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# TOTAL BILIRUBIN L3K<sup>®</sup> ASSAY FOR THE CLINICAL LABORATORY

## INTRODUCTION

Bilirubin is an orange-yellow pigment derived from the breakdown of the heme moiety of hemoglobin during the destruction of red blood cells by the reticuloendothelial system. Determination of total bilirubin levels is useful in the diagnosis and management of liver disease, hemolytic disorders and jaundice. Measurement of total bilirubin levels in serum includes an "indirect" unconjugated fraction loosely bound to albumin and "direct" reacting fractions composed of bilirubin conjugated to glucuronic acid and delta bilirubin ( $\delta$ -bilirubin, also sometimes termed biliprotein). Biliprotein is produced by reaction of conjugated bilirubin with albumin; it has a half-life of about 17-20 days (the same as albumin), accounting for prolonged jaundice in patients recovering from hepatitis or biliary obstruction.



## TEST PRINCIPLE

Traditional methods of measuring bilirubin are based on the reaction of bilirubin with a diazo reagent to form the colored compound Azo-bilirubin. The diazo reaction can be accelerated by the addition of various chemicals so that conjugated and unconjugated bilirubin fractions are measured. For example, Malloy-

Evelyn used methanol; Jendrassik-Grof used caffeine; and Walters-Gerarde used DMSO. Modifications of these methods included the addition of surfactants as solubilizing agents. In the DCL Total Bilirubin L3K method, a 2,4 dichlorophenyldiazonium salt is used as the diazo reagent and the reaction is facilitated by the use of surfactants and additives which result in reduced hemoglobin interference.

## KEY FEATURES & BENEFITS

- **Virtually Interference Free Testing** – DCL's Total Bilirubin L3K provides significantly reduced interference from hemolysis and lipemia for accurate results with clinically challenging specimens.
- **Liquid Stable Format** – Liquid stable technology eliminates the need for reagent reconstitution procedures, reducing errors, saving time, labor and reagent waste.
- **Wide Linear Range** – With a linear range of up to 30.0 mg/dL, repeat testing is substantially reduced, saving both time and expense.
- **Minimal Sample Requirements** – Each test requires only four (4)  $\mu$ L of sample, making it ideal for pediatric, geriatric and veterinary testing and research.
- **Flexible Testing** – Well suited for use with fully automated procedures, with an extensive listing of instrument applications readily available.
- **Fast Test Turnaround** – Able to generate accurate test results by automated methods in ten (10) minutes.
- **Convenient Choice of Packaging Design** – DCL's Total Bilirubin L3K is offered in a choice of packaging formats, ideally suited for any laboratory regardless of workflow demands.

## SPECIFIC PERFORMANCE

### CHARACTERISTICS

- **Reportable Range (NCCLS EP6-P)** – The reportable range of the assay using automated procedures will depend on the sample to reagent ratio, as well as other factors. However, for the majority of automated procedures, the assay provides a reportable range of 0.06 – 30.00 mg/dL.
- **Accuracy (NCCLS EP9-P)** – The performance of this method (y) was compared with the performance of another commercially available method (x) on a Roche Hitachi® 717 clinical chemistry analyzer. Forty (40) samples ranging from 0.17 mg/dL to 26.61 mg/dL were tested which gave a correlation coefficient of 0.9998. This study yielded a linear regression equation of  $y = 1.05x + 0.13$  mg/dL.
- **Precision (NCCLS EP5-T2)** – Estimates for Intra-Run performance were obtained on two (2) separate levels of commercially available serum control materials, with concentrations of 0.83 mg/dL and 4.65 mg/dL run a total of twenty (20) times. The resulting SD's were 0.02 mg/dL and 0.05 mg/dL respectively, generating CV%'s of 2.3 and 1.1. Estimates for Total Precision performance were obtained on two (2) separate levels of commercially available serum control materials, with concentrations of 0.84 mg/dL and 4.63 mg/dL. These were assayed in forty (40) runs over twenty (20) days. The resulting SD's were 0.03 mg/dL and 0.13 mg/dL respectively, generating CV%'s of 3.1 and 2.8.

## ORDERING INFORMATION

PRODUCT	CATALOGUE NUMBER	PACKAGING CONFIGURATION
Total Bilirubin L3K	285-10	R1: 1 x 100 mL R2: 1 x 25 mL
Total Bilirubin L3K	285-30	R1: 3 x 100 mL R2: 1 x 75 ml
Total Bilirubin L3K (R1)	285-50A	1 x 1000 mL
Total Bilirubin L3K (R2)	285-50B	1 x 300 mL
SUPPORTING PRODUCTS		
DC-Cal Calibrator	SE-035	5 x 3 mL
DC-Trol Level 1 Control	SM-052	10 x 5 mL
DC-Trol Level 2 Control	SM-056	10 x 5 mL

REFER TO PACKAGE INSERT AND/OR MSDS FOR ADDITIONAL TECHNICAL INFORMATION

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**Diagnostic Chemicals Limited**

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