AGD
CliniPak

# BILIRUBIN DIRECT

(Modified Bergh & Muller Single Reagent)

| Code | Pack Size |
|---|---|
| AGDSP - BLMD100 | DB : 5 X 20 mL |
| AGDSP - BLMD50 | DB: 10 X 5ML |

## INTENDED USE

This reagent kit is intended for in vitro quantitative determination of Direct Bilirubin in serum.

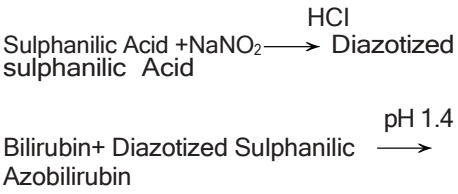
## CLINICAL SIGNIFICANCE

Direct bilirubin determination in serum is used for the diagnosis, differentiation and follow-up of jaundice. Generally, jaundice is classified into three types namely hemolytic, hepatic and obstructive.

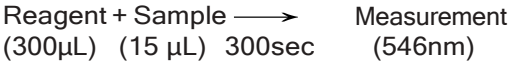
**Increased levels :** are observed in hemolytic jaundice due to excessive hemolysis, obstructive jaundice due to regurgitation while hepatic jaundice is associated with increase in both conjugated and unconjugated bilirubin in serum.

## PRINCIPLE

Bilirubin reacts with diazotized sulphanilic acid to form an azo compound the color of which is measured at 546nm (530-560 nm) and is proportional of bilirubin. In the presence of accelerator only conjugated bilirubin reacts with Direct Bilirubin. The readings for Direct Bilirubin are taken after 5 min of incubation.




## PROCEDURE




## REAGENT COMPOSITION

Reagent Direct Bilirubin

| | |
|---|---|
| Sulphanilic Acid | ≈ 32 mmol/L |
| Sodium Nitrite | ≈ 29 mmol/L |
| Hydrochloric Acid | ≈ 165 mmol/L |

## REAGENT STORAGE AND STABILITY

Bilirubin Direct reagent is ready to use.

The reagent is stable till the expiry date stated on the reagent bottle label, when stored at 2-8 °C and protected from sunlight.

## SAMPLE

Serum is preferred; plasma with heparin as anticoagulant may be used. Serum or plasma should be separated as early as possible Avoid exposure of samples to direct light during processing and storage.

## BASIC PARAMETER

| | |
|---|---|
| SHORT NAME | BILIRUBIN D |
| NAME | BILIRUBIN DIRECT |
| METHOD | MODIFIED BERGH & MULLER |
| ASSAY | End point (two point reagent blank) |
| MAIN WAVE | 546nm |
| SUB WAVE | 630nm |
| DECIMAL | 2 |
| UNIT | mg/dL |
| R1 VOLUME | 300µL |
| INCUBATION | 36 secs |
| R2 VOLUME | 0 |
| SAMPLE VOLUME | 15µL |
| INCUBATION | 0 |
| MIXING SPEED | 0 |
| REACTION TIME ( Delay) | 260 sec |
| CHECK TIME (Read) | 40 sec |
| LINEAR RANGE | 20mg/dL |
| ABSORBANCE RANGE | 0-2.5 |
| CALIBRATION TYPE | SINGLE SPOT LINEARITY |
| DILUTION RATIO | 6 |
| SAMPLE VOLUME | 50 |

*Enter calibrator value as per the lot of calibrator and method.

## LINEARITY

Reagent is linear up to 20mg/dL. Dilute the sample appropriately and re-assay if Direct bilirubin concentration exceeds 20mg/dL. Multiply result with dilution factor.

## REFERENCE NORMAL VALUE

Direct Bilirubin : 0.0-0.25 mg/dL

It is recommended that each laboratory should assign its own normal range.

## QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

## LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

## REFERENCES


- Tietz. NW,ed. Clinical Guide to laboratory tests, 3rd ed.Phildelphia Pa: W.B.Saunders,1995



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ISO 13485:2016 ISO 9001:2015

EU REP


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