sample screen will appear when the test strip is correctly inserted.

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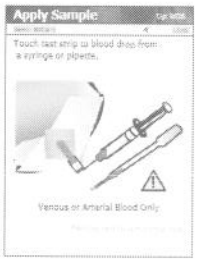
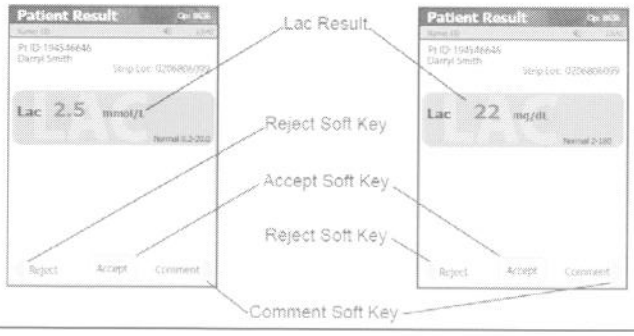
Lactate Using Nova StatStrip Lactate Hospital Meter System,
Continued

Patient Testing Procedure, continued

Step	Action
5	**Draw the required fresh whole blood sample and add sample to the strip:** • Use either the syringe or a pipette to add a fresh venous or arterial blood drop to the Lactate test strip. • Touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.  ***Warning!*** ***The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip into a biohazardous container and repeat the test with a new strip.***
6	**Lactate Test Results** • **Do not** remove the test strip while the countdown is in progress. • The test results will appear in **13 seconds.** • A **single up arrow** displays for abnormal high result and **2 up arrows** for critical high value. A **single down arrow** displays for abnormal low result and **2 down arrows** for critical low value. • Press the Accept soft key to accept the result. • Press the Reject soft key to reject the result. • All data are stored into memory 

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
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Patient Testing Procedure, continued

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>7</td><td>Lactate Test Results
<table>
<tr><th>Description</th><th>Result</th><th>Action</th></tr>
<tr><td>High Lactate Values (HI)</td><td>Higher than 20 mmol/L</td><td>Retest using a new strip. If same result, contact the local Point of Care coordinator</td></tr>
<tr><td>Low Lactate Values (LO)</td><td>Lower than 0.3 mmol/L</td><td>Retest suing a new strip. If same result, contact the local Point of Care Coordinator</td></tr>
<tr><td>Expected Values /Reference Range</td><td>0.5-1.9 mmol/L</td><td>Accept the result</td></tr>
<tr><td>Alert Values</td><td>Greater than 1.9 mmol/L</td><td>Accept the result</td></tr>
</table></td></tr>
<tr><td>8</td><td>When patient testing is completed, clean and disinfect the Nova StatStrip Lactate Hospital Meter after each use and prior to testing with a new patient specimen. Follow the Cleaning and Disinfecting the Meter procedure header block.

Note:
Discard the used test strips in the biohazardous waste.</td></tr>
</table>

Method Performance Specifications

- Reportable range: 0.3-20.0 mmol/L
- For samples exhibiting values at or above 20.0 mmol/L, the screen displays **HI**
- Analytic Accuracy (bias) = 0.14; a calculation factor of (times) 1.15 of StatStrip measured value is used and configured in the meter for patient testing only to equate the regular clinical laboratory performed test value.

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
Continued

Limitations

- Do NOT use for testing newborns.
- Do NOT use serum, plasma, or capillary whole blood.
- Do NOT collect whole blood specimens using EDTA (purple top), Citrate Oxalate or Sodium Fluoride (gray top) tubes
- Test results are best obtained when used within the operating relative humidity of up to 90% (non-condensing).

Lactate Interferences

The StatStrip Lactate Meter exhibits no interference from the following substances up to the concentration levels indicated in the table below:

Interfering Substances	Concentration Level
Acetaminophen	20.0 mg/dL
Ascorbic Acid	10.0 mg//dL
Bilirubin	15.0 mg//dL
Cholesterol	500.0 mg//dL
Creatinine	6.0 mg//dL
Dopamine	10.0 mg//dL
Ephedrine	0.9 mg//dL
Glucose	900.0 mg//dL
Ibuprofen	48.0 mg//dL
L-Dopa	100.0 mg//dL
Methyl-Dopa	1.0 mg//dL
Salicylate	30.0 mg//dL
Tetracycline	30.0 mg//dL
Tolazamide	15.0 mg//dL
Triglycerides	750.0 mg//dL
Uric Acid	20.0 mg//dL

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Non-Controlled Documents

The following non-controlled documents support this procedure:

- Nova Biomedical StatStrip Lactate Hospital Meter *Instructions for Use Manual,* REF 47632
- Nova Biomedical StatStrip Lactate Test Strips, Package Insert (02/04/2013)
- Nova Biomedical StatStrip Lactate Control Solution –Level 1 (11/08/2012)
- Nova Biomedical StatStrip Lactate Control Solution –Level 2 (11/08/2012)
- Nova Biomedical StatStrip Linearity Kit (11/08/2012)

Controlled Documents

The following controlled document supports this procedure.

Reference
Regional Point-of-Care Quality Assurance Program

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Lactate Using Nova StatStrip Lactate Hospital Meter System,
Continued

Reviewed and approved by:

Signature	Date
	2/18/15
Ji Yeon Kim, MD, MPH **CLIA Laboratory Director SCPMG Target Laboratories**	

Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
	2/24/15
Name: Charles Park **Operations Director, Area Laboratory**	
	2/24/15
Name: Jana Pindur, MD **CLIA Laboratory Director**	

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HISTORY PAGE

Type of Change: New, Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
New					