CORALYZER
System Pack

Auto Bilirubin Kit

(Mod. Jendrassik & Grof's Method)

For the determination of Direct & Total Bilirubin in serum.
(For Invitro Diagnostic Use Only)

Summary

Bilirubin is mainly formed from the heme portion of aged or damaged RBC's. It then combines with albumin to form a complex which is not water soluble. This is referred to as indirect or unconjugated Bilirubin. In the liver this Bilirubin complex is combined with glucuronic acid into a water soluble conjugate. This is referred to as conjugated or direct Bilirubin. Elevated levels of bilirubin are found in liver diseases (Hepatitis, cirrhosis), excessive hemolysis / destruction of RBC (hemolytic jaundice) obstruction of the biliary tract (obstructive jaundice) and in drug induced reactions. The differentiation between the direct and indirect bilirubin is important in diagnosing the cause of hyperbilirubinemia.

Principle

Bilirubin reacts with diazotised sulphanilic acid to form a coloured azobilirubin compound. The unconjugated bilirubin couples with the sulphanilic acid in the presence of a caffein-benzoate accelerator. The intensity of the colour formed is directly proportional to the amount of bilirubin present in the sample.

Bilirubin + Diazotized Sulphanilic acid ⟶ **Azobilirubin Compound**

Normal reference values

Serum	(Direct)	:	upto 0.2 mg/dl
	(Total)	:	upto 1.0 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population.

Contents

Coralyzer 100 System Packs	**60 ml**	**180 ml**
L1 : Direct Reagent	30 ml	3 x 30 ml
L2 : Total Reagent	30 ml	3 x 30 ml
L3 : Diazo A Reagent	30 ml	2 x 30 ml
L4 : Diazo B Reagent	6 ml	6 ml

Coralyzer 200 System Packs	**60 ml**	**300 ml**
L1 : Direct Reagent	30 ml	3 x 42 ml
L2 : Total Reagent	30 ml	3 x 42 ml
L3 : Diazo A Reagent	30 ml	2 x 30 ml
L4 : Diazo B Reagent	6 ml	6 ml

Storage / stability

Contents are stable at R.T. till the expiry mentioned on the labels.

Reagent preparation

Reagents are ready to use. Protect from bright light.

Working Diazo preparation

Prepare a Working Diazo reagent by mixing 10 parts Diazo A Reagent (L3) with 1 part of Diazo B Reagent (L4). Let stand for 30 min. before use.

This Working Diazo has to be used as the second reagent for both the Direct and Total Bilirubin. The Working Diazo Reagent is stable for 2 weeks at 2 - 8 ^{0}C or for 2 days at 15 - 25 ^{0}C. Keep tightly closed when not in use.

Sample material

Serum. Bilirubin is reported to be stable in the sample for 4 days at 2 - 8 ^{0}C. Protect from light as it is photosensitive.

Calibration

Calibrator is recommended for calibration of this assay.

Linearity

This procedure is linear up to 15 mg/dl for Direct Bilirubin and upto 25 mg/dl for Total Bilirubin.

Note

In the programming for Coralyzer 100, both Direct and Total Bilirubin is the same except for the Test Points and the Range Setup.

Test Points - Direct Bilirubin Start - 31 End - 32
Total Bilirubin Start - 31 End - 32

Care should be taken regarding the reagent position. The Working Diazo can be placed at one reagent position and same can be used for both the Direct and Total Bilirubin assay.

Lipemic and hemolysed samples should not be used.

References

Jendrassik, L., Grof, P., (1938) Biochem. 2,297 : 81
Titez Textbook of Clinical Chemistry. 2nd edition
Practical Clinical Chemistry. Harold Varley. 5th edition

Programming on	CORALYZER 100/200
Item	BIL
Full Name	BILIRUBIN
Test Method	End Point
Base Information	
Unit	mg/dl
Filter	546 nm
Sub. Filter	670 nm
Decimal	xx.xx
High pollute	No
Reagent Blank	
Blank Medium	Serum
Blank Value	0
Blank Low	0
Blank High	1
Sample	
Sample Volume	25
Dilution Times	1
Range Setup	
Reagent	
Rgt. 1 Volume	250
Rgt. 2 Volume	50
Linearity	25
Read data for check	
Assistant Start	12
Assistant End	13
Range Low	0
Range High	2
Test Point Start	31(Direct); 32(Total)
Test Point End	31(Direct); 33(Total)
Standard	
Number of standard	1
Factor	1
Correct Factor	1
Standard Cup	User Defined
Conc.	See Calibrator

Manufactured by :
Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
Gitanjali, Dr. Antonio Do Rego Bagh,
Bambolim Complex P.O. GOA - 403 202, INDIA

BIL2(C)/0121/VER-02