TRAINING UPDATE

Lab Location:	FWMC	**Date Distributed:**	2/2/2023
Department:	Core Lab	**Due Date:**	3/1/2023

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Title: (attached)

- **Specific Gravity Using the Refractometer (AHC.U14)**
- **Urinalysis by Clinitek Advantus (GEC.E102)**
- **Form: Quality Control Log (AG.F346)**

Description of change(s):

Refractometer training for FWMC

- Read the SOP, Specific Gravity using the Refractometer (AHC.U14)
- Note references to refractometer in Advantus SOP (GEC.E102)
- Familiarize yourself with the daily QC Log for Refractometer
- Take the MTS quiz
- Reach out to your supervisor to ensure completion of your hands-on training; complete the training document; return document to your supervisor before March 1, 2023

This process will be implemented March 14, 2023

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

AHC.U14 Specific Gravity Using the Refractometer

Copy of version 3.0 (approved and current)

Periodic review not required

Effective Date 12/30/2022

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Printed By Demetra Collier (110199)

Organization Fort Washington Medical Center

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	12/30/2022	3.0	Senda Beltaifa Senda Beltaifa	

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	6/6/2022	12/30/2022	Indefinite

Linked Documents

- AG.F346 Refractometer Quality Control Log

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.		

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TEST INFORMATION

Assay	Method/Instrument	Local Code
Specific Gravity	Refractometer	USPG

Synonyms/Abbreviations
SG

Department
Urinalysis

1. 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.

2. 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	Clean or sterile container

Criteria		
Volume - Optimum **- Minimum**	2 mL 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 2 hours for other containers
	Refrigerated:	24 hours
	Frozen:	Unacceptable
Timing Considerations	Test the urine within two hours after voiding.	
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.

3. REAGENTS

N/A

4. CALIBRATORS/STANDARDS

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

5. 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 **Unopened**: Stable until expiration date printed on the bottle **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. • 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 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.

6. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Refractometer (TS Meter)

7.3 Supplies

Disposable pipettes

7. 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.

8. CALCULATIONS

Not applicable

9. 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** (WOMC) **GCL** (GEC) or **FCL** (FWMC)
Test code: **USPG**

10. EXPECTED VALUES

11.1 Reference Ranges

1.005 – 1.030

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

11. 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).

12. PROCEDURE NOTES

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

13. 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

14. 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.

15. 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)

16. 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.

17. 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

Version	Date	Section	Reason	Reviser	Approval
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 for above CRR	L Barrett	R SanLuis
1	5/21/18	15	Update to new standard wording	L Barrett	R SanLuis
2	6/6/22	Header Footer	Changed site to All Laboratories Changed prefix to AHC	D Collier	R SanLuis
2	6/6/22	10.6	Changed WAH to WOMC and added FWMC	D Collier	R SanLuis

18. ADDENDA

None

Adventist HealthCare

☐ Fort Washington Medical Center
☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ White Oak Medical Center

Refractometer Quality Control

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

Date	Tech Acceptable Range:	H2O 0.009 – 1.001	5% NaCl 1.023 - 1.025	QC OK? Y / N	Comments / Corrective Action
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
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31					

Weekly Review:	Weekly Review:	Weekly Review:
Weekly Review:	Weekly Review:	Monthly Review:

GEC.E 102 Urinalysis, Clinitek Advantus

Copy of version 3.0 (approved and current)

Periodic review not required

Effective Date 6/7/2022

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Printed By Demetra Collier (110199)

Organization Fort Washington Medical Center

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	4/29/2022	3.0	Senda Beltaifa	
Approval	Lab Service director	4/27/2022	3.0	Robert SanLuis Robert SanLuis	
Approval	Lab Director	9/29/2021	2.0	Senda Beltaifa	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	4/15/2022	6/7/2022	Indefinite
2.0	Retired	Major revision	7/9/2020	9/29/2021	6/7/2022

Linked Documents

- AG.F 531 Clinitek Advantus QC Log
- AG.F 532 Clinitek Advantus Daily Maintenance Log

Technical SOP

Title	**Urinalysis, Clinitek Advantus**	
Prepared by	Demetra Collier	Date: 6/5/2020
Owner	Robert SanLuis	Date: 6/5/2020

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

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Urinalysis	Clinitek Advantus	UAI
Urinalysis with reflex to culture	Clinitek Advantus	UAIRX

Synonyms/Abbreviations
Urine Macroscopic, UA, UA with reflex to culture

Department
Urinalysis

2. ANALYTICAL PRINCIPLE

The Clinitek Advantus is a reflectance spectrophotometer that analyzes color and intensity of light reflected from the reagent areas on the Multistix 10 SG and reports the results in clinically meaningful units.

a. Protein: This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reaction.
b. Occult Blood: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.
c. Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.
d. Nitrite: This test depends upon the conversion of nitrate to nitrite to by action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with ρ-arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydrbenzo(h)quinolin-3ol to produce a pink color.
e. Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of fluconic acid and dydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidze the chromogen to colors ranging from green to brown.
f. Ketone: This test is based on the development of colors ranging from buff-pink, for a negative reading, to maroon when acetoacetic acid reacts with nitroprusside.

g. pH: The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
h. Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
i. Bilirubin: This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan.
j. Urobilinogen: This test is based on a modified Ehrlich reaction in which ρ-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting 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 None	
Collection Container	Clean or sterile container	
Volume - Optimum **- Minimum**	12 mL 1 mL	
Transport Container and Temperature	Urine Collection Kit (Urine Analysis Preservative Tube preferred) or container at room temperature. *If order is UAIRX then specimen must be placed/received in a marble and gray collection tubes	
Stability & Storage Requirements	Room Temperature:	24 hours in Urine Analysis Preservative Tube 2 hours for other containers
	Refrigerated:	24 hours

Criteria	
	Frozen: Unacceptable
Timing Considerations	Test the urine within two hours after voiding, sooner if testing for bilirubin or urobilinogen.
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 refrigerated, let it return to room temperature before testing. The container should allow for complete dipping of all reagent strip areas.
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

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

Primary Reagent	Supplier & Catalog Number
Multistix 10 SG Reagent Strips	Siemens Reagent Strips Cat. No. 2161

4.2 Reagent Preparation and Storage

Reagent	Multistix 10 SG Reagent Strips
Container	Plastic Bottle
Storage & Stability	Store at temperatures between 15-30°C. • All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become un-reactive. • Do not use strips after the expiration date printed on the original bottle. • Do not store the bottle in direct sunlight and do not remove the desiccant from the bottle. • Never leave the container uncapped.

Preparation	None

5. CALIBRATORS/STANDARDS

Calibration is performed automatically each time a Reagent Strip is analyzed.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Human Urinalysis Control level I	KOVA-Trol™ HYCOR® Cat. No. 91017
Human Urinalysis Control level II	KOVA-Trol™ HYCOR® Cat. No. 87128
Human Urinalysis Control Level III	KOVA-Trol™ HYCOR® Cat. No. 87328

6.2 Control Preparation and Storage

Control	**Level I Urine control**
Preparation	Reconstitute the vial of control with exactly 15 mL of Reagent Grade water. Allow the reconstituted material to stand at room temperature for 15 minutes and gently rotate the bottle intermittently until all of the material has dissolved.
Storage/Stability	Once reconstituted, the controls remain stable for 7 days at 2-8°C in its original capped vial.

Control	**Level II and Level III Urine controls**
Preparation	Reconstitute each vial of control with exactly 60 mL of Reagent Grade water. Allow the reconstituted material to stand at room temperature for 15 minutes and gently rotate the bottle intermittently until all of the material has dissolved.
Storage/Stability	Once reconstituted, the controls remain stable for 7 days at 2-8°C in its original capped vial.

6.3 Frequency

All three levels of Human Urinalysis Control are tested once per day.
The analyzer will prompt for QC after 24 hours.

Daily QC Procedure:

1. From the HOME page select MENU.
2. Select QC.
3. Enter the QC ID and press ENTER.
4. Dip QC and place on the platform
5. Repeat steps 1-4 for each level.

6.4 Tolerance Limits and Criteria for Acceptable QC

All QC Values must be within acceptable limits listed in manufacture's package insert.

IF the result is …	THEN…
not acceptable	• Verify it is the correct control/reagent. • Verify the control/reagent has not expired. • Check for technical/clerical errors. • Visually inspect the condition of the control/reagent. • Inspect the instrument status, do maintenance and troubleshoot. • Repeat the QC test. • Notify the Supervisor if these results are not acceptable.

6.5 Documentation

- Save the instrument printed paper. Record results on "Clinitek Advantus QC Log", located in Urinalysis Quality Control 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

- 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.
- 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

Clinitek Advantus

7.2 Equipment

- Centrifuge, 1600 RPM
- Refractometer

7.3 Supplies

- Disposable pipettes
- Plastic Conical Urinalysis tubes

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.	Verify that lot number and expiration date stored in the instrument matches the lot number of Multistix SG10 in use. Update the Lot number and expiration date of the Mutistix SG whenever a new lot is started. • Select MENU • Select the " Primary Strip Lot Number" to change the lot number • Enter the lot # and expiration date, ENTER • Verify that the information entered is correct • Return to Home menu by selecting the Home Icon (Advantus will save new lot information).
2.	Select ID and Scan or enter patient's accession number.
3.	Select the color and clarity description for each specimen. Use "OTHER" for colors not listed. If "OTHER" is selected, the result will hold in DI. Use DI to enter your result using "insert coded entry". See Addendum B
4.	Completely immerse all reagent areas of a Multistix 10 SG Reagent Strip in fresh, well-mixed, un-centrifuged urine.
5.	Immediately remove the Reagent Strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine. **Do not blot the edge of the strip against a paper towel.**
6.	Place the Reagent Strip, **with reagent areas facing up,** onto the strip supports of the strip loading station.
7.	The presence of the reagent strip is detected as soon as it is placed on the loading station. The push bar moves the strip along the loading station to the read area.

Some medications cause urine to become abnormally colored (GREEN, AMBER, ORANGE or PINK) and the Clinitek Advantus will report false positive results. For urines that are abnormally colored:

8.2	Color Interference
1.	Run the strip through the Clinitek Advantus
2.	Verify the specific gravity by manual refractometer (rounding to the nearest .005). Report the results of the manual refractometer.
3.	Tests that are NEGATIVE on the Clinitek Advantus can be reported as negative.
4.	Report the Color and Clarity as you see it.
5.	Enter the comment COLINT, which expands out to “Results not reported due to color interference”, for the remainder of the tests.
6.	Perform a microscopic exam on all abnormally colored urines.

8.3	Bloody Urines
1.	Measure the specific gravity by manual refractometer (rounding to the nearest .005). Report the results of the manual refractometer.
2.	Report the Color as BLOODY and the Clarity as you see it.
3.	Centrifuge the specimen. Pour the supernatant into a plastic conical urinalysis tube
4.	Perform dipstick testing on the supernatant and run through the Clinitek Advantus.
5.	Report the remaining results of the supernatant from the Clinitek Advantus (GLU, BIL, KET, PH, PRO, URO, NIT, and LEU).
6.	Perform a microscopic exam on the sediment.

8.4	RESEND or REPRINT a result
1.	From the HOME screen select MENU
2.	Select MEMORY.
3.	Select result to recall
4.	Select RESEND (a circle with an arrow icon) or REPRINT (a printer icon).

8.5	Instrument Maintenance
1.	Refer to Addendum A for maintenance instructions.
2.	Record maintenance on the appropriate log.

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

Macroscopic Analysis

Test	Report As
Color	Yellow, Orange, Pink, Green, Amber, Brown, Bloody, Dark Yellow, Straw
Appearance	Clear, Cloudy, Slightly Cloudy, Turbid
Specific Gravity	1.005 – 1.030 (in increments of 0.005)
pH	5.0 – 9.0 (in increments of 0.5)
Glucose	Negative, Trace, 1+, 2+, 3+, 4+
Bilirubin	Negative, 1+, 2+, 3+
Urobilinogen	0.2, 1.0, 2.0, 4.0, 8.0
Ketone	Negative, Trace, 1+, 2+, 3+, 4+
Occult Blood	Negative, Trace, 1+, 2+, 3+
Protein	Negative, Trace, 1+, 2+, 3+, 4+
Nitrite	Negative, Positive
Leukocytes Esterase	Negative, Trace, 1+, 2+, 3+

Microscopic Analysis

Power Field Instructions for Microscopy	
High Power Field (HPF)	**Low Power Field (LPF)**
RBCs and WBCs	Squamous Epithelial Cells
Renal & Transitional Epithelial Cells	All Casts
Bacteria / Yeast / Crystals	Mucus

Test	# seen	LIS translation
WBC (average # / HPF)	0 - 2	O0
	3-5	O3
	6-10	O6
	11-20	O11
	21-100	O21
	>100	TNTC
RBC (average # / HPF)	0 - 2	O0
	3-5	O3
	6-10	O6
	11-20	O11
	21-100	O21
	>100	TNTC

Test	# seen	LIS translation
Epithelial (average # / LPF)	0 - 2	Rare
	3-5	Occasional
	6-10	1+
	11-20	2+
	21-100	3+
	> 100	4+
Casts (average # / LPF)	0-1	O01
	2-5	O2
	6-10	O6
	11-20	O11
	21-100	O21
	TNTC	TNTC
Bacteria / HPF	None seen	Negative
	Few	1+
	Small	2+
	Moderate	3+
	Large	4+
	Packed	TNTC

Only report these analytes if seen during microscopic review:		
Test	**# seen**	**LIS translation**
Transitional Epithelial Cells (average # / HPF)	1-2	Rare
	3-5	Occasional
	6-10	1+
	11-20	2+
	21-100	3+
	> 100	4+
Renal Epithelial Cells (average # / HPF)	1-2	Rare
	3-5	Occasional
	6-10	1+
	11-20	2+
	21-100	3+
	> 100	4+
Crystals (average # / HPF)	1-5	Few
	6-10	1+
	11-20	2+
	>21	3+
Mucus / LPF	Occasional	Occasional
	Small	1+
	Moderate	2+
	Large	3+
	Packed	4+

Only report these analytes if seen during microscopic review:		
Test	**Test**	**Test**
Yeast / HPF	Occasional	Occasional
	Small	1+
	Moderate	2+
	Large	3+
	Packed	4+
Trichomonas	No quantitation – report "present" if seen	
Enterobius Vermicularis	No quantitation – report "present" if seen. **Consult with pathologist prior to releasing results.**	
Schistoma Haematobium	No quantitation – report "present" if seen. **Consult with pathologist prior to releasing results.**	
Oval Fat Bodies	No quantitation – report "present" if seen	

10.2 Rounding

N/A

10.3 Units of Measure

Urobilinogen EU/dL

10.4 Clinically Reportable Range (CRR)

N/A

10.5 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.

10.6 Repeat Criteria and Resulting

Test	If the result is…	Then…
Bilirubin	1+, 2+ and 3+	The ETC (English Text Code) of **UPPB** will be appended to the result by LIS. The code translates to "Presumptive positive bilirubin. Consider confirmation by serum bilirubin if clinically indicated."

- Microscopic Exam:
    1. Review the results. The following macroscopic abnormalities trigger a microscopic exam:
        a. Occult Blood: any positive
        b. Protein: any positive
        c. Nitrite: any positive

d. Leukocytes: any positive
e. Clarity (Character): Slightly Cloudy, Cloudy or Turbid

2. Centrifuge the specimens that require a microscopic exam at 1600 RPM for 5 minutes.
3. Refer to procedure "Microscopic Examination of Urine" for instructions on performing microscopic examination of urine.
4. Enter Microscopic results using DI (See Addendum B).

- Test UMM (UR Microscopic Added?) is added to the Urine Chemistry group. If criteria to perform a microscopic is met then UMM is resulted with TADD (Test Added). If not met then it is resulted with NIND (Not Indicated)

- Urinalysis with reflex to culture (UAIRX): Any of the following macroscopic or microscopic abnormalities will trigger a reflex to Urine culture (XURNC) by Sunquest(LIS):
  a. Nitrite: positive
  b. Leukocyte: 2+, 3+
  c. WBC: >10

11. EXPECTED VALUES

11.1 Reference Ranges

Glucose	Negative
Bilirubin	Negative
Ketones	Negative
Specific gravity (SG)	1.005 – 1.030
Occult Blood	Negative
pH	5.0 – 9.0
Protein	Negative
Urobilinogen (URO)	0.2 – 1.0 EU/dL
Nitrite	Negative
Leukocyte	Negative
Color	Yellow
Clarity	Clear

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The strips are intended for use in at-risk patient groups to assist diagnosis in the following areas: Kidney function, urinary tract infections, carbohydrate metabolism and liver function. The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

Protein: In normal urine, less than 150 mg of total protein is excreted per day. Clinical proteinuria is indicated at greater than 500 mg of protein per day. Positive results may also indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections, and acute illness with fever.

Occult Blood: Normally, no hemoglobin is detectable in urine. Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological and bleeding disorders. Small amounts of blood are sufficiently abnormal to require further investigation. The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case.

Leukocytes: Normal urine specimens generally yield negative results. An increase in leukocytes is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract; however, pyuria may often be present in non-infection conditions. A strip result of small or greater is a useful of indicator of infection. Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant.

Nitrite: Normally no nitrite is detectable in urine. Many enteric gram-negative organisms give positive results when their number is greater than 10^5/mL.

Glucose: Small amounts of glucose are normally excreted by the kidney. These amounts are usually below the sensitivity of this test but on occasion may produce a color between the Negative and the 100 mg/dL color blocks and that is interpreted by the instrument as a positive result. Results at the first positive level may be significantly abnormal if found consistently.

Ketone: Normally, no ketone is detectable in urine. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine at levels of 10 mg/dL or higher before serum ketone levels are elevated. Clinical judgment is needed to determine the significance of trace results, which may occur during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.

pH: The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.

Specific Gravity: The normal SG of urine ranges from 1.001 – 1.035. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

Bilirubin: Normal adult urine contains about 0.02 mg/dL of bilirubin, which is not detectable by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Since very small amounts of bilirubin may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Siemens Reagent Strips to bilirubin is sufficient for the intended use.

Urobilinogen: Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL. A result of 2.0 mg/dL represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further for hemolytic and hepatic disease.

13. PROCEDURE NOTES

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

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

Bloody urine and color interference explained in sections 8.2 and 8.3

For all tests, false positive results and/or false negative results can occur when substances that cause abnormal urine color are present, such as:

- visible levels of blood or bilirubin
- drugs containing dyes
- nitrofurantoin
- riboflavin

14.4 Clinical Sensitivity/Specificity/Predictive Values

Sensitivities listed in the following table depend upon the presence or absence of inhibitory and matrix factors typically found in urine, such as specific gravity and pH.

Test Name	*False Positive or Increased values*	*False Negative or Decreased values*
Glucose	Temperature	▪ Ascorbic acid (≥ 50mg/dL) may affect a 75 to 125 mg/dL glucose level

Test Name	*False Positive or Increased values*	*False Negative or Decreased values*
		▪ Ketones (≥ 40mg/dL) may affect a 75 to 125 mg/dL glucose level ▪ High specific gravity ▪ Temperature
Bilirubin	▪ Indican (indoxyl sulfate) may impart a yellow-orange to red color on the pad ▪ Metabolites of Lodine (etodolac)	▪ Ascorbic acid (≥ 25mg/dL). ▪ Urine specimen was more than one hour old (instability of bilirubin). ▪ Contamination with chlorhexidine (found in some skin cleansers)
Ketone	▪ Highly pigmented urines ▪ Large amounts of levodopa (L-dopa) metabolites ▪ Compounds that contain sulfhydryl groups	
Specific Gravity	▪ Moderate (100 – 750 mg/dL) quantities of protein ▪ Contamination with chlorhexidine (found in some skin cleansers)	▪ Highly buffered/alkaline urines
Occult Blood	▪ Oxidizing contaminants (e.g. bleach) ▪ Microbial peroxidase from urinary tract infections	▪ High specific gravity ▪ Capoten® (Captopril)
pH	▪ Bacterial growth that converts urea to ammonia	▪ Run-over from the protein reagent pad
Protein	▪ Highly buffered or alkaline urines ▪ Contamination with quarternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers)	
Urobilinogen	▪ Temperature > 26°C (79°F) ▪ ρ-aminosalicylic acid (PAS) and sulfonamides ▪ ρ-aminobenzoic acid (PABA) may cause atypical color development	▪ Temperature < 22°C (72°F) ▪ Formalin
Nitrite		▪ Infections caused by organisms that don't contain reductase ▪ Urine was not in bladder long enough (at least 4 hours) ▪ Absence of dietary nitrate ▪ High specific gravity ▪ Ascorbic acid (≥ 25 mg/dL) may affect a low positive nitrate level (< 0.06 mg/dL nitrate ion)
Leukocytes	▪ Formalin ▪ Temperature >26°C (79°F)	▪ Elevated glucose (≥ 3,000 mg/dL) ▪ High specific gravity ▪ Cephalexin (Keflex®) or Cephalothin (Keflin®) ▪ High concentrations of oxalic acid

Test Name	*False Positive or Increased values*	*False Negative or Decreased values*
		▪ Tetracycline ▪ Temperature <22°C (72°F)
Color	▪ Concentration ▪ Food Pigments ▪ Dyes ▪ Blood ▪ Various pathological conditions	▪ These all can affect negatively as well.

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. Specific Gravity Using the Refractometer, Urinalysis procedure
6. Microscopic Examination of Urine, Urinalysis procedure
7. Clinitek Advantus QC Log (AG.F531)
8. Clinitek Advantus Daily Maintenance Log (AG.F532)
9. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
10. Current package insert Multistix 10 SG (manufacturer provides alert when changes are made)

17. REFERENCES

1. Operator's Guide, Siemens Clinitek Advantus, Siemens Healthcare Diagnostics, Inc., revised 8/2013 (*a copy is located on the AHC G drive at LD USERS, GEC, Advantus Operator Guide and Multistix 10 SG package insert)*
2. Package Insert, Siemens Multistix 10 SG, Siemens Healthcare Diagnostics, Inc. revised 7/2017 (*a copy is located on the AHC G drive*)
3. Package Insert, KOVA-Trol™ HYCOR, P/N 91017-09, 10/2016.
4. CLINITEK ADVANTUS Technical Procedure, doc # 035103. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals-3rd Edition (GP2-A3), 1996.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	7/6/20	10.1	Added microscopic tables	L Barrett	R SanLuis
1	7/6/20	10.6	Deleted instruction for pH >8.0	L Barrett	R SanLuis
1	7/6/20	Add. B	Deleted spec. gravity confirmation	L Barrett	R SanLuis
2	3/17/22	1	Added UAIRX(UA with reflex to culture) and updated Synonyms	M Sabonis	R SanLuis
		3.2	Add UAIRX aliquoting to gray tube	M Sabonis	R SanLuis
		10.1	Replaced "Blood" with "Occult Blood"	M Sabonis	R SanLuis
		Addendum B	Replaced Coded Entry with drop down resulting from DI	M Sabonis	R SanLuis
		Addendum B	Added new "REQUIRED ELEMENTS" screen shot for DI Added FMWC UA keyboard	M Sabonis	R SanLuis
		Addendum B	Added auto-release of urine chemistry and updated order of release	M Sabonis	R SanLuis
		Addendum B	Added URTYP description and updated screen shot Added info and screen on process for UAIRX(UA with reflex to culture)	M Sabonis	R SanLuis
		Header	Added site FWMC	D Collier	R SanLuis

19. ADDENDA

A. Clinitek Advantus Maintenance
B. DI (Data Innovations) Information and Actions

Addendum A

Clinitek Advantus Maintenance

A. Daily Maintenance
1. From the main screen, press the back key until you are at the Ready/Run screen.
2. Turn off the instrument. The on/off switch is located in the lower left, in the rear of the instrument.
3. Remove the push bar by tilting it slightly upwards and pulling straight out.
4. Remove the waste bin and discard the used strips, into the appropriate container. Inspect the liner. If it has any cracks or is extremely dirty it should be replaced.
5. Remove the fixed platform by pulling the entire assembly towards you. Remove the moving table in the same manner.
6. Remove the hold-down plate from the fixed platform by pressing up against the tab at the back of the plate. Then pull the other end from its retaining hole.
7. Clean all parts with water and mild soap. A toothbrush may be used if sediment accumulation is observed.
Note: DO NOT use solvent or alcohol
8. When cleaning the fixed platform, Do NOT wipe across the two white calibration bars. The white calibrator bars should be GENTLY cleaned with water on a cotton-tipped applicator.
9. Rinse and dry all parts with paper towel except the calibrator pads. Use mild soap if necessary. The calibrator pads should be allowed to air dry. Check the white calibration bars for scratches or discoloration. Notify the supervisor/designee if they appear overly scratched.
10. Reinstall the moving table as follows:
    a) Hold the table with the small rectangle to the back.
    b) Align the two grooves on the bottom of the table with the edges of the platform on which the table rests.
    c) Gently push the table in as far as it will go. It must be pushed past a dent in order to be correctly in position.
11. Reinstall the hold-down on the fixed platform.
12. Position the hold-down with the arrow side facing up and the arrow pointing to the back. Place the pin on the front of the hold-down into the hole at the front of the platform. Then align the tab at the back of the hold-down with the slot at the back of the platform and snap the hold-down into place. Make sure the white calibration bars are visible.

13. Reinstall the clean fixed platform by:
    a) Aligning the two flared grooves on the bottom of the fixed platform with the arms extending from the instrument
    b) Gently push the platform in as far as it will go. (It must be pushed past a slight dent to be correctly positioned.)
    c) Ensure the moving platform is correctly positioned.

14. Hold the push bar by its flattened end and, with this end slightly upward; insert the peg on the other end of the bar into the hole in the pusher mechanism. Lower the push bar into place.

15. Clean the display screen with lens paper dampened with water.
    Notes:
    - Dry with lens paper. Do NOT use Kimwipes or paper towels as this may scratch the screen.
    - Do NOT put water directly on the screen.
    - Do NOT use bleach

16. Turn the instrument on. The Clinitek will go through a verification check that all parts have been correctly positioned.
    Note: If the instruments gives an error (e.g; "table not positioned properly"), refer to the Clinitek Advantus Urine Chemistry Analyzer Operating manual - Troubleshooting section.

17. Run quality control according to section 6 of this procedure

18. Complete the daily Maintenance log sheet to document that maintenance was performed.

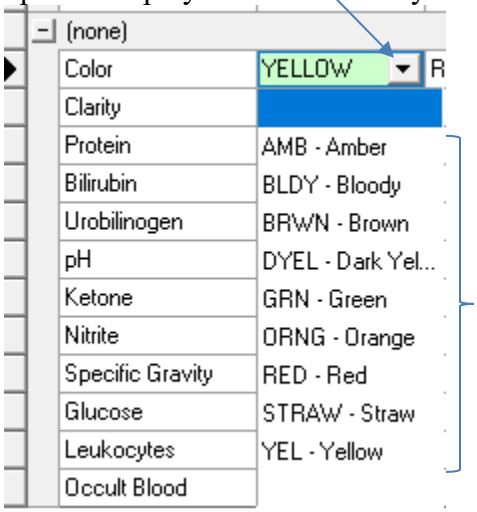
Addendum B

DI (Data Innovations) Information and Actions

1. Result Processing

A. Changing Result -Click on the result cell that you want to edit.

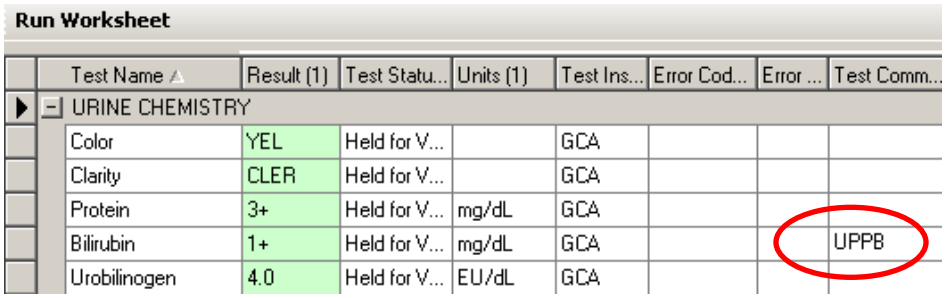
- If applicable, a drop down button displays. Click on the drop down button and result options display. Click on result you want to change to.



Example: of drop down displaying result options to select.

B. Positive Bilirubin

If Bilirubin is resulted with 1+, 2+ or 3+, DI will add the English text code **UPPB** to the test comment. UPPB translates to "Presumptive positive bilirubin. Consider confirmation by serum bilirubin if clinically indicated."



Test Name	Result (1)	Test Statu...	Units (1)	Test Ins...	Error Cod...	Error ...	Test Comm...
URINE CHEMISTRY							
Color	YEL	Held for V...		GCA			
Clarity	CLER	Held for V...		GCA			
Protein	3+	Held for V...	mg/dL	GCA			
Bilirubin	1+	Held for V...	mg/dL	GCA			UPPB
Urobilinogen	4.0	Held for V...	EU/dL	GCA			

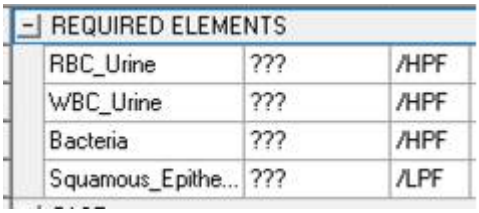
2. Performing Manual Microscopy using the Urinalysis Keyboard

   A. Before you begin, you must select a "keyboard":
      - Select the "Cell COUNTER" tab
      - If at GEC, then, select "GEC UA Keyboard" from the drop-down menu
      - If at FWMC, then select "FWMC UA Keyboard" from the drop-down menu

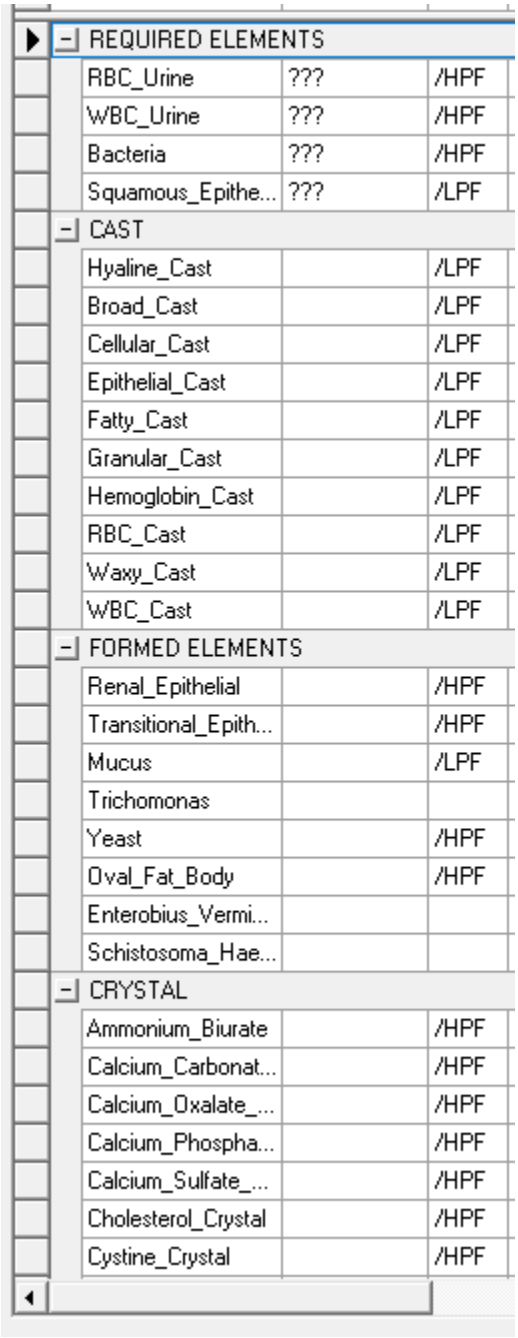
   B. Once you have selected your keyboard, right-click on your macroscopic results, and select "Verify with Cell Counter" from the drop down menu.

The Urinalysis keyboard is used to enter the observational results from the manual microscopy. Each test on the keyboard can be resulted by left- clicking on the result field for that test and selecting the drop-down arrow to reveal a list of available results.

Under the 'REQUIRED ELEMENTS" section there are four elements denoted with "???". These **MUST ALWAYS BE REPORTED.**



REQUIRED ELEMENTS		
RBC_Urine	???	/HPF
WBC_Urine	???	/HPF
Bacteria	???	/HPF
Squamous_Epithe...	???	/LPF



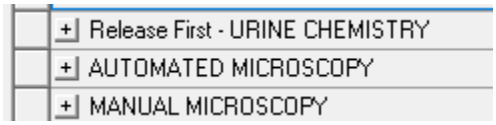
REQUIRED ELEMENTS		
RBC_Urine	???	/HPF
WBC_Urine	???	/HPF
Bacteria	???	/HPF
Squamous_Epithe...	???	/LPF
CAST		
Hyaline_Cast		/LPF
Broad_Cast		/LPF
Cellular_Cast		/LPF
Epithelial_Cast		/LPF
Fatty_Cast		/LPF
Granular_Cast		/LPF
Hemoglobin_Cast		/LPF
RBC_Cast		/LPF
Waxy_Cast		/LPF
WBC_Cast		/LPF
FORMED ELEMENTS		
Renal_Epithelial		/HPF
Transitional_Epith...		/HPF
Mucus		/LPF
Trichomonas		
Yeast		/HPF
Oval_Fat_Body		/HPF
Enterobius_Vermi...		
Schistosoma_Hae...		
CRYSTAL		
Ammonium_Biurate		/HPF
Calcium_Carbonat...		/HPF
Calcium_Oxalate_...		/HPF
Calcium_Phospha...		/HPF
Calcium_Sulfate_...		/HPF
Cholesterol_Crystal		/HPF
Cystine_Crystal		/HPF

3. Order of Release

The Urinalysis results consist of 3 to 4 groups in DI. They must be released in DI in a certain order to ensure proper filing into Sunquest. The order is explained below.

Note:

- The Urine Chemistry group is ALWAYS auto-released to Sunquest, unless held on DI.
- If you have to manually release the results ALWAYS release the URINE CHEMISTRY first as noted in the header description (see below).



Note: To release or reject a group, follow the steps below:

a. Right click on the test within the group to be released/rejected and select the appropriate action. Example: If you select "Release URINE CHEMISTRY/Reject Other Runs" is selected, DI will release the selected Urine Chemistry group and reject other Urine Chemistry group from a different run

To Reject a test, follow the steps below:

a. Right click on the test within the group to be rejected and select the appropriate action. Example: if you select "Reject Result" is selected, DI will reject that result. Once rejected, that result can no longer be released from DI.

<u>Results with just Urine Chemistry</u>

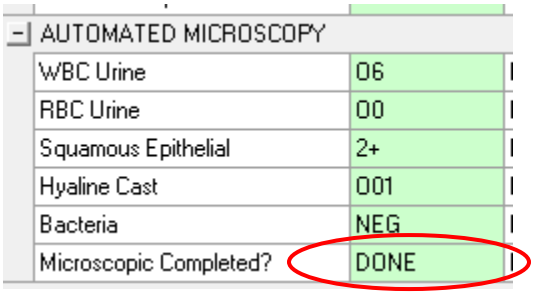
- Release the Urine Chemistry group

<u>Results with Urine Chemistry and Manual Microscopy</u>

- Release the Chemistry group
- Release the Manual Microscopy group

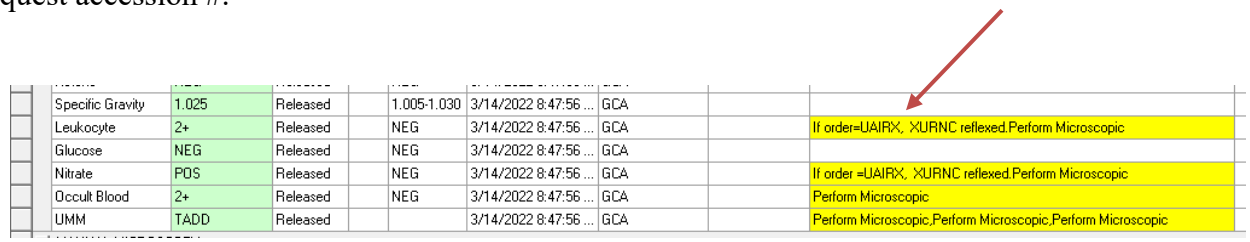
4. Microscopic Billing

DI will add a billing testcode of Microscopic completed? to the Manual Microscopy group whenerver there is a microscopic test done. This test code is resulted with "DONE." This test code must be released together with the rest of the group.



AUTOMATED MICROSCOPY	
WBC Urine	06
RBC Urine	00
Squamous Epithelial	2+
Hyaline Cast	001
Bacteria	NEG
Microscopic Completed?	DONE

5. If the orderable is for a UAIRX and the criteria is met to reflex to a urine culture. Then DI will display an Error Message "If order UAIRX XURNC reflexed". Once results are release from DI to Sunquest. Sunquest will generate the reflex for a XURNC (Urine culture) and assign it a new Sunquest accession #.



	Specific Gravity	1.025	Released		1.005-1.030	3/14/2022 8:47:56 ...	GCA	
	Leukocyte	2+	Released		NEG	3/14/2022 8:47:56 ...	GCA	If order=UAIRX, XURNC reflexed.Perform Microscopic
	Glucose	NEG	Released		NEG	3/14/2022 8:47:56 ...	GCA	
	Nitrate	POS	Released		NEG	3/14/2022 8:47:56 ...	GCA	If order =UAIRX, XURNC reflexed.Perform Microscopic
	Occult Blood	2+	Released		NEG	3/14/2022 8:47:56 ...	GCA	Perform Microscopic
	UMM	TADD	Released			3/14/2022 8:47:56 ...	GCA	Perform Microscopic,Perform Microscopic,Perform Microscopic

**Collection label for XURNC will print on Sunquest lab printer at GEC and FWMC.