

## Overview

### Useful For

Assessing liver function

Evaluating a wide range of diseases affecting the production, uptake, storage, metabolism, or excretion of bilirubin

Monitoring the efficacy of neonatal phototherapy

### Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
BILIT	Bilirubin Total, S	Yes	Yes
BILID	Bilirubin, Direct	Yes	Yes

### Method Name

Total Bilirubin: Photometric, Diazonium Salt

Direct Bilirubin: Colormetric Diazo Method

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Shipping Instructions

[Ship specimen in amber vial to protect from light.](#)

### Necessary Information

Patient's age and sex are required.

### Specimen Required

**Supplies:** Amber Frosted Tube, 5 mL (T915)

**Collection Container/Tube:**

**Preferred:** 2 Serum gel Microtainers

**Acceptable:** 2 Red top Microtainers

**Submission Container/Tube:** Amber vial

**Specimen Volume:** 0.5 mL

**Collection Instructions:**

1. Serum gel microtainers should be centrifuged within 2 hours of collection.
2. Red-top microtainers should be centrifuged, and the serum aliquoted into an amber vial within 2 hours of collection.

### Specimen Minimum Volume

0.25 mL

### Reject Due To

Gross hemolysis	Reject
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### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Ambient	6 hours	LIGHT PROTECTED
	Refrigerated (preferred)	24 hours	LIGHT PROTECTED
	Frozen	30 days	LIGHT PROTECTED

### Clinical & Interpretive

#### Clinical Information

Bilirubin is one of the most frequently used tests to assess liver function. Approximately 85% of the total bilirubin produced is derived from the heme moiety of hemoglobin, while the remaining 15% is produced from red blood cell precursors destroyed in the bone marrow and from the catabolism of other heme-containing proteins. After production in peripheral tissues, bilirubin is rapidly taken up by hepatocytes where it is conjugated with glucuronic acid to produce bilirubin mono- and diglucuronide, which are then excreted in the bile.

A number of inherited and acquired diseases affect 1 or more of the steps involved in the production, uptake, storage, metabolism, and excretion of bilirubin. Bilirubinemia is frequently a direct result of these disturbances.

The most commonly occurring form of unconjugated hyperbilirubinemia is that seen in newborns and referred to as physiological jaundice.

The increased production of bilirubin, that accompanies the premature breakdown of erythrocytes and ineffective erythropoiesis, results in hyperbilirubinemia in the absence of any liver abnormality.

The rare genetic disorders, Crigler-Najjar syndromes type I and type II, are caused by a low or absent activity of bilirubin [uridine 5'-diphospho](#)-glucuronosyltransferase. In type I, the enzyme activity is totally absent, the excretion rate of bilirubin is greatly reduced, and the serum concentration of unconjugated bilirubin is greatly increased. Patients with this disease may die in infancy owing to the development of kernicterus.

In hepatobiliary diseases of various causes, bilirubin uptake, storage, and excretion are impaired to varying degrees. Thus, both conjugated and unconjugated bilirubin are retained and a wide range of abnormal serum concentrations of each form of bilirubin may be observed. Both conjugated and unconjugated bilirubins are increased in hepatitis,

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space-occupying lesions of the liver, and obstructive lesions such as carcinoma of the head of the pancreas, common bile duct, or ampulla of Vater.

**Reference Values****DIRECT**

> or =12 months: 0.0-0.3 mg/dL

Reference values have not been established for patients who are younger than 12 months of age.

**TOTAL**

0-6 days: Refer to [www.bilitool.org](http://www.bilitool.org) for information on age-specific (postnatal hour of life) serum bilirubin values.

7-14 days: 0.0-14.9 mg/dL

15 days to 17 years: 0.0-1.0 mg/dL

> or =18 years: 0.0-1.2 mg/dL

**Interpretation**

The level of bilirubinemia that results in kernicterus in a given infant is unknown. In preterm infants, the risk of a handicap increases by 30% for each 2.9 mg/dL increase of maximal total bilirubin concentration. While central nervous system damage is rare when total serum bilirubin (TSB) is less than 20 mg/dL, premature infants may be affected at lower levels. The decision to institute therapy is based on a number of factors including TSB, age, clinical history, physical examination, and coexisting conditions. Phototherapy typically is discontinued when TSB level reaches 14 to 15 mg/dL.

Physiologic jaundice should resolve in 5 to 10 days in full-term infants and by 14 days in preterm infants.

When any portion of the biliary tree becomes blocked, bilirubin levels will increase.

**Cautions**

Specimens should be protected from light and analyzed as soon as possible.

Grossly hemolyzed specimens should be rejected because hemoglobin inhibits the diazo reaction and falsely decreased results may be seen.

Compounds that compete for binding sites on serum albumin contribute to lower serum bilirubin levels (eg, penicillin, sulfisoxazole, acetylsalicylic acid).

**Supportive Data**

See Individual Unit Codes.

**Clinical Reference**

1. Rifai N, Chiu RWK, Young J, Burnham CD, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023
2. Scharschmidt BF, Blanckaert N, Farina FA, et al. Measurement of serum bilirubin and its mono- and diconjugates: Applications to patients with hepatobiliary disease. *Gut* 1982;23(8):643-649
3. Practice parameter: management of hyperbilirubinemia in the healthy term newborn. American Academy of Pediatrics. Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia [published correction appears in *Pediatrics*. *Pediatrics*. 1994;94(4 Pt 1):558-565.

## Performance

### Method Description

Total bilirubin, in the presence of a suitable solubilizing agent, is coupled with 3,5-dichlorophenyl diazonium in a strongly acidic medium. The color intensity of the red azo dye formed is directly proportional to the total bilirubin and can be determined photometrically. (Package insert: Bilirubin Total Gen. 3, 09/2016. Roche Diagnostics, Indianapolis, IN)

Direct bilirubin in the presence of acidified sodium nitrite produces nitrous acid, which reacts with sulfanilic acid (in acidic solution) to form a diazonium salt. The diazotized sulfanilic acid then reacts with bilirubin to form isomers of azobilirubin. In the direct bilirubin assay, only conjugated bilirubin is converted by the diazotized sulfanilic acid. The intensity of the red color of azobilirubin is measured photometrically and is proportional to the direct (conjugated) bilirubin concentration. (Package insert: Cobas Direct Bilirubin, June 2015, Roche Diagnostics, Indianapolis, IN)

### PDF Report

No

### Day(s) Performed

Monday through Sunday

### Report Available

Same day/1 to 2 days

### Specimen Retention Time

See Individual Unit Codes.

### Performing Laboratory Location

Rochester

## Fees & Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

### Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information

82247

82248

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
NBILI	Neonatal Bilirubin, S	34543-9

Result ID	Test Result Name	Result LOINC® Value
BILID	Bilirubin, Direct	1968-7
BILIT	Bilirubin Total, S	1975-2