**TRAINING UPDATE**

| | | | |
|---|---|---|---|
| **Lab Location:** | GEC, SGMC & WAH | **Date Distributed:** | 6/4/2018 |
| **Department:** | Core Lab | **Due Date:** | 6/26/2018 |
| | | **Implementation:** | **6/26/2018** |

**DESCRIPTION OF PROCEDURE REVISION**

**Name of procedure:**

## Specific Gravity Using the Refractometer SGAH.U14 v2

*This has been converted to a system SOP*

**Description of change(s):**

*Most changes are to make SOP match practice or format updates*

| Section | Reason |
|---|---|
| Header | Add other sites |
| 5,6 | Remove individual section labeling instructions and add general one |
| 10.5 | Move patient review from section 6 |
| 10.6 | Add reporting above CRR |
| 15 | Update to new standard wording |

This revised SOP will be implemented on June 26, 2018

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

Technical SOP

| | |
|---|---|
| **Title** | **Specific Gravity Using the Refractometer** |
| **Prepared by** | Ashkan Chini Date: 2/14/2012 |
| **Owner** | Robert SanLuis Date: 3/18/2016 |

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

| **Review** | | |
|---|---|---|
| **Print Name** | **Signature** | **Date** |
| | | |
| | | |
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| | | |
| | | |
| | | |

Form revised 10/31/02

## TABLE OF CONTENTS

1. Test Information....2
2. Analytical Principle....3
3. Specimen Requirements....3
4. Reagents....4
5. Calibrators/Standards....4
6. Quality Control....4
7. Equipment And Supplies....6
8. Procedure....6
9. Calculations....7
10. Reporting Results And Repeat Criteria....7
11. Expected Values....8
12. Clinical Significance....8
13. Procedure Notes....8
14. Limitations Of Method....8
15. Safety....8
16. Related Documents....9
17. References....9
18. Revision History....9
19. Addenda....9

## 1. TEST INFORMATION

| Assay | Method/Instrument | Local Code |
|---|---|---|
| Specific Gravity | Refractometer | USPG |

| Synonyms/Abbreviations |
|---|
| SG |

| Department |
|---|
| Urinalysis |

## 2. ANALYTICAL PRINCIPLE

Specific gravity is a ratio of the weight, or mass, per unit volume. It can be measured on a refractometer. By holding the instrument toward a light source, a convergent light beam strikes the surface between the unknown sample of index and a prism of known index. The beam is so oriented that some of its rays just graze the surface so that one observes in the transmitted light, a sharp boundary between light and dark fields when a specimen is present in the instrument.

## 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 urine may be used for samples to be analyzed by this method. Transfer contents to Urine Collection Kit to better preserve the sample. |
| **Special Collection Procedures** | A first-morning specimen is preferred but random collections are acceptable. |
| **Other** | If Urine Collection Kit is not used, submit to Laboratory within 2 hours of collection. |

### 3.2 Specimen Type & Handling

| Criteria | | |
|---|---|---|
| **Type -Preferred**<br>**-Other Acceptable** | Urine, freshly voided<br>Random urine | |
| **Collection Container** | Clean or sterile container | |
| **Volume - Optimum**<br>**- Minimum** | 2 mL<br>1 mL | |
| **Transport Container and Temperature** | Urine Collection Kit or container at room temperature | |
| **Stability & Storage Requirements** | Room Temperature: | 24 hours in Urine Analysis Preservative Tube<br>2 hours for other containers |
| | Refrigerated: | 24 hours |
| | Frozen: | Unacceptable |
| **Timing Considerations** | Test the urine within two hours after voiding. | |

Form revised 10/31/02

| Criteria | |
|---|---|
| **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** | If specimen is refrigerated, let it return to room temperature before testing. |
| **Other Considerations** | After testing samples will be held until the next successful QC performance. |

**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.**

## 4. REAGENTS

N/A

## 5. CALIBRATORS/STANDARDS

Calibration is checked daily by using reagent grade water and saline. Refer to section 6.

## 6. QUALITY CONTROL

### 6.1 Controls Used

| Controls | Supplier and Catalog Number |
|---|---|
| Reagent grade water | NERL Diagnostics (Cat. No. 0015) |
| 5 % NaCl | Thermo Scientific (Cat. No. 23-535-435) |

### 6.2 Control Preparations and Storage

| Control | NERL Reagent Grade Water |
|---|---|
| **Preparation** | Ready for use |
| **Storage/Stability** | Room temperature<br>**Unopened**: Stable until expiration date printed on the bottle<br>**Opened**: Expiration date is 30 days |

| | |
|---|---|
| **Control** | **5% NaCl** |
| **Preparation** | Ready for use |
| **Storage/Stability** | Room temperature, stable until expiration date printed on bottle. |

### 6.3 Frequency

Both levels of Quality Control are tested once per day.

### 6.4 Tolerance Limits and Criteria for Acceptable QC

| QC Material | Expected Reading | Acceptable Range |
|---|---|---|
| Reagent grade water | 1.000 | 0.009 – 1.001 |
| 5 % NaCl | 1.023 | 1.023 – 1.025 |

Both QC Values must be within acceptable limits.

| IF the result is … | THEN… |
|---|---|
| not acceptable | • Verify it is the correct control.<br>• Verify the control has not expired.<br>• Check for technical/clerical errors.<br>• Visually inspect the condition of the control.<br>• Repeat the QC test.<br>• Notify the Supervisor if these results are not acceptable. |

If the QC result is still not within normal ranges, report all patient results using urine chemistry strips. Refer to SOP Urinalysis, Multistix 10 SG Reagent Strips.

### 6.5 Documentation

- Record results on Refractometer Quality Control log, located in the appropriate QC binder.
- 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

- 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.
- Consult the Laboratory QC program for complete details.

## 7. EQUIPMENT and SUPPLIES

### 7.1 Assay Platform

N/A

### 7.2 Equipment

Refractometer (TS Meter)

### 7.3 Supplies

Disposable pipettes

## 8. PROCEDURE

**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 | Test Run |
|---|---|
| 1 | Clean the surfaces of the cover and prism of the refractometer with a damp cloth and dry. |
| 2 | Close the cover |
| 3 | Apply a drop of specimen at the notched section of the cover. Allow the specimen to flow over the prism surface by capillary action. |
| 4 | Point the refractometer toward the light source at an angle that gives optimum contrast when looking through the eyepiece. |
| 5 | Rotate the eyepiece until the scale is in focus. |
| 6 | Read directly on the specific gravity scale, the sharp line dividing light and dark represents the reading. |

Some medications cause urine to become abnormally colored (GREEN, AMBER, ORANGE or PINK). For urines that are abnormally colored:

| 8.2 | Color Interference |
|---|---|
| 1. | Verify the specific gravity by manual refractometer (rounding to the nearest .005). Report the results of the manual refractometer. |

| 8.3 | Bloody Urines |
|---|---|
| 1. | In the case of urines that are grossly bloody, attempt to read the specific gravity on the refractometer. If the blood interferes with the reading proceed to step 2. |
| 2. | Centrifuge the specimen. Pour the supernatant into a separate test tube. |
| 3. | Measure the specific gravity on the supernatant by manual refractometer. |

**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

Not applicable

## 10. REPORTING RESULTS AND REPEAT CRITERIA

### 10.1 Interpretation of Data

N/A

### 10.2 Rounding

Report results up to three decimal points.

### 10.3 Units of Measure

N/A

### 10.4 Clinically Reportable Range (CRR)

1.000 - 1.035

### 10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results. Resolve any problems noted before issuing patient reports. Repeat patient samples with other methodologies if necessary.

### 10.6 Repeat Criteria and Resulting

| IF the result is … | THEN… |
|---|---|
| > 1.035 | Report as: > 1.035 |

Results are recorded in the LIS
Function: **MEM**
Worksheet: **SCL** (SGMC), **WCL** (WAH) or **GCL** (GEC)
Test code: **USPG**

## 11. EXPECTED VALUES

### 11.1 Reference Ranges

1.005 – 1.030

### 11.2 Critical Values

None established

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Considerable variation in the specific gravity of random specimens is seen over a 24-hour period. Early morning samples are usually the most concentrated. The inability to concentrate or dilute urine is an indication of renal disease or hormonal deficiency (ADH).

## 13. PROCEDURE NOTES

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

## 14. LIMITATIONS OF METHOD

### 14.1 Analytical Measurement Range (AMR)

1.000 – 1.035

### 14.2 Precision

N/A

### 14.3 Interfering Substances

Various substances such as radiographic dyes, glucose and protein can increase the Specific Gravity in urine.

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

## 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. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Quest Diagnostics Records Management Procedure
5. Urinalysis, Multistix 10 SG Reagent Strips (UA procedure)
6. Refractometer Quality Control Log (AG.F346)

## 17. REFERENCES

1. Refractometer User Guide, NSG Precision Cells, Inc. Farmingdale, NY
2. Laboratory Test handbook, David S. Jacobs 3rd Edition, 1994.
3. School of Health Care Services, USAF. Medical Laboratory Technician. (Chemistry and Urinalysis). Extension Course Institute, 1976.

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| | | | Supersedes U013.001 | | |
| 000 | 3/18/16 | | Update owner | L Barrett | R SanLuis |
| 000 | 3/18/16 | 3.1, 3.2 | Add urine collection kit and stability for preservative tube | A Chini | R SanLuis |
| 000 | 3/18/16 | 6.4 | Edit acceptable range for water | L Barrett | R SanLuis |
| 000 | 3/18/16 | 6.6 | Edit QC form | L Barrett | R SanLuis |
| 000 | 3/18/16 | 10.2 | Add number of decimals | A Chini | R SanLuis |
| 000 | 3/18/16 | 10.4 | Display CRR as range (remove > sign) | A Chini | R SanLuis |
| 000 | 3/18/16 | 16 | Add QC form | L Barrett | R SanLuis |
| 000 | 3/18/16 | 19 | Remove UA form | L Barrett | R SanLuis |
| 000 | 3/18/16 | Footer | Version # leading zero's dropped due to new EDCS in use as of 10/7/13 | L Barrett | R SanLuis |
| 1 | 5/21/18 | Header | Add other sites | L Barrett | R SanLuis |
| 1 | 5/21/18 | 5,6 | Remove individual section labeling instructions and add general one | L Barrett | R SanLuis |
| 1 | 5/21/18 | 10.5 | Review data moved from section 6 | L Barrett | R SanLuis |
| 1 | 5/21/18 | 10.6 | Add reporting above CRR | L Barrett | R SanLuis |
| 1 | 5/21/18 | 15 | Update to new standard wording | L Barrett | R SanLuis |

## 19. ADDENDA

None