**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.C3031 | Glucose (GluH-3) by Atellica CH Analyzer |
| SGMC.C3006 | Calcium (CA-2) by Atellica CH Analyzer |
| SGMC.C3042 | Carbon Dioxide, Concentrated (CO2-c) by Atellica CH Analyzer |
| SGMC.C3022 | Creatinine (Crea-2) by Atellica CH Analyzer |
| SGMC.C3054 | A-Lyte Integrated Multisensor (IMT Na K Cl) by Atellica CH Analyzer |
| SGMC.C3027 | Urea Nitrogen (UN-c) 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** | **Calcium (CA-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 |
|---|---|---|
| Calcium | Atellica CH Analyzer | CA |

| Synonyms/Abbreviations |
|---|
| CA |

| Department |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

Calcium ions form a colored complex with Arsenazo III, which is measured at 658/694 nm. The amount of calcium present in the sample is directly proportional to the intensity of the colored complex formed.

## 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**<br>**-Other Acceptable** | Plasma (Lithium Heparin)<br>Serum |
| **Collection Container** | Plasma: Mint green top tube (PST)<br>Serum: Red top tube, Serum separator tube (SST) |
| **Volume - Optimum**<br>**- Minimum** | 1.0 mL<br>0.5 mL |
| **Transport Container and Temperature** | Collection container or Plastic vial at room temperature |

| Criteria | |
|---|---|
| **Stability & Storage Requirements** | Room Temperature: 8 hours |
| | Refrigerated: 2 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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| Calcium-2 (CA-2) | Siemens, Atellica CH, Cat. No. 11097644 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **Calcium-2 (CA-2)** |
|---|---|
| **Storage** | Store at 15-25°C |
| **Stability** | Onboard per well: 63 days |
| **Preparation** | Reagent is liquid and ready to use. |

# 5. CALIBRATORS/STANDARDS

## 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| Chemistry Calibrator (CHEM CAL) | Siemens Atellica CH, Cat. No. 11099411 |

## 5.2 Calibrator Preparation and Storage

| | |
|---|---|
| **Calibrator** | Chemistry Calibrator (CHEM CAL) |
| **Preparation** | 1. Shake to break up lyophilized cake.<br>2. Open each vial carefully.<br>3. Using a calibrated pipette, add exactly 3.0 mL of reagent grade water into the vial. Replace the stopper.<br>4. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete.<br>5. Prior to use, mix by inversion at least 5 times to ensure homogeneity.<br>6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly. |
| **Storage/Stability** | • Protect from heat and light sources.<br>• Store at 2-8°C<br>• **Unopened:** stable until expiration date stamped on the box.<br>• **Reconstituted:** remains stable for 48 hours |

## 5.3 Calibration Parameter

| Criteria | Special Notations |
|---|---|
| **Reference Material** | Chemistry Calibrator (CHEM 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.<br>• At the end of the lot calibration interval (180 days), for a specified lot of calibrated reagent on the system.<br>• At the end of pack calibration interval (63 days), for calibrated reagent packs on the system.<br>• When indicated by quality control results.<br>• After major maintenance or service.<br><br>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<br>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<br>**Thawed and Unopened**: 30 days at 2-8C for calcium<br>**Thawed and Opened**: 14 days at 2-8C for calcium<br>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. |

| Step | Action |
|---|---|
| 2 | **Run Rejection Criteria**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 Calcium-2 (CA-2) is required to perform this test.

Calcium 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. |

| 8.2 | Specimen Testing |
|---|---|
| 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).<br>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 Calcium 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)

1.0 – 32.0 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… |
|---|---|
| < 1.0 mg/dL | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 1.0 mg/dL |
| ≥ 16.0 mg/dL | **On Board Automated Dilution:** Results ≥ 16.0 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 2. No multiplication is necessary. |
| > 32.0 mg/dL | If the recommended dilution does not give results within the clinically reportable range, report as: "> 32.0 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):** | 8.4 – 10.6 mg/dL | 8.4 – 10.6 mg/dL |
| | | |
| **Pediatric:** | | |
| 16 –19 years | 9.0 - 10.7 | 9.0 - 10.7 |
| 14 –15 years | 9.3 - 10.7 | 9.3 - 10.7 |
| 12 –13 years | 9.0 - 10.6 | 9.0 - 10.6 |
| 10 –11 years | 9.0 - 10.1 | 9.0 - 10.1 |
| 7 – 9 years | 9.0 - 10.1 | 9.0 - 10.1 |
| 4 – 6 years | 9.0 - 10.1 | 9.0 - 10.1 |
| 1 – 3 years | 8.9 - 9.9 | 8.9 - 9.9 |
| 6 – 11 months | 8.1 - 11.0 | 8.0 - 10.9 |
| 91– 180 days | 8.0 - 11.4 | 8.5 - 11.3 |
| 31– 90 days | 8.2 - 11.0 | 8.7 - 11.2 |
| 8 – 30 days | 8.6 - 11.8 | 8.8 - 11.6 |
| 0 – 7 days | 7.8 - 11.2 | 7.6 - 11.3 |

### 11.2 Critical Values

All ages, male and female

Low < 6.0 mg/dL
High > 13.0 mg/dL

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal diseases and tetany (intermittent muscular contractions or spasms).

## 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)

1.0 – 16.0 mg/dL

### 14.2 Precision

| Material | Mean mg/dL | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Plasma | 6.1 | 0.07 | 0.10 |
| Serum 1 | 10.2 | 0.07 | 0.08 |
| Serum 2 | 14.1 | 0.09 | 0.10 |

### 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 (hemolysate) | 1000 mg/dL | 5.8 | 3.4 |
| Bilirubin (unconjugated) | 50 mg/dL | 5.9 | -1.7 |
| Bilirubin (conjugated) | 50 mg/dL | 5.9 | 1.7 |
| Lipemia Intralipid® | 1000 mg/dL | 5.9 | 6.8 |

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

## 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 Calcium-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, Calcium-2 Reagent, Siemens Healthcare Diagnostics Inc., 03/2019.
3. Package Insert, Chemistry Calibrator (CHEM CAL), Siemens Healthcare Diagnostics Inc., 04/2020.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

## 19. ADDENDA

None

Technical SOP

| | |
|---|---|
| **Title** | **Urea Nitrogen (UN-c) by Atellica CH Analyzer** |
| **Prepared by** | Ashkan Chini Date: 4/27/2021 |
| **Owner** | Robert SanLuis Date: 4/27/2021 |

| **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 |
|---|---|---|
| Urea Nitrogen | Atellica CH Analyzer | BUN |

| Synonyms/Abbreviations |
|---|
| Blood Urea Nitrogen, BUN |

| Department |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide. The ammonia reacts with 2‑oxoglutarate in the presence of glutamate dehydrogenase and reduced nicotinamide adenine dinucleotide (NADH). The oxidation of NADH to oxidized nicotinamide adenine dinucleotide (NAD) is measured as an inverse rate reaction at 340/410 nm.

## 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**<br>**-Other Acceptable** | Plasma (Lithium Heparin)<br>Serum |
| **Collection Container** | Plasma: Mint green top tube (PST)<br>Serum: Red top tube, Serum separator tube (SST) |
| **Volume - Optimum**<br>**- Minimum** | 1.0 mL<br>0.5 mL |

| Criteria | |
|---|---|
| **Transport Container and Temperature** | Collection container or Plastic vial at room temperature |
| **Stability & Storage Requirements** | Room Temperature: 3 – 5 days |
| | Refrigerated: 7 days |
| | Frozen: Indefinitely |
| **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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| Urea Nitrogen (UN-c) | Siemens, Atellica CH, Cat. No. 11097593 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **Urea Nitrogen (UN-c)** |
|---|---|
| **Storage** | Store at 2-8°C |
| **Stability** | Reagents are stable onboard the system for 90 days. |
| **Preparation** | Reagent is liquid and ready to use. |

# 5. CALIBRATORS/STANDARDS

## 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| Chemistry Calibrator (CHEM CAL) | Siemens Atellica CH, Cat. No. 11099411 |

## 5.2 Calibrator Preparation and Storage

| | |
|---|---|
| **Calibrator** | Chemistry Calibrator (CHEM CAL) |
| **Preparation** | 1. Shake to break up lyophilized cake.<br>2. Open each vial carefully.<br>3. Using a calibrated pipette, add exactly 3.0 mL of reagent grade water into the vial. Replace the stopper.<br>4. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete.<br>5. Prior to use, mix by inversion at least 5 times to ensure homogeneity.<br>6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly. |
| **Storage/Stability** | • Protect from heat and light sources.<br>• Store at 2-8°C<br>• **Unopened:** stable until expiration date stamped on box<br>• **Reconstituted:** remains stable for 48 hours |

## 5.3 Calibration Parameter

| Criteria | Special Notations |
|---|---|
| **Reference Material** | Chemistry Calibrator (CHEM 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.<br>• At the end of the lot calibration interval (75 days), for a specified lot of calibrated reagent on the system.<br>• At the end of pack calibration interval (6 days), for calibrated reagent packs on the system.<br>• When indicated by quality control results.<br>• After major maintenance or service.<br><br>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<br>**Thawed and Unopened**: 30 days at 2-8C for BUN<br>**Thawed and Opened**: 14 days at 2-8C for BUN<br>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. |

| Step | Action |
|---|---|
| 2 | **Run Rejection Criteria**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 Urea Nitrogen (UN-c) is required to perform this test.

Urea Nitrogen 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. |

| 8.2 | Specimen Testing |
|---|---|
| 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).<br>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 Urea Nitrogen 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 as a whole number.

### 10.3 Units of Measure

mg/dL

### 10.4 Clinically Reportable Range (CRR)

5 – 300 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… |
|---|---|
| < 5 mg/dL | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 5 mg/dL |
| ≥ 150 mg/dL | **On Board Automated Dilution:**<br>Results ≥ 150 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 2.<br>No multiplication is necessary. |
| > 300 mg/dL | If the recommended dilution does not give results within the clinically reportable range, report as: "> 300 mg/dL -REP"<br>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

| Plasma / Serum | Male/Female | Units |
|---|---|---|
| **Adult (>19 years):** | 7 – 20 | mg/dL |
| | | |
| **Pediatric:** | | |
| 14 – 19 years | 7 - 21 | mg/dL |
| 4 – 13 years | 6 - 17 | mg/dL |
| 1 – 3 years | 4 - 17 | mg/dL |
| 4 – 11 months | 1 - 14 | mg/dL |
| 1 – 3 months | 1 - 12 | mg/dL |
| 8 – 30 days | 1 - 16 | mg/dL |
| 0 – 7 days | 1 - 13 | mg/dL |

### 11.2 Critical Values

None established

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Urea is the major nitrogen-containing metabolic product of protein catabolism in humans. The principal utility of urea nitrogen determination lies in conjunction with measurement of

creatinine in serum or plasma to discriminate between pre-renal and post-renal azotemia. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases. Increases in serum urea nitrogen may be due to pre-renal, renal, or post-renal causes.

## 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)

5 – 150 mg/dL

### 14.2 Precision

| Material | Mean mg/dL | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Serum | 16 | 0.5 | 0.55 |
| Serum QC | 39 | 0.55 | 0.92 |
| Serum QC | 67 | 0.46 | 1.06 |
| Plasma | 118 | 0.91 | 2.96 |

### 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 | 200 mg/dL | 8 | 7 |
| Bilirubin (unconjugated) | 30 mg/dL | 8 | 0 |
| Bilirubin (conjugated) | 30 mg/dL | 9 | -7 |
| Lipemia Intralipid® | 650 mg/dL | 8 | 0 |

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

## 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 Urea Nitrogen 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, Urea Nitrogen Reagent, Siemens Healthcare Diagnostics Inc., 08/2020.
3. Package Insert, Chemistry Calibrator (CHEM CAL), Siemens Healthcare Diagnostics Inc., 04/2020.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

## 19. ADDENDA

None

Technical SOP

| | |
|---|---|
| **Title** | **Glucose (GluH-3) 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 |
|---|---|---|
| Glucose | Atellica CH Analyzer | GLUC |
| Glucose, nonfasting | | GLUCN |
| Glucose, CSF | | CGLUC |
| Glucose, Fluid | | FGLUC |
| Glucose Tolerance Tests (GTT) | | GTT1T, GTT2T, GTT3T, GTT5T |
| GTT, Gestational | | GTT1P, GTT3P |

| Synonyms/Abbreviations |
|---|
| Glucose |

| Department |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

The Atellica CH Glucose Hexokinase-3 (GluH-3) assay uses a two-component reagent. Sample is added to Reagent 1, which contains the buffer, ATP, and NAD. Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Reagent 2 is added, which initiates the conversion of glucose and the development of absorbance at 340/410 nm. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

## 3. SPECIMEN REQUIREMENTS

### 3.1 Patient Preparation

| Component | Special Notations |
|---|---|
| **Fasting/Special Diets** | N/A |
| **Specimen Collection and/or Timing** | Normal procedures for collecting serum, plasma, CSF, and body fluid may be used for samples to be analyzed by this method. Avoid prolonged contact of the serum and plasma with separated red cells. |
| **Special Collection Procedures** | Refer to Field Operations procedure *Glucose Tolerance Tests* for details on GTT scheduling, restrictions and collection. |
| **Other** | N/A |

### 3.2 Specimen Type & Handling

| Criteria | | |
|---|---|---|
| **Type -Preferred**<br>**-Other Acceptable** | Plasma (Lithium Heparin), CSF, Body Fluid<br>Serum, Plasma (Sodium Fluoride Potassium Oxalate) | |
| **Collection Container** | Plasma: Mint green top tube (PST), grey top tube<br>Serum: Red top tube, Serum separator tube (SST)<br>CSF / Body Fluid: Sterile container | |
| **Volume - Optimum**<br>**- Minimum** | 1.0 mL<br>0.5 mL | |
| **Transport Container and Temperature** | Collection container or Plastic vial at room temperature | |
| **Stability & Storage Requirements** | Room Temperature: | Plasma/Serum/CSF: 8 hours<br>Body fluid: To be determined |
| | Refrigerated: | Plasma/Serum/CSF: 3 days<br>Body fluid: To be determined |
| | Frozen: | Not established |
| **Timing Considerations** | CSF may be contaminated with bacteria or other cells and should be analyzed immediately for glucose. If a delay in measurement is unavoidable, keep the specimen refrigerated. | |
| **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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| Glucose Hexokinase-3 (GluH-3) | Siemens, Atellica CH, Cat. No. 11097592 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **Glucose Hexokinase-3 (GluH-3)** |
|---|---|
| **Storage** | Store at 2-8°C |
| **Stability** | Reagents are stable onboard the system for 62 days. |
| **Preparation** | Reagent is liquid and ready to use. |

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| Chemistry Calibrator (CHEM CAL) | Siemens Atellica CH, Cat. No. 11099411 |

### 5.2 Calibrator Preparation and Storage

| **Calibrator** | Chemistry Calibrator (CHEM CAL) |
|---|---|
| **Preparation** | 1. Shake to break up lyophilized cake.<br>2. Open each vial carefully.<br>3. Using a calibrated pipette, add exactly 3.0 mL of reagent grade water into the vial. Replace the stopper.<br>4. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete.<br>5. Prior to use, mix by inversion at least 5 times to ensure homogeneity.<br>6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly. |
| **Storage/Stability** | • Protect from heat and light sources.<br>• Store at 2-8°C<br>• **Unopened:** stable until expiration date stamped on the box.<br>• **Reconstituted:** remains stable for 48 hours |

### 5.3 Calibration Parameter

| **Criteria** | **Special Notations** |
|---|---|
| **Reference Material** | Chemistry Calibrator (CHEM 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.<br>• At the end of the lot calibration interval (182 days), for a specified lot of calibrated reagent on the system.<br>• At the end of pack calibration interval (30 days), for calibrated reagent packs on the system.<br>• When indicated by quality control results.<br>• After major maintenance or service.<br><br>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<br>Cat. No. 12008256, 12008258 |
| Liquichek Spinal Fluid Control Levels 1 & 2 | Bio-Rad Laboratories<br>Cat. No. 751, 752 |

### 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<br>**Thawed and Unopened**: 30 days at 2-8C for glucose<br>**Thawed and Opened**: 14 days at 2-8C for glucose<br>Note: stability varies by assay |

| | |
|---|---|
| **Control** | **Liquichek Spinal Fluid Control, Levels 1 & 2** |
| **Preparation** | Allow to reach room temperature before sampling. Gently swirl vial several time to ensure homogeneity. |
| **Storage/Stability** | **Unopened**: until expiration date at 2-8C<br>**Opened**: stable for 30 days at 2-8C, store tightly capped. |

### 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**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 Glucose Hexokinase-3 (GluH-3) is required to perform this test.

Glucose Hexokinase-3 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).<br>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 Glucose 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 as a whole number.

### 10.3 Units of Measure

mg/dL

### 10.4 Clinically Reportable Range (CRR)

4 – 2100 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… |
|---|---|
| < 4 mg/dL | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 4 mg/dL |
| ≥ 700 mg/dL | **On Board Automated Dilution:** Results ≥ 700 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 3. No multiplication is necessary. |
| > 2100 mg/dL | If the recommended dilution does not give results within the clinically reportable range, report as: "> 2100 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

| Plasma / Serum Glucose | Female | Male |
|---|---|---|
| **Adult (>18 years):** | 74 – 105 mg/dL | 74 – 105 mg/dL |
| | | |
| **Pediatric:** | | |
| 1 month - 18 years | 70 - 110 | 70 - 110 |
| 8 – 30 days | 54 - 117 | 54 - 117 |
| 1 – 7 days | 47 - 110 | 47 - 110 |
| 0 – 1 day | 36 - 89 | 36 - 110 |

Glucose, fasting 65 - 99 mg/dL
Glucose, nonfasting (Post Prandial) 70 - 139 mg/dL
Glucose, CSF 40 - 75 mg/dL

### 11.2 Critical Values

Plasma / Serum Glucose

| Age | LOW | HIGH |
|---|---|---|
| 0 – 30 days | ≤ 30 mg/dL | ≥ 300 mg/dL |
| > 1 month | ≤ 40 mg/dL | ≥ 500 mg/dL |

### 11.3 Standard Required Messages

The following comment is automatically appended to GTT 2 hour and GTT 3 hour (non-pregnancy) tests by the LIS:

Diabetes mellitus may be diagnosed if any of the following criteria are met, alone or in combination, on two separate days:
1). Symptoms of diabetes plus random plasma glucose >=200 mg/dL.
2). Fasting plasma glucose >=126 mg/dL.
3). 2 hr plasma glucose >=200 mg/dL during OGTT (75g. glucose load).

Reference: Diabetes Care 29:S43-S48, 2006

The following comment is automatically appended to gestational GTT 1 hour test by the LIS:

If 1Hr plasma glucose value >=140 mg/dL, after 50g load, the American Diabetes Assn. recommends scheduling patient for a 3 hour, 100g OGTT for a confirmation of Gestational Diabetes.
A cutoff of 140 mg/dL detects 80% of patients with GDM.

Reference: Diabetes Care 29:S43-S48, 2006

The following comment is automatically appended to gestational GTT 3 hour test by the LIS:

*Diagnosis criteria for GDM using the 100 gram OGTT*
Diagnosis of GDM requires any two values to meet or exceed those listed below.
Fasting 95 mg/dL
1 hour 180 mg/dL
2 hour 155 mg/dL
3 hour 140 mg/dL

Reference: Diabetes Care 29:S43-S48, 2006

## 12. CLINICAL SIGNIFICANCE

The hexokinase method is the generally accepted reference method for measuring glucose. Glucose measurements are used in the diagnosis and treatment of disorders of carbohydrate metabolism such as diabetes mellitus, neonatal hypoglycemia, and insulinma.

## 13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared for plasma, serum and CSF
- **FDA Status:** FDA Approved/modified for body fluid
- **Validated Test Modifications:** Testing validated for body (serous) fluid specimens

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)

4 – 700 mg/dL

### 14.2 Precision

| Material | Mean mg/dL | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Serum QC | 59 | 0.5 | 2 |
| Serum Pool | 90 | 0.6 | 1.4 |
| Plasma Pool | 292 | 1.4 | 1.1 |
| Serum Pool | 483 | 1.8 | 1 |
| CSF Pool | 42 | 0.8 | 2.3 |
| CSF Pool | 96 | 0.6 | 1.2 |

### 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 | 1000 mg/dL | 82 | 4 |
| Bilirubin (unconjugated) | 30 mg/dL | 84 | 1 |
| Bilirubin (conjugated) | 30 mg/dL | 85 | -1 |
| Lipemia Intralipid® | 1000 mg/dL | 83 | -5 |

### 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 ≤ 4 mg/dL for serum and plasma. The assay is designed to have a LoB ≤ LoD and LoD ≤ 4 mg/dL for CSF. The LoD corresponds to the lowest concentration of glucose that can be detected with a probability of 95%. The LoD for the Atellica CH GluH-3 assay is 1 mg/dL for serum and plasma, and 2 mg/dL for CSF, and were determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0 mg/dL for serum and plasma, and 1 mg/dL for CSF.

## 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 Glucose Hexokinase-3 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, Glucose Hexokinase-3 Reagent, Siemens Healthcare Diagnostics Inc., 08/2020.
3. Package Insert, Chemistry Calibrator (CHEM CAL), Siemens Healthcare Diagnostics Inc., 04/2020.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020
5. Package Insert, Liquichek Spinal Fluid Controls, Bio-Rad Laboratories, 07/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

## 19. ADDENDA

None

Technical SOP

| | |
|---|---|
| **Title** | **Carbon Dioxide, Concentrated (CO2-c) 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 |
|---|---|---|
| Carbon Dioxide | Atellica CH Analyzer | CO2 |

| Synonyms/Abbreviations |
|---|
| ECO2, CO2, Included in Batteries/Packages: BMP, COMP, and RENP |

| Department |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

The Atellica CH CO2-c assay is based on a phosphoenolpyruvate carboxylase (PEPC) catalyzed reaction followed by an indicator reaction. The indicator reaction uses malate dehydrogenase (MDH) as a catalyst for the oxidization of a reduced nicotinamide adenine dinucleotide (NADH) analog. PEPC catalyzes the first reaction which generates oxaloacetate. In the presence of MDH, the NADH analog is oxidized by oxaloacetate to NAD+ analog. The oxidation of NADH analog is measured by the decreased absorbance at 410/478 nm, which is proportional to the amount of CO2 in the sample.

## 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**<br>**-Other Acceptable** | Plasma (Lithium Heparin)<br>Serum |
| **Collection Container** | Plasma: Mint green top tube (PST)<br>Serum: Red top tube, Serum separator tube (SST) |

| Criteria | |
|---|---|
| **Volume - Optimum**<br>**- Minimum** | 1.0 mL<br>0.5 mL |
| **Transport Container and Temperature** | Collection container or Plastic vial at room temperature |
| **Stability & Storage Requirements** | Room Temperature: To be determined |
| | Refrigerated: 3 days |
| | Frozen: 60 days |
| **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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| Carbon Dioxide (CO2-c) | Siemens, Atellica CH, Cat. No. 11097521 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **Carbon Dioxide (CO2-c)** |
|---|---|
| **Storage** | Store at 2-8°C |
| **Stability** | Onboard per well: 27 days |
| **Preparation** | Reagent is liquid and ready to use. |

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| CO2 Calibrator/Diluent (CO2 CAL) | Siemens Atellica CH, Cat. No. 11099401 |

### 5.2 Calibrator Preparation and Storage

| | |
|---|---|
| **Calibrator** | CO2 Calibrator/Diluent (CO2 CAL) |
| **Preparation** | Calibrators are liquid and ready to use. |
| **Storage/Stability** | • Store at 2-8°C<br>• **Unopened:** stable until expiration date stamped on the box.<br>• **Opened:** 30 days when recapped immediately after use. |

### 5.3 Calibration Parameter

| Criteria | Special Notations |
|---|---|
| **Reference Material** | CO2 Calibrator/Diluent (CO2 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.<br>• At the end of the lot calibration interval (30 days), for a specified lot of calibrated reagent on the system.<br>• At the end of pack calibration interval (6 days), for calibrated reagent packs on the system.<br>• When indicated by quality control results.<br>• After major maintenance or service.<br><br>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 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<br>**Thawed and Unopened**: 30 days at 2-8C for CO2<br>**Thawed and Opened**: 8 hours at 2-8C for CO2<br>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**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |

| Step | Action |
|---|---|
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 Carbon Dioxide, Concentrated (CO2-c) is required to perform this test.

Carbon Dioxide 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).<br>Investigate any flagged results and repeat as necessary. |

| 8.2 | Specimen Testing |
|---|---|
| 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 Carbon Dioxide 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 as a whole number.

### 10.3 Units of Measure

mmol/L

### 10.4 Clinically Reportable Range (CRR)

10 – 80 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… |
|---|---|
| < 10 mmol/L | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 10 mmol/L |

| IF the result is … | THEN… |
|---|---|
| ≥ 40 mmol/L | **On Board Automated Dilution:**<br>Results ≥ 40 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 2.<br>No multiplication is necessary. |
| > 80 mmol/L | If the recommended dilution does not give results within the clinically reportable range, report as: "> 80 mmol/L -REP"<br>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 (>18 years):** | 21 – 32 mmol/L |
| **Pediatric:** | |
| 2 – 18 years | 21 - 32 |
| 13 - 23 months | 16 - 25 |
| 6 – 12 months | 14 - 23 |
| 1 – 5 months | 13 - 23 |
| 7 – 30 days | 13 - 22 |
| 0 – 6 days | 13 - 21 |

### 11.2 Critical Values

< 10 mmol/L

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Increase in serum CO2 content for the most part reflects increase in serum bicarbonate concentration rather than dissolved CO2 gas (which accounts for only a small fraction of the total). Increased serum bicarbonate is seen in compensated respiratory acidosis and in metabolic alkalosis. Diuretics (thiazides, ethacrynic acid, furosemide, mercurials), corticosteroids (in long term use), and laxatives (when abused) may cause increased bicarbonate. Decreased in blood CO2 is seen in metabolic acidosis and compensated respiratory alkalosis. Substances causing metabolic acidosis include ammonium chloride, acetazolamide, ethylene glycol, methanol, paraldehyde, and phenformin. Salicylate

poisoning is characterized by early respiratory alkalosis followed by metabolic acidosis with attendant decreased bicarbonate.

## 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)

10 – 40 mmol/L

### 14.2 Precision

| Material | Mean mmol/L | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Control 1 | 15.0 | 0.21 | 4.17 |
| Control 2 | 24.4 | 0.42 | 4.13 |
| Control 3 | 31.8 | 0.39 | 3.57 |
| Serum Pool A | 17.3 | 0.19 | 0.60 |

### 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 | 600 mg/dL | 17.2 | -4 |
| Bilirubin (unconjugated) | 30 mg/dL | 18.4 | -1 |
| Bilirubin (conjugated) | 30 mg/dL | 17.0 | -2 |
| Lipemia Intralipid® | 750 mg/dL | 16.7 | 1 |

### 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 ≤ 1.0 mmol/L. The LoD corresponds to the lowest concentration of carbon dioxide in human serum and plasma (lithium heparin) that can be detected with a probability of 95%. The LoD for the Atellica CH CO2-c assay is 0.9 mmol/L, and was determined using 165 determinations, with 90 blank and 75 low level replicates, and a LoB of 0.4 mmol/L.

## 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 Carbon Dioxide, Concentrated 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, Carbon Dioxide, Concentrated Reagent, Siemens Healthcare Diagnostics Inc., 04/2019.
3. Package Insert, CO2 Calibrator/Diluent (CO2 CAL), Siemens Healthcare Diagnostics Inc., 05/2017.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

## 19. ADDENDA

None

Technical SOP

| | |
|---|---|
| **Title** | **A-Lyte Integrated Multisensor (IMT Na K Cl) by Atellica CH 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.* | | |

## TABLE OF CONTENTS

## 1. TEST INFORMATION

| Assay | Method/Instrument | Test Code |
|---|---|---|
| Sodium, Plasma/Serum | Atellica CH Analyzer | SOD |
| Urine Sodium, Random | | UNAR |
| Urine Sodium, 24 hour | | UNA24 |
| Potassium, Plasma/Serum | | K |
| Urine Potassium, Random | | UKR |
| Urine Potassium, 24 hour | | UK24 |
| Chloride, Plasma/Serum | | CL |

| **Synonyms/Abbreviations** |
|---|
| Electrolytes, Lytes, Sodium / $Na^+$, Potassium/$K^+$, Chloride/$Cl^-$<br>Sodium, Potassium, and Chloride are part of batteries BMP, COMP, LYTE, and RENP |

| **Department** |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

A diluted sample (1:10 with A‑LYTE IMT Diluent (IMT Diluent)) is positioned in the sensor and Na+, K+ or Cl- ions establish equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

## 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.<br>Random Urine: Clean catch specimen. Deliver to laboratory promptly.<br>24 Hour Urine: Record duration of collection on requisition and container. |

| Component | Special Notations |
|---|---|
| **Special Collection Procedures** | 24 Hour Urine:<br>**Inpatient:** See Laboratory Test Directory (electronic) for details. No preservative should be added. Refrigerate during collection.<br>**Outpatient:** Provide patient with prepared instruction sheet and container. |
| **Other** | N/A |

### 3.2 Specimen Type & Handling

| Criteria | | | |
|---|---|---|---|
| **Type -Preferred**<br>**-Other Acceptable** | Plasma (Lithium Heparin), Urine<br>Serum | | |
| **Collection Container** | Plasma: Mint green top tube (PST)<br>Serum: Red top tube, Serum separator tube (SST)<br>24 Hour Urine: 24-hour container, without additives<br>Random Urine: Urine collection cup | | |
| **Volume - Optimum**<br>**- Minimum** | Plasma/Serum:<br>1.0 mL<br>0.5 mL | 24 hour urine:<br>Total volume collected in 24 hours | Random Urine:<br>10 mL<br>5 mL |
| **Transport Container and Temperature** | Serum/Plasma: Collection container or plastic vial at room temperature.<br>Urine Random: Collection kit or container at room temperature submitted within 2 hour of collection.<br>Urine 24 hour: Collection container at room temperature. | | |
| **Stability & Storage Requirements** | Room Temperature: | Serum/Plasma: To be determined<br>Urine: To be determined | |
| | Refrigerated: | Serum/Plasma/Urine: 7 days | |
| | Frozen: | Serum/Plasma/Urine: 30 days | |
| **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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| A-Lyte Integrated Multisensor (IMT Na K Cl) | Siemens, Atellica CH, Cat. No. 11099315 |
| A-Lyte IMT Dilution Check | Siemens, Atellica CH, Cat. No. 11099325 |
| A-Lyte IMT Diluent | Siemens, Atellica CH, Cat. No. 11099305 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **A-Lyte Integrated Multisensor (IMT Na K Cl)** |
|---|---|
| **Storage** | Store at 2-8°C |
| **Stability** | **Unopened:** until expiration date stamped on the box<br>**Onboard:** remains stable onboard the system for 14 days or 5000 samples per multisensory |
| **Preparation** | It is ready to use. |

| **Reagent** | **A-Lyte IMT Dilution Check** |
|---|---|
| **Storage** | Store at 2-30°C |
| **Stability** | **Unopened:** until expiration date stamped on the box<br>**Opened**: use immediately |
| **Preparation** | It is liquid and ready to use. |

| **Reagent** | **A-Lyte IMT Diluent** |
|---|---|
| **Storage** | Store at 2-30C |
| **Stability** | **Unopened:** until expiration date stamped on the box<br>**Onboard**: 90 days |
| **Preparation** | It is liquid and ready to use. |

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| A-Lyte IMT Standard A | Siemens, Atellica CH, Cat. No. 11099304 |
| A-Lyte IMT Standard B + Salt Bridge | Siemens, Atellica CH, Cat. No. 11099306 |

### 5.2 Calibrator Preparation and Storage

| **Reagent** | **A-Lyte IMT Standard A / Standard B + Salt Bridge** |
|---|---|
| **Storage** | Store at 2-30°C |
| **Stability** | **Unopened:** until expiration date stamped on the box<br>**Onboard**: 30 days |
| **Preparation** | It is liquid and ready to use. |

### 5.3 Calibration Parameter

| **Criteria** | **Special Notations** |
|---|---|
| **Reference Material** | **Standard A, Standard B and Salt Bridge** |
| **Assay Range** | See Reagent Package Insert for specific AMR values. |
| **Suggested Calibration Level** | See Reagent Package Insert for lot specific assigned values |
| **Frequency** | • Every new reagent lot.<br>• IMT system performs a two point automatic calibration in duplicate every 4 hours. In addition, the system will routinely perform a one point calibration check with each sample measurement.<br>• When major maintenance is performed on the analyzer.<br>• When control data indicates a significant shift in assay. |

### 5.4 Calibration Procedure

For calibration of the A‑LYTE IMT Na K Cl, the system performs a two point automatic calibration in duplicate every 4 hours. In addition, the system will routinely perform a one point calibration check with each sample measurement. Auto-calibration occurs after power-on, with the changing of A‑LYTE IMT Standard A, A‑LYTE IMT Standard B + Salt Bridge, or a sensor and when the system software is reset. Calibration can be initiated at any time a sample is not being run. Perform a calibration when indicated by quality control results and after major maintenance or service, if indicated by quality control results.

### 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 Assayed Multiqual Control Levels 1 & 3 | Bio-Rad Laboratories<br>Cat. No. 12008256, 12008258 |
| InteliQ Urine Chemistry Control Levels 1 & 2 | Bio-Rad Laboratories<br>Cat. No. 12009995, 12009996 |

### 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<br>**Thawed and Unopened**: 30 days at 2-8C for Lytes<br>**Thawed and Opened**: 14 days at 2-8C for Lytes<br>Note: stability varies by assay |

| **Control** | **InteliQ Urine Chemistry Control, Levels 1 & 2** |
|---|---|
| **Preparation** | Remove cap and place in instrument for testing |
| **Storage/Stability** | **Unopened**: until expiration date at 2-8C<br>**Opened & On-board**: 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. |

| Step | Action |
|---|---|
| 2 | **Run Rejection Criteria**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 A-Lyte Integrated Multisensor is required to perform this test.

Electrolytes are 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 |

| 8.2 | Specimen Testing |
|---|---|
| 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).<br>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 electrolytes in mmol/L.

Anion gap is calculated electronically by the LIS using the following formula:

$Na^+ – (Cl^- + CO_2) = AGAP$ mmol/L

**Notes:**

- If the calculation yields a negative number, LIS will replace it with "HIDE".
- For 24 hour urines, the LIS will calculate the result per 24hrs if the random urine result from the aliquot is within the CRR. If the urine random value is above or below the CRR, then report the 24hr value as UTC (unable to calculate).

## 10. REPORTING RESULTS AND REPEAT CRITERIA

### 10.1 Interpretation of Data

None required

### 10.2 Rounding

No rounding is necessary. Instrument reports Sodium and Chloride as a whole number and reports Potassium up to one decimal point.

### 10.3 Units of Measure

mmol/L

### 10.4 Clinically Reportable Range (CRR)

| Analyte | Serum/Plasma | Urine |
|---|---|---|
| Sodium | 50 – 200 mmol/L | 10 – 300 mmol/L |
| Potassium | 1.0 – 10.0 mmol/L | 2.0 – 300.0 mmol/L |
| Chloride | 50 – 200 mmol/L | N/A |

### 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… |
|---|---|
| Plasma/serum<br><br>Na >200 mmol/L<br>K >10.0 mmol/L<br>Cl >200 mmol/L | Repeat the assay using the primary sample. If results are still greater than the CRR, bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results. |
| Urine results<br><br>Na >300 mmol/L<br>K >300.0 mmol/L | Repeat the assay using a freshly prepared aliquot from the primary sample. If results are still greater than the CRR, 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

**Plasma/Serum:**

| Age | Sodium | Potassium | Chloride |
|---|---|---|---|
| **Adult (>18 years):** | 135 – 145 mmol/L | 3.5 – 5.1 mmol/L | 98 – 107 mmol/L |
| | | | |
| **Pediatric:** | | | |
| > 2 years | 135 - 145 | 3.5 - 5.1 | 98 - 107 |
| 13 – 24 months | 132 - 141 | 3.3 - 4.7 | 97 - 107 |
| 6 – 12 months | 131 - 140 | 3.5 - 6.1 | 97 - 106 |
| 1 – 5 months | 132 - 140 | 3.5 - 5.8 | 97 - 108 |
| 7 – 30 days | 132 - 142 | 3.4 - 6.1 | 97 - 108 |
| 0 – 6 days | 131 - 144 | 3.5 - 5.7 | 97 - 108 |

**Anion gap** 4 – 14 mmol/L

**Random Urine:**

| Age | Sodium | Potassium |
|---|---|---|
| **All** | 40 – 220 mmol/L | 25.0 – 125.0 mmol/L |

**24 hour Urine:**

| Age | Sodium | Potassium |
|---|---|---|
| **All** | 40 – 220 mmol/24hr | 25.0 – 125.0 mmol/24hr |

### 11.2 Critical Values

**Plasma/serum:**

| Analyte | Low Critical Values | High Critical Values |
|---|---|---|
| Na | < 120 mmol/L | > 160 mmol/L |
| K | < 3.0 mmol/L | > 6.1 mmol/L |
| Cl | < 75 mmol/L | > 126 mmol/L |

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Sodium, potassium, and chloride are commonly analyzed together in a metabolic panel since their concentrations provide the most relevant information about osmotic, hydration, and pH status of the body. The methods for measurement of electrolytes include flame photometry, spectrophotometry and direct or indirect ion selective electrode potentiometry.

## 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)

| Analyte | Serum / Plasma | Urine |
|---|---|---|
| Sodium | 50 – 200 mmol/L | 10 – 300 mmol/L |
| Potassium | 1.0 – 10.0 mmol/L | 2.0 – 300.0 mmol/L |
| Chloride | 50 – 200 mmol/L | N/A |

## 14.2 Precision

| Material | Mean mmol/L | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Na Serum Pool | 73.6 | 0.36 | 0.5 |
| Na Serum QC | 116 | 0.69 | 0.6 |
| Na Urine Pool | 32.2 | 0.33 | 1.0 |
| Na Urine QC | 80.3 | 0.52 | 0.6 |
| K Serum QC | 2.64 | 0.01 | 0.4 |
| K Serum Pool | 5.92 | 0.03 | 0.5 |
| K Urine QC | 31.2 | 0.15 | 0.5 |
| K Urine Pool | 258 | 2.01 | 0.8 |
| Cl Serum QC | 78.1 | 0.73 | 0.9 |
| Cl Serum Pool | 189 | 1.01 | 0.5 |

## 14.3 Interfering Substances

- Hemolyzed samples may give incorrect elevated potassium results. Intracellular potassium concentration is 30-50 fold greater than that of extracellular serum or plasma.
- Samples exposed to Benzalkonium salts present in certain blood catheter devices will cause falsely elevated sodium and potassium measurements.
- Salicylate at 50 mg/dL increases the chloride result at 98.5 mmol/L by 11%.
- Iron at 1 g/dL increases the potassium result at 2.69 mmol/L by 17%.
- Citrate at 1 g/dL decreases the chloride result at 82.4 mmol/L by -12%.
- Fluoride at 1 g/dL increases the chloride result at 81.7 mmol/L by 40%.
- Iodine at 50 mg/dL increases the chloride result at 82.2 mmol/L by 16%.
- Bromide at 200 mg/dL increases the chloride result at 82.1 mmol/L by 55%.

**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 % |
|---|---|---|---|
| Na Hemoglobin | 750 mg/dL | 123 | 2 |
| Na Bilirubin (conjugated) | 60 mg/dL | 122 | 2 |
| Na Bilirubin (unconjugated) | 60 mg/dL | 127 | 0 |
| Na Lipemia Intralipid® | 3000 mg/dL | 129 | -1 |
| K Bilirubin (conjugated) | 60 mg/dL | 2.72 | -1 |
| K Bilirubin (unconjugated) | 60 mg/dL | 2.73 | -1 |
| K Lipemia Intralipid® | 3000 mg/dL | 2.87 | 4 |
| Cl Hemoglobin | 750 mg/dL | 84.1 | 3 |
| Cl Bilirubin (conjugated) | 60 mg/dL | 83.4 | 1 |
| Cl Bilirubin (unconjugated) | 60 mg/dL | 84.6 | 0 |
| Cl Lipemia Intralipid® | 3000 mg/dL | 87 | -1 |
| Cl Salicylate | 30 mg/dL | 87 | 7 |

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

**Detection Capability**
The Na assay is designed to have a limit of quantitation (LoQ) ≤ 50 mmol/L with ≤ 20% total error for serum and plasma, and ≤ 10 mmol/L with ≤ 30% total error for urine. The K assay is designed to have a LoQ ≤ 1 mmol/L with ≤ 20% total error for serum and plasma, and ≤ 2 mmol/L with < 30% total error for urine. The Cl assay is designed to have a LoQ ≤ 50 mmol/L with ≤ 20% total error for serum and plasma, and ≤ 20 mmol/L with ≤ 30% total error for urine.

## 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 A-Lyte Integrated Multisensor 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, A-Lyte Integrated Multisensor Reagent, Siemens Healthcare Diagnostics Inc., 09/2019.
3. Package Insert, A-Lyte IMT System Fluids, Siemens Healthcare Diagnostics Inc., 05/2020.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020
5. Package Insert, InteliQ Urine Chemistry Controls, Bio-Rad Laboratories, 11/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

## 19. ADDENDA

None

Technical SOP

| | |
|---|---|
| **Title** | **Creatinine (Crea-2) by Atellica CH Analyzer** |
| **Prepared by** | Ashkan Chini Date: 4/27/2021 |
| **Owner** | Robert SanLuis Date: 4/27/2021 |

| **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 |
|---|---|---|
| Creatinine, Serum/Plasma | Atellica CH Analyzer | CREAT |
| Creatinine, Urine, Random | | UCRR |
| Creatinine, Urine, 24 hour | | UCR24 |
| Creatinine, Body Fluid | | FCREAT |
| Creatinine Clearance | | CRCL |

| **Synonyms/Abbreviations** |
|---|
| Serum/Plasma Creatinine, Random Urine Creatinine, 24hour Urine Creatinine, Body Fluid Creatinine, CREAT |

| **Department** |
|---|
| Chemistry |

## 2. ANALYTICAL PRINCIPLE

The Atellica CH Crea-2 assay reacts with picric acid in an alkaline medium to produce a red-colored creatinine picrate complex. The rate of complex formation is measured at 505/571 nm and is proportional to the creatinine concentration. The Atellica CH Crea-2 assay is a modification of the Jaffe method, using rate blanking and intercept correction. Rate blanking is used to minimize bilirubin interference. Also, because non-specific serum/plasma protein interactions with this reagent have been found to produce a positive bias of approximately 0.3 mg/dL, serum/plasma measurements are automatically corrected by subtracting 0.3 mg/dL from each result.

## 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, plasma, urine, and body fluid (serous) may be used for samples to be analyzed by this method. |

| Component | Special Notations |
|---|---|
| **Special Collection Procedures** | Preferred method for random urine is Urine Collection Kit with specimen transferred to Urine Chemistry Collection Tube (yellow top).<br>24 hour urine must be stored at 2-8°C and analyzed within 4 days.<br>**Creatinine Clearance:** a serum creatinine level must be drawn within 24 hours of the 24-hr urine collection beginning or ending time. |
| **Other** | Submit random urine specimens to Laboratory within 2 hours of collection.<br>For Creatinine Clearance calculations, patient's height and weight are required. |

## 3.2 Specimen Type & Handling

| Criteria | | |
|---|---|---|
| **Type -Preferred** | | Plasma (Lithium Heparin), Urine and Body Fluid (serous fluid only) |
| **-Other Acceptable** | | Serum |
| **Collection Container** | | Plasma: Mint green top tube (PST)<br>Serum: Red top tube, Serum separator tube (SST)<br>Urine: Urine Collection Kit, sterile specimen container, 24 hour container<br>Body Fluid: Sterile/Clean container or tube |
| **Volume - Optimum** | | 1.0 mL |
| **- Minimum** | | 0.5 mL |
| **Transport Container and Temperature** | | Plasma/Serum/Body Fluid: Collection container or plastic vial at room temperature.<br>Urine, Random: Urine Chemistry Collection Tube (yellow top) or container at room temperature submitted within 2 hours of collection.<br>Urine, 24 hours: Collection container at room temperature. |
| **Stability & Storage Requirements** | Room Temperature: | Plasma/Serum: 24 hours<br>Body Fluid: To be determined<br>Urine: Not recommended |
| | Refrigerated: | Plasma/Serum: 7 days<br>Body Fluid: To be determined<br>Urine: 4 days |
| | Frozen: | Plasma/Serum: 3 months<br>Body Fluid /Urine: Not established |
| **Timing Considerations** | | Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection. |

| Criteria | |
|---|---|
| **Unacceptable Specimens & Actions to Take** | Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Urine samples in Urine Analysis Preservative Tubes and synovial fluid are NOT acceptable.<br>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.<br>Before placing on system, ensure samples are free of:<br>• Bubbles or foam<br>• 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 |
|---|---|
| Creatinine-2 (Crea-2) | Siemens, Atellica CH, Cat. No. 11097596 |

### 4.2 Reagent Preparation and Storage

| **Reagent** | **Creatinine-2 (Crea-2)** |
|---|---|
| **Storage** | Store at 15-25°C |
| **Stability** | Onboard per well: 17 days |
| **Preparation** | Reagent is liquid and ready to use. |

## 5. CALIBRATORS/STANDARDS

## 5.1 Calibrators/Standards Used

| Calibrator | Supplier and Catalog Number |
|---|---|
| Chemistry Calibrator (CHEM CAL) | Siemens Atellica CH, Cat. No. 11099411 |

## 5.2 Calibrator Preparation and Storage

| **Calibrator** | Chemistry Calibrator (CHEM CAL) |
|---|---|
| **Preparation** | 1. Shake to break up lyophilized cake.<br>2. Open each vial carefully.<br>3. Using a calibrated pipette, add exactly 3.0 mL of reagent grade water into the vial. Replace the stopper.<br>4. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete.<br>5. Prior to use, mix by inversion at least 5 times to ensure homogeneity.<br>6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly. |
| **Storage/Stability** | • Protect from heat and light sources.<br>• Store at 2-8°C<br>• **Unopened:** stable until expiration date stamped on the box.<br>• **Reconstituted:** remains stable for 48 hours |

## 5.3 Calibration Parameter

| **Criteria** | **Special Notations** |
|---|---|
| **Reference Material** | Chemistry Calibrator (CHEM 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.<br>• At the end of the lot calibration interval (180 days), for a specified lot of calibrated reagent on the system.<br>• At the end of pack calibration interval (6 days), for calibrated reagent packs on the system.<br>• When indicated by quality control results.<br>• After major maintenance or service.<br><br>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 |
| InteliQ Urine Chemistry Control Levels 1 & 2 | Bio-Rad Laboratories Cat. No. 12009995, 12009996 |

### 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<br>**Thawed and Unopened**: 30 days at 2-8C for CREAT<br>**Thawed and Opened**: 14 days at 2-8C for CREAT<br>Note: stability varies by assay |

| **Control** | **InteliQ Urine Chemistry Control Levels 1 & 2** |
|---|---|
| **Preparation** | Before use, gently invert to ensure homogeneity. |
| **Storage/Stability** | **Unopened**: until expiration date at 2-8C<br>**Opened & On-board**: 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**<br>• 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.<br>• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem. |
| 3 | **Corrective Action**:<br>• 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.<br>• Corrective action documentation must follow the Laboratory Quality Control Program. |
| 4 | **Review of QC**<br>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.<br>• 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 Creatinine-2 (Crea-2) is required to perform this test.

Creatinine-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. |

| 8.2 | 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).<br>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 Creatinine in mg/dL.
The LIS performs the following calculations.

### 9.1 Creatinine Clearance

Units for this formula:
Volume in mL
Height in inches
Weight in pounds

$$\left[\left(\frac{\text{Urine Creat.}}{\text{Serum Creat.}}\right) \text{ x } \left(\frac{\text{Volume}}{\text{number of hours x 60 min } (24 \text{ x } 60 = 1440).}\right)\right] \text{ X } \left[\frac{1.73}{\left(\sqrt[2.35294]{\left(\frac{\text{weight}}{2.2}\right)}\right) \text{ x } \left(\sqrt[1.3793103]{(\text{height x } 2.54)}\right) \text{ x } \left(\frac{71.84}{10000}\right)}\right]$$

### 9.2 24 hour Urine Creatinine

$$\frac{\text{Urine Creatinine X Volume in mL}}{100}$$

### 9.3 Estimated Glomerular Filtration Rate (eGFR)

For non-black individuals:
186 x (Serum Creatinine)$^{-1.154}$ x (Age)$^{-0.203}$ x (0.742 **if female**)

For black individuals:
186 x (Serum Creatinine)$^{-1.154}$ x (Age)$^{-0.203}$ x (0.742 **if female**) x (1.210)

**Notes:**

- eGFR is only reported on patients 18 years of age or older.
- eGFR is calculated once per 12 hours.

- If the creatinine result is corrected after initial reporting, verify that GFR has also been corrected

## 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. Calculated values are reported at whole numbers.

### 10.3 Units of Measure

Creatinine and 24 hour creatinine: mg/dL
Creatinine Clearance: mL/min/$m^2$
eGFR: mL/min/1.73$m^2$

### 10.4 Clinically Reportable Range (CRR)

Serum/Plasma/Body Fluid: 0.15 – 60.00 mg/dL
Urine: 3.00 – 735.00 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.

**Serum/Plasma/Body Fluid:**

| IF the result is … | THEN… |
|---|---|
| < 0.15 mg/dL | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.15 mg/dL |
| ≥ 30.00 mg/dL | **On Board Automated Dilution:**<br>Results ≥ 30.00 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 2.<br>No multiplication is necessary. |

| IF the result is … | THEN… |
|---|---|
| > 60.00 mg/dL | If the recommended dilution does not give results within the clinically reportable range, report as: "> 60.00 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. |

**Urine**:

| IF the result is … | THEN… |
|---|---|
| < 3.00 mg/dL | Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 3.00 mg/dL |
| ≥ 245.00 mg/dL | **On Board Automated Dilution:** Results ≥ 245.00 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 3. No multiplication is necessary. |
| > 735.00 mg/dL | If the recommended dilution does not give results within the clinically reportable range, report as: "> 735.00 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

**Serum/Plasma:**

| Age | Female | Male |
|---|---|---|
| **Adult (>18 years):** | 0.55 – 1.02 mg/dL | 0.70 – 1.30 mg/dL |
| | | |
| **Pediatric:** | | |
| 16 – 18 years | 0.80 - 1.20 | 0.80 - 1.40 |
| 13 – 15 years | 0.70 - 1.10 | 0.60 - 1.20 |
| 10 – 12 years | 0.60 - 1.00 | 0.60 - 1.00 |
| 7 – 9 years | 0.50 - 0.90 | 0.60 - 0.90 |
| 4 – 6 years | 0.50 - 0.80 | 0.50 - 0.80 |
| 1 – 3 years | 0.40 - 0.70 | 0.40 - 0.70 |
| 1 – 11 months | 0.40 - 0.60 | 0.40 - 0.70 |
| 0 – 30 days | 0.50 - 0.90 | 0.50 - 1.20 |

**Body Fluid:**
0.50 – 2.00 mg/dL

**Urine:**
30.00 – 125.00 mg/dL

**24 hour Urine:**
600 – 2500 mg/24 hours

**Creatinine Clearance:**
80 – 120 mL/min/$m^2$

### 11.2 Critical Values

None established

### 11.3 Standard Required Messages

Each eGFR result has the following comment automatically reported by the LIS:

The eGFR equation utilized is the MDRD for Adults (patients 18 and older). The equation does not require weight as we utilize a normalized body surface area of 1.73m2.

The table below shows population estimates for mean (average) estimated glomerular filtration (eGFR) by age. These means are derived from the NHANES III survey of over 10,000 individuals, demonstrating that eGFR varies across age groups and that kidney function tends to decline with age.

| Age Years | Mean eGFR |
|---|---|
| 18-29 | 116 mL/min/1.73m2 |
| 30-39 | 107 mL/min/1.73m2 |
| 40-49 | 99 mL/min/1.73m2 |
| 50-59 | 93 mL/min/1.73m2 |
| 60-69 | 85 mL/min/1.73m2 |
| 70+ | 75 mL/min/1.73m2 |

## 12. CLINICAL SIGNIFICANCE

The creatinine method employs a modification of the kinetic Jaffe reaction. This method has been reported to be less susceptible than conventional methods to interference from non-creatinine, Jaffe-positive compounds. Creatinine is generally regarded as the most useful endogenous substance to measure for the assessment of kidney function. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

## 13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared for plasma, serum and urine
- **FDA Status:** FDA Approved/modified for body fluid
- **Validated Test Modifications:** Testing validated for body (serous) fluid specimens

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)

Serum/Plasma/Body Fluid: 0.15 – 30.00 mg/dL
Urine: 3.00 – 245.00 mg/dL

### 14.2 Precision

| Material | Mean mg/dL | Standard Deviation (%CV) | |
|---|---|---|---|
| | | Repeatability | Within-Lab |
| Serum | 0.38 | 0.006 | 0.010 |
| Plasma Pool | 0.66 | 0.008 | 0.018 |
| Serum Pool | 1.16 | 0.010 | 0.017 |
| Serum QC | 1.97 | 0.018 | 0.024 |
| Serum Pool | 19.31 | 0.053 | 0.145 |
| Urine QC | 59.62 | 0.153 | 0.376 |
| Urine | 188.61 | 0.522 | 1.779 |

### 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 (hemolysate) | 500 mg/dL | 1.53 | 4.4 |
| Bilirubin (unconjugated) | 10 mg/dL | 1.62 | 2.5 |
| Bilirubin (conjugated) | 20 mg/dL | 1.61 | -7.3 |
| Lipemia Intralipid® | 500 mg/dL | 1.55 | -1.1 |

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

**Detection Capability:**
The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the Atellica CH Crea-2 assay is 0.03 mg/dL for serum and plasma, and 0.35 mg/dL for urine. The LoD is the smallest amount that this assay can reliably detect to determine presence or absence of an analyte. The LoD for the Atellica CH Crea-2 assay is 0.08 mg/dL for serum and plasma, and 0.51 mg/dL for urine. The LoB and LoD values are determined with proportions of false positives less than 5% and false negatives less than 5%, based on 120 determinations of 60 blanks and 60 low level sample replicates for each of 3 lots. For serum and plasma, the LoQ is 0.15 mg/dL based on 2250 determinations, with a total error of ≤ 0.1 mg/dL. For urine the LoQ is 3.00 mg/dL based on 2250 determinations, with a total error of ≤ 1.5 mg/dL.

## 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.

Atellica Creatinine_2 reagent may be corrosive to metals. Causes severe skin burns and eye damage. Wear protective gloves/protective clothing/eye protection/face protection. Immediately call a POISON CENTER or doctor/physician. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
**Contains:** Sodium hydroxide

## 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 Creatinine-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, Creatinine-2 Reagent, Siemens Healthcare Diagnostics Inc., 07/2019
3. Package Insert, Chemistry Calibrator (CHEM CAL), Siemens Healthcare Diagnostics Inc., 04/2020
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 07/2020
5. Package Insert, InteliQ Urine Chemisty Controls, Bio-Rad Laboratories, 11/2020

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

## 19. ADDENDA

None