

## DIAZO-CHEK

Test for Urine Bilirubin.

For *In Vitro* Diagnostic Use

Catalog No. B1009

**INTENDED USE:** The DIAZO-CHEK test is used to qualitatively detect bilirubin in urine or confirm the positive results obtained by a reagent strip. The Test is intended for use by the appropriately trained laboratory professionals.

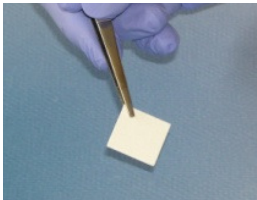
**PRINCIPLE and BACKGROUND:** The presence of bilirubin in urine implies liver disorder and can be an early feature of obstructive hepatobiliary disease. The DIAZO-CHEK test is indicated to detect small amounts (~0.1 mg/dl or greater) of bilirubin in urine which may appear in the earliest stages of hepatic disease. The test is based on the diazo coupling reaction between the adsorbed bilirubin and a stabilized diazonium salt of Nitrobenzene. The reaction results in the development of varying grades of purple to bluish-purple color which is easily visible by the naked eye.

**REAGENTS:** 1. Each reagent disc is impregnated with stabilized Nitrobenzenediazonium salt and Sulfosalicylic acid. 2. Precut TEST PAD SQUARES

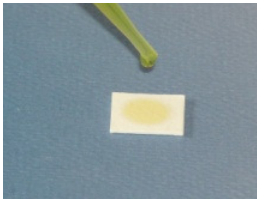
**SPECIMEN REQUIREMENTS:** Bilirubin is a labile molecule and breaks down rapidly once excreted in urine. Since it is particularly sensitive to heat and light, the specimen should be refrigerated for no longer than 4-6 hours if not tested immediately. The commonly used urinary preservatives do not prevent its decomposition.

Note: The provided micropipettes are intended for dispensing distilled water only. To dispense urine, use regular large drop disposable transfer pipettes.

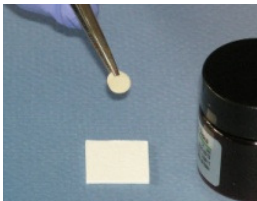
### TEST PROCEDURE



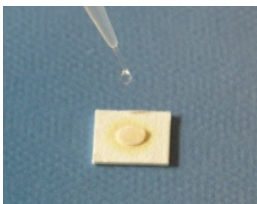
1. Place a precut Test Pad Square onto a paper towel or gauze.



2. Gradually place four drops of urine (approx. 45-55  $\mu$ l each) into the center of the Test Pad Square with a disposable large drop transfer pipette (not provided).

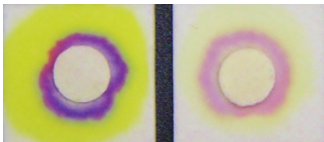


3. With a forceps (provided) remove a reagent disc from the jar and place it in the center of the Test Pad Square.



4. With a micropipette (provided) gradually add 2-3 small drops (~ 20-25  $\mu$ l each) of distilled water directly onto the reagent disc. Note: Use the provided micropipette only for dispensing distilled water.

5. Look for the color development around the disc periphery at 30-60 seconds.



Two representative positive test results for urine bilirubin.

### RESULTS

Varying grades of bluish purple to light purple color around the reagent disc, proportional to the amount of bilirubin present in the specimen, indicate a positive reaction. No color development or a light grayish-pink halo is a negative reaction. Presence of any other color is to be disregarded. Increased levels of urobilinogen produce a diffusing orange to tan color; however, it is differentiable from the shades of purple produced by bilirubin. The disc may be displaced to facilitate the interpretation of results.

### PRECAUTIONS

Use standard laboratory safety measures for handling and disposal of urine specimens including use of gloves. The reagents are only meant for *in vitro* diagnostic purpose and are not for internal use. If refrigerated, acclimatize the disc container to room temperature before opening. Use the provided forceps to remove the discs. Do not insert wet objects into the container. Do not remove the desiccant from the disc jar and replace the cap promptly and securely after opening. To maintain proper reactivity it is imperative to protect reagent discs from light, moisture and temperatures above 10°C. The normal reagent disc color is off white. Do not use if the disc displays brownish yellow or tan color. The Test Square Pads are white in color. The reagent discs contain organic acid and may cause irritation or burn on contact. In case of accidental contact with skin or eyes, wash with copious amount of water.

### LIMITATIONS

Certain drugs may interfere with the **DIAZO-CHEK** performance. Chlorpromazine and Etodolac (NSAID) metabolites in urine may cause unusual or false positive results. Metabolites of Phenazopyridine produce bright orange color urine and may mask the color from small amounts of bilirubin present in the urine. The normal urine contains approximately up to 0.02 mg/dl of bilirubin which is usually not detectable by diazo reaction. The **DIAZO-CHEK** reagent discs, in conjunction with the adsorbent test pad squares, are able to detect bilirubin as low as ~0.1mg/dl of urine.

### STORAGE

The unopened reagent discs/Kits should be stored between 2–10 °C. For the frequent user labs: The discs jar can be left at room temperature if the discs are used up within 3-4 weeks of opening the jar. Do not remove the desiccant pouch. Close promptly and securely. Keep away from sunlight or fluorescent light.

### QUALITY CONTROL

Follow your hospital/institutional guidelines for quality control. In general, a daily quality control is suggested with known bilirubin positive and negative urine specimens or commercially available controls.

### AVAILABILITY

The **DIAZO-CHEK** kit contains a jar of 100 reagent discs and precut Test Pad Squares Six reusable micropipettes, to dispense water only, and a forceps to handle discs are also included..  
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### BIBLIOGRAPHY

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