TRAINING UPDATE

Lab Location:	SGMC	**Date Distributed:**	5/26/2021
Department:	Core Lab	**Due Date:**	6/26/2021

DESCRIPTION OF PROCEDURES

Name of procedure:

SOP #	Title
SGMC.C3009	C-Reactive Protein (CRP-2) by Atellica CH Analyzer
SGMC.C3046	Procalcitonin (PCT) by Atellica IM Analyzer
SGMC.C3053	Lactic Acid (Lac-2) by Atellica CH Analyzer

Description of change(s):

These are the new assay SOPs for the Atellica Solution analyzers. Core technical staff must review and be familiar with -

- Specimen requirements
- Reagent, calibrator & QC stability and storage
- Ranges and dilutions

These SOPs were implemented on May 19, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**C-Reactive Protein (CRP-2) by Atellica CH Analyzer**
Prepared by	Ashkan Chini Date: 4/25/2021
Owner	Robert SanLuis Date: 4/25/2021

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
C-Reactive Protein	Atellica CH Analyzer	CRP

Synonyms/Abbreviations
CRP

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Atellica CH C-Reactive Protein-2 (CRP-2) latex reagent is a suspension of uniform polystyrene latex particles coated with anti-CRP antibody. When serum or plasma containing CRP is mixed with the latex reagent agglutination takes place resulting in an increase in the turbidity. This turbidity is measured at 571 nm. The CRP concentration in serum or plasma is determined from a calibration curve that is generated with the calibrators.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL

Criteria	
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: To be determined
	Refrigerated: 3 days
	Frozen: 6 months
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation. Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
C-Reactive Protein-2 (CRP-2)	Siemens, Atellica CH, Cat. No. 11097631

4.2 Reagent Preparation and Storage

Reagent	C-Reactive Protein-2 (CRP-2)
Storage	Store at 2-8°C
Stability	Onboard per well: 30 days
Preparation	Reagent is liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
C-Reactive Protein-2 Calibrator (CRP-2 CAL)	Siemens Atellica CH, Cat. No. 11099430

5.2 Calibrator Preparation and Storage

Calibrator	C-Reactive Protein-2 Calibrator (CRP-2 CAL)
Preparation	Calibrators are liquid and ready to use. Mix by gentle inversion at least five times to ensure homogeneity prior to use.
Storage/Stability	• Store at 2-8°C • **Unopened:** stable until expiration date stamped on the box. • **Opened:** 60 days when recapped immediately after use.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	C-Reactive Protein-2 Calibrator (CRP-2 CAL)
Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (60 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (30 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service. At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.
Procedure	Refer to the Atellica Solution Operating, QC, Calibration and Maintenance procedure for specific instructions.

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis

IF……	THEN……
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
InteliQ Immunology Control, Levels 1, 2 & 3	Bio-Rad Laboratories Cat. No. 12009941, 12009942, 12009943

6.2 Control Preparation and Storage

Control	InteliQ Immunology Control Levels 1, 2 & 3
Preparation	Allow to thaw at room temperature (18-25C) for approximately 45 minutes or until completely thawed. Once thawed, gently invert the tube several times to ensure homogeneity.
Storage/Stability	**Frozen**: Until expiration date when unopened at -20 to -70C. **Thawed**: • Unopened for 45 days at 2-8C • Opened & off board for 10 days at 2-8C Opened & onboard for 30 days at 2-8C

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Siemens Atellica QC Schedule and the Siemens Atellica Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported.

Step	Action
	• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.

- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens Atellica CH Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

Atellica CH C-Reactive Protein-2 (CRP-2) is required to perform this test.

CRP-2 is performed on the Atellica CH Analyzer after the method is calibrated and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

8.3	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.

8.3	Specimen Testing
4.	Follow protocol in section 10.6 "Repeat Criteria and Resulting" for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of CRP in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results up to one decimal point.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

0.4 – 91.2 mg/dL

10.5 Review Patient Data

Each result is reviewed for error messages. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 0.4 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.4 mg/dL

IF the result is …	THEN…
≥ 30.4 mg/dL	**On Board Automated Dilution:** Results ≥ 30.4 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 3. No multiplication is necessary.
> 91.2 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 91.2 mg/dL -REP" Bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>19 years):	0.0 - 0.3 mg/dL	0.0 - 0.3 mg/dL
Pediatric:		
15 – 18 years	0.1 - 0.8	0.1 - 0.8
11 – 14 years	0.1 - 0.8	0.1 - 0.8
4 – 10 years	0.1 - 1.0	0.1 - 0.8
1 – 4 years	0.1 - 0.8	0.1 - 1.1
3 – 12 months	0.1 - 0.8	0.1 - 1.1
0 – 90 days	0.1 - 1.6	0.1 - 1.6

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

CRP is one of the 'acute-phase' proteins, whose serum or plasma levels rise during general, nonspecific response to infectious and non-infectious inflammatory processes. CRP is synthesized in the liver and is normally present as a trace constituent of serum or plasma. In various disease states resulting in tissue injury, infection or acute inflammation, CRP values may rise to 2.0 to 50.0 mg/dL. As elevated CRP values are always associated with pathological changes, the CRP method provides useful information for the diagnosis, therapy and monitoring of inflammatory processes and associated diseases. Increases in CRP values are non-specific and should not be interpreted without a complete clinical history.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.4 – 30.4 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Lithium heparin plasma	0.7	0.02	2.3
Serum	3.3	0.05	1.4
Serum	6.5	0.04	0.9
Serum	27.7	0.20	0.8

14.3 Interfering Substances

HIL Interference:
Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2.

Substance tested	Substance Concentration	mg/dL	Bias %
Hemoglobin	750 mg/dL	1.0	-4
Bilirubin (unconjugated)	60 mg/dL	1.0	0
Bilirubin (conjugated)	60 mg/dL	0.9	0
Lipemia Intralipid®	1000 mg/dL	1.0	0

14.4 Clinical Sensitivity/Specificity/Predictive Values

Detection Capability
The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 0.4 mg/dL, and a limit of quantitation (LoQ) ≤ 0.4 mg/dL with ± 30% total allowable error. The LoD corresponds to the lowest concentration of C-reactive protein that can be detected with a probability of 95%. The LoD for the Atellica CH CRP-2 assay is 0.0 mg/dL, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0.0 mg/dL. The LoQ corresponds to the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error of 26.7%. The LoQ of the Atellica CH CRP-2 assay is 0.3 mg/dL, and was determined using 180 determinations.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Atellica Solution Operating, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of CRP-2 Reagent

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144.
2. Package Insert, CRP-2 Reagent, Siemens Healthcare Diagnostics Inc., 10/2019.
3. Package Insert, C-Reactive Protein-2 Calibrator (CRP-2 CAL), Siemens Healthcare Diagnostics Inc., 07/2019.
4. Package Insert, InteliQ immunology Controls, Bio-Rad Laboratories, 08/2020.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None

Technical SOP

Title	**Procalcitonin (PCT) by Atellica IM Analyzer**
Prepared by	Ashkan Chini Date: 4/30/2021
Owner	Robert SanLuis Date: 4/30/2021

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Procalcitonin	Atellica IM Analyzer	PCT

Synonyms/Abbreviations
PCT

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Atellica IM BRAHMS PCT assay is a 2-site sandwich immunoassay using direct chemiluminescent technology that uses 3 mouse monoclonal antibodies specific for PCT. The first antibody, in the Lite Reagent, is a mouse monoclonal anti‑PCT antibody labeled with acridinium ester. The second and third antibodies, in the Ancillary Reagent, are mouse monoclonal anti‑PCT antibodies labeled with fluorescein. The immunocomplex formed with PCT is captured with mouse monoclonal anti-fluorescein antibody coupled to paramagnetic particles in the Solid Phase. A direct relationship exists between the amount of PCT present in the patient sample and the amount of relative light units detected by the system.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)

Criteria	
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 8 hours
	Refrigerated: 48 hours
	Frozen: Not specified in insert
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation. Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Procalcitonin (PCT)	Siemens, Atellica IM, Cat. No. 11202699
Multi-Diluent 1	Siemens, Atellica IM, Cat. No. 10995637

4.2 Reagent Preparation and Storage

Reagent	**Procalcitonin (PCT)**
Storage	• Store at 2-8°C

	• Store in an upright position. • Protect from heat and light.
Stability	Reagents are stable onboard the system for 60 days.
Preparation	**Note:** The Ancillary Reagent provided in this kit is matched to the Solid Phase and Lite Reagent. Do not mix Ancillary Reagent lots with different lots of Solid Phase and Lite Reagent. Reagent is liquid and ready to use. Before loading primary reagent packs onto the system, mix them by hand and visually inspect the bottom of the reagent pack to ensure that all particles are re-suspended.

Reagent	**Multi-Diluent 1**
Storage	Store at 2-8°C in an upright position.
Stability	Stable onboard the system for 28 days.
Preparation	Liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Procalcitonin (PCT) Calibrator	Siemens, Atellica IM, Cat. No. 11202699

5.2 Calibrator Preparation and Storage

Calibrator	Procalcitonin (PCT) Calibrator
Preparation	1. Add 2.0 mL of reagent grade water into each vial using a calibrated pipette. Replace cap. 2. Let the vials stand for 15–20 minutes at room temperature to allow the lyophilized material to dissolve. 3. Gently mix and invert the vials to ensure homogeneity of the material.
Storage/Stability	• Store at 2-8°C in an upright position. • **Unopened:** stable until expiration date stamped on the box. • **Reconstituted:** remains stable for 8 hours at room temperature, 24 hours refrigerated, and 60 days frozen (thaw up to 2 times ONLY).

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Procalcitonin (PCT) Calibrator

Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in ng/mL
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (82 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (35 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service. At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.
Procedure	To load a new lot of reagent on IM Module: Note: Calibrate the new lot of reagent as soon as it is loaded on the instrument. If the reagent sits un-calibrated for a short period of time (24 hours) then it will not be eligible for a "Lot Calibration" and another new reagent will need to be loaded onboard. 1. From the home page of the IM Module Screen (small screen attached on the IM Module) make sure the analyzer status is in Standby. 2. On the IM Module Screen select Reagent Loader. Make sure the Reagent Drawer status is unlocked. Open the reagent drawer, load the reagent and then close it. Once the reagent is scanned, the IM Module Screen will populate message "Missing TDef for lot" next to the reagent. The Reagent Drawer status remains unlocked. 3. Both Reagent Master Curve and Calibrator Package Insert need to be scanned using the Atellica Solution's main monitor. To differentiate between the two: • Reagent Master Curve has MC TDEF printed right below the assay name. • Calibrator Package Insert has CAL printed right above the assay name. 4. To scan the Reagent Master Curve, go to Set up – Test Definition – IM Test Definition. Scan the barcode. 5. To scan the Calibrator Package Insert, go to Calibration – Calibrator Definition. Scan the barcode.

	6. Re-open the Reagent Drawer and close it. This time its status should change to locked, meaning the reagent is going to be loaded onboard ready for calibration.
Procedure	Refer to the Atellica Solution Operating, QC, Calibration and Maintenance procedure for specific instructions.

5.4 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Lyphocheck Specialty Immunoassay Control, Levels 1, 2 and 3	Bio-Rad Laboratories Cat. No. 27124, 27125, 27126

6.2 Control Preparation and Storage

Control	Lyphocheck Specialty Immunoassay Control, Levels 1, 2 and 3
Preparation	Reconstitute each vial with 2 mL of reagent grade water. Replace the stopper and allow this product to stand for approximately 15 minutes swirling occasionally. Before sampling, gently swirl the vials several times to ensure homogeneity.
Storage/Stability	**Unopened**: until expiration date when stored at 2-8C. **Reconstituted & stored tightly capped at 2-8C**: 3 days for PCT **Reconstituted and stored in tightly capped aliquot vials at -20 to -70°C**: stable for 30 days. Use the content of each aliquot vial only once and discard the remainder.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Siemens Atellica QC Schedule and the Siemens Atellica Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples.

Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.

- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens Atellica IM Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

7.3 Supplies

- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

Atellica IM Procalcitonin (PCT) is required to perform this test.

Procalcitonin is performed on the Atellica IM Analyzer after the method is calibrated and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

8.2	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.
4.	Follow protocol in section 10.6 "Repeat Criteria and Resulting" for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of Procalcitonin in ng/mL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results up to two decimal points.

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

0.04 – 1,000.00 ng/mL

10.5 Review Patient Data

Each result is reviewed for error messages. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 0.04 ng/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.04 ng/mL
≥ 50.00 ng/mL	**On Board Automated Dilution:** Results ≥ 50.00 ng/mL will automatically have repeat testing performed into the instrument using dilution factor of 20. No multiplication is necessary.
> 1000.00 ng/mL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 1000.00 ng/mL -REP" Bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

< 0.10 ng/mL

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Sepsis is a daily challenge in intensive care units. There are various known therapeutic strategies to improve survival in patients with sepsis. Early assessment is important for determination of the appropriate treatment. PCT is the prohormone of the hormone calcitonin, but PCT and calcitonin are distinct proteins. Calcitonin is exclusively produced by C-cells of the thyroid gland in response to hormonal stimuli, whereas PCT can be produced by several cell types and many organs in response to pro-inflammatory stimuli, in particular by bacterial products. In healthy people, plasma PCT concentrations are found to be below 0.1 ng/mL. PCT level rises rapidly within 6 to 12 hours after a bacterial infectious insult with systemic consequences. Early onset of multiple traumas, major surgery, severe burns, or in neonates, PCT levels can be elevated independently of an infectious process, but the return to baseline is usually rapid. Viral infections, bacterial colonization, localized infections, allergic disorders, autoimmune diseases, and transplant rejection do not usually induce a significant PCT response. Therefore, by evaluating PCT concentrations, the physician may use the

findings to aid in the risk assessment for progression to sever sepsis and septic shock. The results should be evaluated in context of all laboratory findings and the total clinical status of the patient. In cases where the laboratory results do not agree with clinical picture or history, additional tests should be performed.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.04 – 50.00 ng/mL

14.2 Precision

Material	Mean ng/mL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Serum A	0.05	0.0	9.7
Serum B	0.27	0.0	1.8
Serum C	0.75	0.01	1.2
Serum D	1.52	0.02	1.4
Serum E	19.14	0.29	1.5

14.3 Interfering Substances

Do not use samples that contain fluorescein. Fluorescein levels >0.10 µg/mL may decrease results in this assay.

HIL Interference:
Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2.

Substance tested	Substance Concentration	ng/mL	Bias %
Hemoglobin	500 mg/dL	0.36	-3.6
Bilirubin (conjugated)	40 mg/dL	0.34	-3.1
Bilirubin (unconjugated)	40 mg/dL	0.34	6.6
Lipemia Intralipid®	1000 mg/dL	0.35	-2.9

14.4 Clinical Sensitivity/Specificity/Predictive Values

Detection Capability
The assay is designed to have a limit of blank (LoB) < 0.03 ng/mL, a limit of detection (LoD) < 0.04 ng/mL, and a limit of quantitation (LoQ) ≤ 0.06 ng/mL.

The LoB of the Atellica IM BRAHMS PCT assay is 0.00 ng/mL.The LoD for the Atellica IM BRAHMS PCT assay is 0.03 ng/mL. The LoQ of the Atellica IM BRAHMS PCT assay is 0.04 ng/mL.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Product causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Contains: reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (in Atellica IM BRAHMS PCT CAL)

16. RELATED DOCUMENTS

1. Atellica Solution Operating, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of Procalcitonin Reagent

17. REFERENCES

1. Package Insert, Procalcitonin Reagent, Siemens Healthcare Diagnostics Inc., 06/2019
2. Package Insert, Lyphocheck Specialty Immunoassay Control, Bio-Rad Laboratories, 04/2019

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None

Technical SOP

Title	**Lactic Acid (Lac-2) by Atellica CH Analyzer**
Prepared by	Ashkan Chini Date: 4/21/2021
Owner	Robert SanLuis Date: 4/21/2021

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Lactic Acid	Atellica CH Analyzer	LACT

Synonyms/Abbreviations
Lactate, LA, Lac-2

Department
Chemistry

2. ANALYTICAL PRINCIPLE

Lactate is oxidized by lactate oxidase to pyruvate and hydrogen peroxide. Lactate is measured by the formation of dye from hydrogen peroxide and a chromogen in the presence of a peroxidase. The corresponding change in absorbance at 545/694 nm is proportional to the plasma lactate concentration.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	The patient should be fasting and at complete rest.
Specimen Collection and/or Timing	Collect blood from a stasis-free vein and store it in an ice bath. Separate the plasma by centrifugation within 30 minutes.
Special Collection Procedures	A delay in separation can lead to an increase in lactate values.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma – Gray Top (Sodium Fluoride) Non
Collection Container	Gray Top Tube
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Plastic vial or spun barrier tube on ice

Criteria	
Stability & Storage Requirements	Room Temperature: Not Recommended
	Refrigerated: 1 day
	Frozen: 30 days
Timing Considerations	Separate the plasma by centrifugation within 30 minutes. Assay the sample immediately.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Lactate-2 (Lac-2)	Siemens, Atellica CH, Cat. No. 11532568

4.2 Reagent Preparation and Storage

Reagent	**Lactate-2 (Lac-2)**
Storage	• Store at 2-8°C • Store in upright position, away from light and heat.
Stability	Onboard per pack: 30 days
Preparation	Prepare Reagent 1: 1. Add a portion of the contents of well 1 of the P1 pack to the contents of the Lac-2 R1 vial. 2. Mix well to ensure homogeneity.

	3. Pour the solution back into well 1 of the P1 pack and mix well. 4. Carefully rinse the Lac-2 R1 vial several times with the contents of well 1 and empty the contents back into well 1 of the P1 pack. **Note:** Do not use reagents that are cloudy, discolored, or contain precipitates.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Special Chemistry Calibrator (SPCL CHEM CAL)	Siemens Atellica CH, Cat. No. 11099438

5.2 Calibrator Preparation and Storage

Calibrator	Special Chemistry Calibrator (SPCL CHEM CAL)
Preparation	1. Open each vial carefully. 2. Add 5.0 mL of reagent grade water into each vial using a calibrated pipette. Replace rubber stopper. 3. Let the vials stand for 30 minutes at room temperature to allow the lyophilized material to dissolve. 4. Prior to use, to ensure homogeneity and to avoid foam formation, mix the contents by gently inverting the vials.
Storage/Stability	• Store at 2-8°C • **Unopened:** until expiration date stamped on the box • **Reconstituted:** stable for 7 days

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Special Chemistry Calibrator (SPCL CHEM CAL)
Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mmol/L
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (62 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (30 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service.

	At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.
Procedure	Refer to the Atellica Solution Operating, QC, Calibration and Maintenance procedure for specific instructions.

5.4 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
InteliQ Assayed Multiqual Control Levels 1 & 3	Bio-Rad Laboratories Cat. No. 12008256, 12008258

6.2 Control Preparation and Storage

Control	InteliQ Assayed Multiqual Control Levels 1 & 3
Preparation	Allow to stand at room temperature (18-25C) until completely thawed but not more than one (1) hour. Once thawed, gently invert several times to ensure homogeneity.
Storage/Stability	**Frozen**: until the expiration date if unopened at -20 to -70C **Thawed and Unopened**: 30 days at 2-8C for lactic acid **Thawed and Opened**: 14 days at 2-8C for lactic acid Note: stability varies by assay

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Siemens Atellica QC Schedule and the Siemens Atellica Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples.

Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.

- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens Atellica CH Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

Atellica CH Lactate-2 (Lac-2) is required to perform this test.

Lactic Acid is performed on the Atellica CH Analyzer after the method is calibrated and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

8.2	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.
4.	Follow protocol in section 10.6 "Repeat Criteria and Resulting" for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of Lactic Acid in mmol/L.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results up to one decimal point.

10.3 Units of Measure

mmol/L

10.4 Clinically Reportable Range (CRR)

0.1 – 122.1 mmol/L

10.5 Review Patient Data

Each result is reviewed for error messages. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 0.1 mmol/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.1 mmol/L
≥ 12.2 mmol/L	**On Board Automated Dilution:** Results ≥ 12.2 mmol/L will automatically have repeat testing performed into the instrument using dilution factor of 10. No multiplication is necessary.
> 122.1 mmol/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 122.1 mmol/L -REP" Bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Male / Female
Adult:	0.4 - 2.0 mmol/L
Pediatric:	
2 – 18 years	1.0 - 2.4
3 months – 2 years	1.0 - 3.3
0 – 3 months	1.0 - 3.5

11.2 Critical Values

> 4.0 mmol/L

For Sepsis Protocol: call values > 1.9 mmol/L only when results are increasing

Example:

First value	1.8	= no call required
Second value	2.8	= call result
Third value	2.2	= no call required (result decreased)
Fourth value	3.0	= call result (result increased)

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Lactate is a product of carbohydrate metabolism. Lactic acid is produced during periods of anaerobic metabolism when cells do not receive oxygen to allow conversion of fuel sources to carbon dioxide and water. Lactic acid will accumulate because of excess production of lactate and decreased removal of lactic acid from blood by liver.

This measurement contributes to the knowledge of acid-base volume in the body and is used to detect lactic acidosis in persons with underlying risk factors that predispose them to this imbalance, such as cardiovascular and renal disease. Lactate will be elevated in a variety of conditions in which hypoxia is present and in liver disease. Lactic acidosis can occur both in diabetics and nondiabetics, and it is an often-fatal form of metabolic acidosis. The presence of an unexplained fall in pH associated with a hypoxia producing condition is reason to suspect lactic acidosis.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.1 – 12.2 mmol/L
Note: manufacturer insert has 2 decimals, rounded to one decimal to match practice)

14.2 Precision

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Control	12.5	0.24	4.9
Plasma Pool 1	48.7	0.46	4.8
Plasma Pool 2	99.0	0.75	4.6

14.3 Interfering Substances

HIL Interference:
Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2.

Substance tested	Substance Concentration	mmol/L	Bias %
Hemoglobin	300 mg/dL	6.6	-8
Bilirubin (unconjugated)	3.75 mg/dL	6.6	-8
Bilirubin (conjugated)	5.18 mg/dL	6.3	-1
Lipemia Intralipid®	1000 mg/dL	6.1	2

14.4 Clinical Sensitivity/Specificity/Predictive Values

Detection Capability
The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ limit of detection (LoD). The Limit of Detection (LoD) corresponds to the lowest concentration of lactate that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ 0.1 mmol/L for plasma.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Atellica Solution Operating, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of Lactate-2 Reagent

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144.
2. Package Insert, Lactate-2 Reagent, Siemens Healthcare Diagnostics Inc., 09/2020.
3. Package Insert, Special Chemistry Calibrator (SPCL CHEM CAL), Siemens Healthcare Diagnostics Inc., 10/2019.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None