

Bilirubin, Direct

WHAT IS BILIRUBIN?

Bilirubin is a degradation product formed during the normal and abnormal destruction of red blood cells. Bilirubin can be in the indirect (unconjugated) form, or in one of the three direct forms – mono- and di-glucuronide conjugated, or δ -bilirubin. This assay measures just the direct fraction of bilirubin. Measurements of bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, as well as the detection of neonatal jaundice and hemolytic disease in newborns (1).

ELEVATED BILIRUBIN (HYPERBILIRUBINEMIA)

Bilirubin is a normal degradation product from the destruction of aged or abnormal red blood cells. However, elevated levels can occur when there is increased breakdown of red blood cells or impaired removal of bilirubin from the body (2). Blockages in the bile ducts of the liver and gallbladder can cause an increase in bilirubin, as well as other liver diseases, such as hepatitis, cirrhosis, or liver cancer (3).

Individuals with hyperbilirubinemia often have dark yellow urine, pale stools, and skin itching. Additional symptoms can include nausea, vomiting, abdominal pain and bloating, headaches, and weight loss. A build up of toxic ammonia (due to impaired liver function) can also lead to poor brain function causing fatigue and confusion (3).

Bilirubin is also increased in individuals with Gilbert's syndrome, an inherited condition in which the liver doesn't properly process bilirubin. Many individuals with Gilbert's syndrome never have symptoms, or only show signs of jaundice during periods of stress (e.g. excessive exercise, dehydration, or fasting). Typically no treatment is needed for Gilbert's syndrome (4).

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or 'milking' the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity c Direct Bilirubin assay on the Alinity ci series analyzer. This assay determines direct bilirubin levels using the diazonium salt methodology, where bilirubin in the blood specimen couples with a diazo reagent in the presence of sulfamic acid to form azobilirubin. This results in an absorbance increase at 548 nm, which is directly proportional to the amount of direct bilirubin in the specimen.

TEST INTERPRETATION

This assay will provide an accurate direct bilirubin level for the tested blood specimen. The normal range for direct bilirubin levels in adult serum or plasma is ≤ 0.3 mg/dL (5). Additional testing may be required to determine the cause of abnormal bilirubin levels.

DISCLAIMERS/LIMITATIONS

Fasting, caffeine, and certain medications and supplements, including some birth control pills, some antibiotics, Valium, and vitamin C can affect bilirubin levels.

These results should be interpreted in conjunction with other laboratory and clinical information. Additional testing is recommended if bilirubin levels are inconsistent with clinical evidence.

Correct specimen collection and handling is required for optimal assay performance.

Patients with Waldenström macroglobulinemia may have artificially elevated bilirubin values from this assay due to certain paraproteins, particularly IgM.

Indocyanine green (ICG) may interfere with this assay. Specimens from individuals undergoing evaluations using ICG must be collected after ICG has been eliminated.

REFERENCES

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4. National Center for Advancing Translational Studies. Gilbert Syndrome. *GARD*. [Online] August 28, 2018.
5. Clinical Diagnosis and Management by Laboratory Methods, 19th Edition, edited by John Bernard Henry, Frederick R. Davey, Chester J. Herman, et al. Saunders, Philadelphia, PA, 2001.