Urinalysis/ 108 ICTOTEST FOR BILIRUBIN

Copy of version 1.0 (approved and current)

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Comments for version 1.0
Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Lab Director	7/25/2023	1.0	Ali Mousa Ramadan MD	
Periodic review	Core Lab Manager	7/25/2023	1.0	Yoseph Belay (106074)	
Approval	Lab Director	8/15/2021	1.0	Ali Mousa Ramadan	
Approval	Laboratory Operations Manager	8/12/2021	1.0	Wendell McMillan	
Approval	Quality Coordinator	8/1/2021	1.0	Lorraine Foster	Initial electronic version

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	7/20/2021	8/15/2021	Indefinite

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Urinalysis/108 ICTOTEST for Bilirubin

Principle:

ICTOTEST Reagent Tablets are used to test for the presence of bilirubin in urine. The presence of bilirubin is an important finding in the evaluation of liver function. The test is based on the diazotization reaction. ICTOTEST Reagent Tablets were first made available in 1953 and several evaluations have been published. The ICTOTEST Confirmation must be performed on all urine that is positive for Bilirubin.

Specimen Type:

1. Refer to Specimen Requirements for Urinalysis procedure.
2. Fresh random urine (first morning void preferred) refrigerate urine specimens if they cannot be tested immediately.
3. The specimen container must be sterile and leak proof and properly labeled.

Handling Conditions:

Bilirubin is rapidly decomposed once excreted, particularly in the presence of light or heat. Consequently, it is important that ICTOTEST Reagent Tablets be used with a fresh specimen. It this is not possible, the urine must be refrigerated immediately and tested as soon as possible.

Equipment/Supplies:

- ICTOTEST Reagent Tablets
- DI water
- Absorbent mat
- Dropper

Storage Requirements - Reagent:

Deterioration may be noted by tan-to-brown discoloration of the tablet. If this is evident, or when test results are questionable or inconsistent with expected findings, the following steps are recommended:

1. Confirm that the vial is within expiration date shown on label.
2. Check performance against a known positive control material.
3. If proper result is not obtained, discard and retest with fresh product.

4. ICTOTEST Reagent Tablets are stable until the expiration date in the unopened container if stored at temperatures 15-30°C.
5. Do not store the bottle in direct sunlight.
6. Replace cap promptly and tightly after use.
7. PROTECTION AGAINST EXPOSURE TO LIGHT, HEAT AND AMBIENT MOISTURE IS MANDATORY TO GUARD AGAINST ALTERED REAGENT REACTIVITY.

Quality Control:

1. CA/CB quality control is performed for each day of patient specimen testing for ICOTEST, when a new bottle and/or lot are opened.

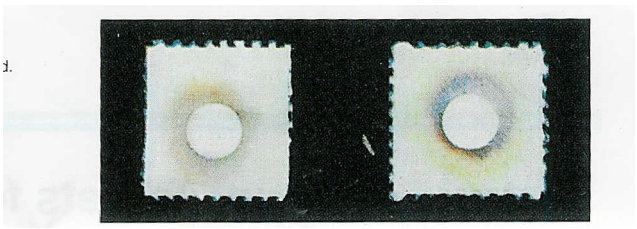
Procedure:

1. Place a square of the absorbent test mat supplied onto a paper towel. Place 10 drops of urine onto the center of the test mat.
2. Shake one ICTOTEST Reagent Tablet in to the bottle cap and transfer the tablet to the center of the moistened mat. Do not handle tablet with the fingers. Recap the bottle promptly.
3. Place one drop of water onto the tablet. Wait 5 seconds, then place a second drop of water onto the tablet so that the water runs off the tablet onto the mat.
4. At 60 seconds observe the color of the mat around the tablet.

Calculations: Not Applicable

Interpretation:

Results with ICTOTEST Reagent Tablets are negative if no blue or purple color develops on the mat within 60 seconds. If a blue or purple color develops on the mat within 60 seconds, the result is positive. Pink or red color should be ignored.



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Reference Ranges:

Bilirubin is not normally found in the urine in concentrations sufficient to give a positive result with ICTOTEST Reagent Tablets.

Limitations:

1. Metabolites of Pyridium give bright red-orange color, which may mask the reaction of small amount of bilirubin.
2. Elevated concentrations of urobilinogen do not mask the reaction of small amount of bilirubin, but atypical orange colors are produced.
3. Chlorpromazine in large amounts may give a false positive result, and metabolites of iodine (etodolac) may cause false positive or atypical results.

References:

- ICTOTEST Reagent Tablets for Urinalysis, Package Insert; Bayer Corporation, Elkhart, IN 46515, Revised 9/95
- MLO's Tips from the Clinical Experts, edited by Daniel M. Baer, MD, August 2002.
- NCCLS GP16-A2, Vol.21 No.19; Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline- 2nd Edition, 2001

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Replaces Core Lab/Urinalysis/426/2015/2. Approval and revision of documentation maintained electronically.