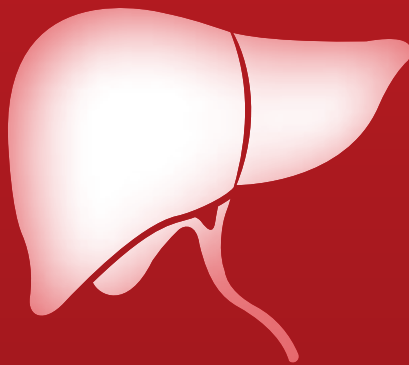


RANDOX

TOTAL BILE ACIDS FIFTH GENERATION



AN ENZYMATIC COLORIMETRIC METHOD FOR BILE ACID TESTING

TOTAL BILE ACIDS

THE FIFTH GENERATION TEST

The fifth generation bile acids test offered by Randox is a 2 shot liquid, enzymatic colorimetric assay for the quantitative in vitro determination of bile acids in serum or EDTA Heparinized plasma.

The fifth generation assay incorporates a more complex enzyme cycling method compared to previous generations to amplify the signal: ultimately improving sensitivity and precision while also reducing interference from haemolytic and lipaemic samples. Haemolysis and lipaemia is common in neonate and pregnant patients, making the fifth generation test ideal for testing on these patients.

A smaller sample volume is needed for the fifth generation test ensuring suitability for use with paediatric and geriatric samples, whilst maintaining precision and sensitivity of the assay.

CLINICAL SIGNIFICANCE OF BILE ACIDS

Testing serum bile acids can be used in the diagnosis and prognosis of liver diseases and may detect some forms of liver disease earlier than standard liver tests because bile acid levels correspond to liver function, rather than liver damage. Abnormal levels in fasting patients or immediately after a meal can be an indicator of liver disease and damage, impaired liver function, intestinal dysfunction, gall bladder blockages or obstetric cholestasis during pregnancy.

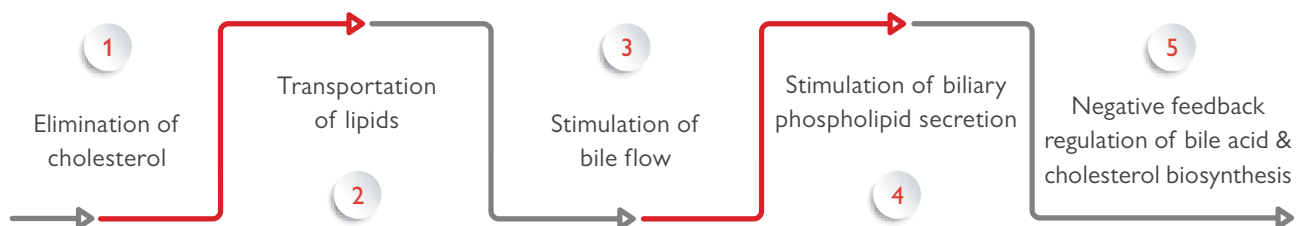
Intrahepatic cholestasis of pregnancy (ICP) or obstetric cholestasis is a pregnancy-specific liver disorder. It can be indicated by pruritus, jaundice, elevated total bile acids and/or serum transaminases and usually affects women during their second and third trimester of pregnancy. According to several reports total bile acids levels in ICP can reach as high as 100 times the upper limit of a normal pregnancy. It has been reported that a doubling in maternal serum bile acids results in a 200% increased risk of stillbirth and elevated bile acids are also thought to trigger the onset of preterm labour⁽¹⁾.

BIOLOGICAL SIGNIFICANCE OF BILE ACIDS

Bile acids are water-soluble and amphipathic end products of cholesterol metabolism formed in the liver. Bile is stored in the gall bladder and released into the intestine when food is consumed.

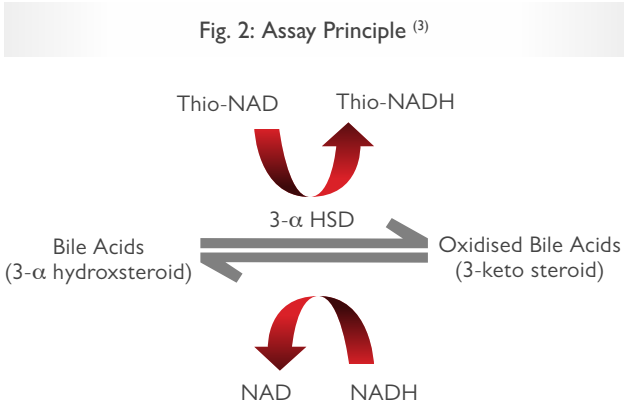
The fundamental role of bile acids is to aid in the digestion and absorption of fats and fat-soluble vitamins in the small intestine. In effect, bile acids have five physiological functions within the body. ⁽²⁾

Fig. 1: The five physiological functions of bile acids ⁽²⁾



ASSAY PRINCIPLE

Two reactions are combined in this kinetic enzyme cycling method. In the first reaction, bile acids are oxidised by 3- α hydroxysteroid dehydrogenase with the subsequent reduction of Thio-NAD to Thio-NADH. In the second reaction, the oxidised bile acids are reduced by the same enzyme with the subsequent oxidation of NADH to NAD. The rate of formation of Thio-NADH is determined by measuring the specific absorbance change at 405nm. Enzyme cycling means multiple Thio-NAD molecules are generated from each bile acid molecule giving rise to a much larger absorbance change, increasing the sensitivity of the assay.



KEY FEATURES OF THE RANDOX FIFTH-GENERATION BILE ACIDS TEST

- **Superior methodology** utilising an advanced enzyme cycling method, the test displays outstanding sensitivity and precision when compared to traditional enzymatic based tests
- **Excellent measuring range** of 2.16 - 238 μ mol/l. The normal upper range for bile acids in a fasting serum sample is 10 μ mol/l
- **Exceptional correlation** of r=0.99 when compared against other commercially available methods
- **Two shot liquid ready-to-use reagent** for convenience and ease-of-use
- **Stable to expiry** when stored at +2 to +8 $^{\circ}$ C
- **Applications available** detailing instrument-specific settings for a wide range of clinical chemistry analysers
- **Complementary controls and calibrators available** offering the complete testing package

ORDERING DETAILS

Description	Cat. No.	Size
5 th Generation Bile Acids Kit	BI3863	R1 2 x 18ml R2 2 x 8ml
Bile Acids Kit	BI2672	R1 10 x 10ml R2 1 x 30ml

CONTROLS AND CALIBRATORS FOR THE FIFTH GENERATION BILE ACIDS KIT

Description	Cat. No.	Size
Assayed Chemistry Premium Plus Control Level 2	HN1530	20 x 5ml
Assayed Chemistry Premium Plus Control Level 3	HE1532	20 x 5ml
Assayed Chemistry Premium Plus Control Levels 2 & 3	HS2611	2 x 5 x 5ml
Clinical Chemistry Calibration Serum Level 3	CAL2351	20 x 5ml

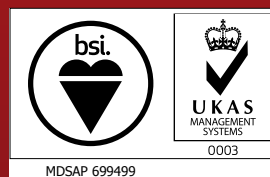
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