Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	4/10/13
Department:	Core	**Due Date:**	5/1/13

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Title			
Ictotest	**GEC.U01.002**	**SGAH.U01.002**	**WAH.U01.002**
Urinalysis, Clinitek 500	**GEC.U08.001**	**SGAH.U10.001**	**WAH.U11.001**
Urinalysis, Multistix 10 SG Reagent Strips	**GEC.U09.001**	**SGAH.U11.001**	**WAH.U12.001**
Routine Urinalysis by IQ 200 Series Analyzer® Iris		**SGAH.U02.003**	**WAH.U02.003**

Description of change(s):

Section	Reason
3.1	Add urine collection kit
10.1	Add process if reagent unavailable

Changes are shown in colored text on the attached SOP.
Only the Ictotest SOP is attached, revisions to the other SOPs are the same

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

Approved draft for training all sites (version 002)

Technical SOP

Title	**Ictotest**	
Prepared by	Wendell McMillan	Date: 2/25/2009
Owner	Robert SanLuis	Date: 3/25/2013

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**

Form revised 3/31/00

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Ictotest	Manual	UICTO

Synonyms/Abbreviations
N/A

Department
Urinalysis

2. ANALYTICAL PRINCIPLE

Ictotest Reagent tablets are used to test for the presence of bilirubin in urine. The test is based on the diazotization reaction. This reaction is based on the coupling of a unique solid diazonium salt with bilirubin in an acid medium to give the blue or purple reaction.

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**	Urine, freshly voided
	-Other Acceptable	None
Collection Container		Clean or sterile container
Volume	**- Optimum**	1.0 ml
	- Minimum	0.2 ml
Transport Container and Temperature		Urine Collection Kit (preferred) or container at room temperature.
Stability & Storage Requirements	Room Temperature:	2 hours
	Refrigerated:	24 hours
	Frozen:	Unacceptable
Timing Considerations		Urine should be tested as soon as possible. Bilirubin is rapidly decomposed once excreted, particularly in the presence of light or heat. Therefore, it is important that Ictotest Reagent Tablets be used with a fresh specimen. If this is not possible the urine should be refrigerated and tested as soon as possible.
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 cancel the test with the appropriate LIS English text code for "test not performed" message. Example: Wrong collection-UNAC. Document the request for recollection in the LIS.

Form revised 3/1/00

Criteria	
Compromising Physical Characteristics	None
Other Considerations	After testing, samples will be held until the next successful QC performance.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Ictotest Reagent Tablet	Siemens Reagent Tablets Cat. No. 2591

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	**Ictotest Reagent Tablet** The Ictotest consists of an absorbent test mat and an Ictotest reagent tablet. The Ictotest tablet contains the following reactive ingredients – 0.46% W/W 2,4-dichlorobenzenediazonium tetrachlorozincate, 87.45% w/w sulfosalicylic acid; and 12.09% w/w nonreactive ingredients.
Container	Dark bottle
Storage/ Stability	Ictotest is good until the date on the vial when stored at room temperature (15-30°C).
Preparation	None

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

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6.1 Controls Used

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

6.2 Control Preparation 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	**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

Quality control is performed once per day and when a new bottle of reagent is placed in use.

6.4 Tolerance Limits

6.4.1 All quality control results are recorded on the Manual Urinalysis QC form.

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

6.4.3 Any quality control failures will be investigated in accordance with the Quality Control Program.

- The first step in the investigation will be repeating the test.

- Confirm the expiration date on the test tablets.
- Check the performance of a known positive control material. If the proper result is not obtained, discard and retest with fresh product.

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results.

6.6 Documentation

Refer to the policies and procedures for QC documentation and for record retention requirements.

6.7 Quality Assurance Program

- Each new lot number or new shipment of the same lot of reagent must be tested with external control material. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Not applicable

7.2 Equipment

None

7.3 Supplies

Disposable pipettes
Reagent Grade Water

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.

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.

8.1	Test Run
1.	Place a square of the absorbent test mat onto a paper towel.
2.	Place 10 drops of the urine onto the center of the test mat.

8.1	Test Run
3.	Shake 1 ICTOTEST Reagent Tablet into the bottle cap and transfer the tablet to the center of the moistened mat. DO NOT HANDLE THE TABLET WITH THE FINGERS. Recap the bottle promptly.
4.	Place one drop of water onto the tablet. Wait five seconds, and then place a second drop of water onto the tablet so that the water runs off the tablet onto the mat.
5.	Observe the color of the mat around the tablet at 60 seconds. The presence of a blue or purple color on the mat indicates that bilirubin is present. A slight pink or red color should be ignored. Review the photographs on the manufacturer's package insert for an example of the color change for a positive.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The results are reported as either positive or negative. Since the Ictotest is used to confirm a positive bilirubin test on a dipstick, the dipstick results are removed from the report and the Ictotest results are reported.

NOTES:

- Since bilirubin is not usually found in urine in concentrations sufficient to give positive results with Ictotest reagent tablets, the expected result is **Negative.**

- Due to a nationwide back order of the Ictotest Reagent Tablet, supplies are running low and likely to be depleted. This shortage may impact the ability to provide bilirubin confirmation testing by Ictotest. If the Ictotest tablet is unavailable the English text code **UTCI** (*Confirmation testing temporarily unavailable, correlate results with clinical findings*) will be attached to the Bilirubin result.

10.2 Rounding

NA

10.3 Units of Measure

NA

10.4 Clinically Reportable Range (CRR)

NA

10.5 Repeat Criteria

None

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Ictotest detects the presence of bilirubin in urine. This is used as a screen for some instances of liver disease. Urine bilirubin is frequently positive in obstructive disease of the biliary tract such as biliary calculi, carcinoma of the pancreas or of bile ducts.

13. PROCEDURE NOTES

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

- Always maintain Ictotest tablets at temperatures from 15 to 30°C
- Do not store the bottle in direct sunlight.
- Replace the cap promptly and tightly after use.
- Ictotest reagent tablets will detect as little as 0.05 to 0.1 mg bilirubin/dL in urine.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

- Metabolites of Pyridium and Serenium give bright red-orange colors which may mask the reaction of small amounts of bilirubin.
- Elevated concentrations of urobilinogen do not mask the reaction of small amounts of bilirubin, but atypical orange colors are produced.
- Chlorpromazine in large amounts may give a false positive result.
- Metabolites of Lodine® may cause false positive or atypical results.

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. Current package insert Ictotest Reagent Tablet

17. REFERENCES

Ictotest Reagent Tablet package insert, Siemens Healthcare Diagnostics, Tarrytown, NY, Revised 09/2009

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP U008.001		
000	8/9/11		Update owner	L. Barrett	C. Reidenauer
000	8/9/11	3.1	Section added	L. Barrett	C. Reidenauer
000	8/9/11	3.2	Update transport requirement and rejection criteria, add retention time.	L. Barrett	C. Reidenauer
000	8/9/11	4.2	Update supplier	L. Barrett	C. Reidenauer
000	8/9/11	6.3	Change QC freq. to once a day	A. Chini	C. Reidenauer
000	8/9/11	6.7	Delete testing with samples	L. Barrett	C. Reidenauer

000	8/9/11	11.2	Update title to local terminology	L. Barrett	C. Reidenauer
000	8/9/11	16	Add current Package Insert	L. Barrett	C. Reidenauer
000	8/9/11	17	Update PI reference	A. Chini	C. Reidenauer
000	8/9/11	19	Remove Package Insert	L. Barrett	C. Reidenauer
001	3/25/13		Update owner	L. Barrett	R. SanLuis
001	3/25/13	3.1	Add urine collection kit	L. Barrett	R. SanLuis
001	3/25/13	10.1	Add process if reagent unavailable	A. Chini	R. SanLuis

19. ADDENDA

Manual Urinalysis QC form (on Link of Infocard)