

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: Core

Date Distributed: 4/4/2016
Due Date: 4/30/2016
Implementation: 5/1/2016

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

**Specific Gravity Using the Refractometer
GEC.U12, SGAH.U14, WAH.U15 v1**

Refractometer Quality Control Log AG.F346.1

Description of change(s):

SOP:

Section	Reason
3.1, 3.2	Add urine collection kit and stability for preservative tube
6.4	Edit acceptable range for water
6.6	Edit QC form
10.2	Add number of decimals
10.4	Display CRR as range (remove > sign)

FORM: Revise H2O acceptable range to match SOP

This revised SOP & FORM will be implemented on May 1, 2016

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

Approved draft for training (version 1)

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		

Review		
Print Name	Signature	Date

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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 -Other Acceptable	Urine, freshly voided Random urine
Collection Container	Urine Collection Kit (Urine Analysis Preservative Tube preferred) or container at room temperature.
Volume - Optimum - Minimum	2 mL 1 mL
Transport Container and Temperature	Collection kit or container at room temperature, submitted within 2 hours of collection.
Stability & Storage Requirements	Room Temperature: 24 hours in Urine Analysis Preservative Tube 2 hours for other containers
	Refrigerated: 24 hours
	Frozen: Unacceptable
Timing Considerations	Test the urine within two hours after voiding.

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.

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

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	NERL Reagent Grade Water
Preparation	Ready for use.
Storage/Stability	Room temperature. Reagent is stable until expiration date printed on the bottle. Open expiration date is 30 days.

Control	5% NaCl
Preparation	Ready for use.
Storage/Stability	Room temperature. Reagent is stable until expiration date printed on the bottle.

6.3 Frequency

Both levels of Quality Control are tested once per day.

6.4 Tolerance Limits

QC Material	Expected Reading	Acceptable Range
Reagent grade water	1.000	±0.0005 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	<ul style="list-style-type: none"> • Verify it is the correct control. • Verify the control has not expired. • Check for technical/clerical errors. • Visually inspect the condition of the control. • Repeat the QC test. • 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 Review Patient Data

Technologist must check for unusual patterns, trends, or distributions in patient results (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.

6.6 Documentation

- Record results on “~~Manual Urinalysis~~ Refractometer QC” sheet, located in Urinalysis Quality Control binder.
- Quality control records are reviewed daily at the bench, weekly by the Lead Technologist 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.

6.7 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.

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 Repeat Criteria and Resulting

Results are recorded in the LIS

Function: **MEM**

Worksheet: **SCL (SGAH), 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 Priority 3 Limit(s)

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

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
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

19. ADDENDA

None ~~Manual Urinalysis QC form (on Link of Infocard)~~

Refractometer Quality Control

Month _____ Year _____ 5% NaCl Lot# _____ Exp: _____

Date	Tech	H2O	5% NaCl	QC OK?	Comments / Corrective Action
	Acceptable Range:	0.009 – 1.001	1.023 - 1.025	Y / N	
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2					
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Weekly Review:	Weekly Review:	Weekly Review:
Weekly Review:	Weekly Review:	Monthly Review: