Status **Active** PolicyStat ID **12767026**

Beaumont

Origination	10/15/2021
Last Approved	12/6/2022
Effective	12/6/2022
Last Revised	12/6/2022
Next Review	12/5/2024

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Area	Laboratory-Chemistry
Applicability	Royal Oak

Bile-Ictotest - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

Urine containing bilirubin combines with 2, 4-dicholorobenzendiazonium tetra chlorozincate in an acid environment to form a blue or purple color. The sodium bicarbonate and a portion of the sulfosalicylic acid provide effervescence, which verifies solution of part of the tablet in the drops of water.

II. CLINICAL SIGNIFICANCE:

The presence of bilirubin is an important finding in the evaluation of liver function.

III. SPECIMEN COLLECTION AND HANDLING:

A. Fresh urine sample—minimum 10 drops required

B. Bilirubin is rapidly decomposed once excreted, particularly in the presence of light or heat. Urine preservatives do not prevent this decomposition. Consequently, it is important that the Ictotest Reagent Tablets be used with a fresh specimen. If this is not possible, the urine should be refrigerated immediately and tested as soon as possible.

IV. REAGENTS:

A. Ictotest Reagent Tablets – 100 tablets per bottle (contains 2, 4-dichlorobenzenediazonium tetrachlorozincate & sulfosalicylic acid)

B. Absorbent Asbestos – cellulose Mats

C. Dropper / plastic pipette

D. DiH_2O

V. QUALITY CONTROL (QC):

A. A commercial urine control, normal and abnormal are tested per the procedure. Results are documented in the Laboratory Information System (LIS) computer.

B. Frequency: DAILY and/or whenever a new lot of Ictotest Tablets are opened.

VI. SPECIAL SAFETY PRECAUTIONS:

A. ICTOTEST Reagent tablets are for in vitro diagnostic use. NOT FOR INTERNAL USE.

B. Avoid contact of reagent tablet with skin. Causes serious eye irritation, skin irritation, may cause respiratory irritation. Follow Personal Protective Equipment (PPE) precautions.

VII. PROCEDURE:

A. Place a square of the absorbent test mat supplied onto a paper towel. Using either side of the test mat, place 10 drops urine.

B. Shake one Ictotest Reagent Table into the bottle cap and transfer the tablet to the center of the moistened mat. Do not handle the tablet with your fingers. Recap the bottle immediately.

C. 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.

D. At 60 seconds, observe the area of mat around the tablet for presence of blue or purple color.

E. Enter the results into the LIS as Negative or Positive.

VIII. INTERPRETATIONS:

A. **NEGATIVE**: No blue or purple color on mat around tablet. A slight pink or red color should be ignored.

B. **POSITIVE**: Mat around tablet turns blue or purple. Speed and intensity of color reaction are proportional to the amount of bilirubin present.

IX. EXPECTED VALUES:

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

X. REPORTABLE RANGE:

Ictotest Reagent Tablets will detect as little as 0.05 – 0.1 mg bilirubin/dL in urine (0.9 – 1.7 umol/L)

XI. LIMITATIONS AND INTERFERING SUBSTANCES:

A. Protect against exposure to light, heat and ambient moisture to guard against altered reagent reactivity.

B. Metabolites of Pyridium 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. Chloropromazine in large amounts may give a false positive result, and metabolites of Lodine (etadolac) may cause false positive or atypical results.

XII. REFERENCES:

1. Henry's Clinical Diagnosis and Management by Laboratory Methods. 24th edition 2022 (Elsevier) pp 482-483
2. Ictotest Package Insert

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	12/6/2022
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	12/6/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	12/5/2022
Lab Chemistry Best Practice Committee	Caitlin Schein: Staff Physician	12/5/2022
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	12/2/2022
	Colette Kessler: Mgr, Division Laboratory	12/2/2022