diatron

TOTAL BILIRUBIN

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0142 **Packaging:** 6 x 40 mL (R1) + 6 x 10 mL (R2) Σ 1200

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of Total Bilirubin in samples of human serum from the general patient population. Measurements of Total Bilirubin are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the evaluation of liver health, the diagnosis, monitoring and severity assessment of hepatobiliary diseases and the investigation and evaluation of jaundice.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE
Bilirubin is the product of normal heme catabolism and is excreted in the bile. Bilirubin is increased in certain diseases as in hepatocellular damage (inflammatory, toxic, neoplasmatic), intra or extrahepatic obstruction of the biliary tree, hemolytic diseases, neonatal physiological jaundice, Crigler-Najjar syndrome, Gilbert disease, Dubin-Johnson syndrome, jaundice from maternal milk syndrome, hypothyroidism, fructose intolerance, familial hyperbilirubinemia.

METHOD PRINCIPLE
The DPD method is applied, whereby 3,5-dichlorophenyldiazonium tetrafluoroborate (DPD) binds directly to total bilirubin in acidic medium, forming azobilirubin, whose rate of absorbance at 550/700 nm is proportional to the concentration of total bilirubin in the sample.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)		Reagent 2 (R2)	
DPD:	2.2 mM	HCl:	120 mM
HCl:	120 mM		
Surfactants			

⚠ **WARNINGS – PRECAUTIONS**
- The reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- Reagent R1 and R2 is highly acidic. Avoid swallowing and contact with eyes, skin and mucous membranes.
- Dispose all waste according to national laws.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
The reagents are ready-to-use. Place one vial of R1 and one vial of R2 in the respective positions on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**
Unopened, the reagents are stable at 2 – 8°C up to the expiry date stated on the label. After opening, they remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum may be used as specimen, preferably morning sample from fasting patient. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Bilirubin (conjugated or not) is oxidized when exposed to white or ultraviolet light, therefore samples should be protected from direct exposure to light. Store samples in a dark place. Total bilirubin remains stable in serum for 1 day at 20 - 25°C, 7 days at 2 - 8°C and 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 916a NIST for serum calibration. Calibrate the assay every 2 weeks when used on Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
- Total bilirubin calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum-plasma:	Adults:	0.3 – 1.2 mg/dl
Children:	0 – 1 day:	1.4 – 8.7 mg/dL
	1 – 2 days:	3.4 – 11.5 mg/dL
	3 – 5 days:	1.5 – 12 mg/dL

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**
Flush waste pipes with water after disposal of any undiluted reagent in the drain.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.
Linearity Up to 30 mg/dL
Lowest detection limit: 0.08 mg/dL
The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run). The results taken in your laboratory may differ from these values.

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
0.50	2.10
10.60	1.00
Level (mg/dL)	**Total CV%**
0.50	4.20
10.60	1.30

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	1800 mg/dL
Hemoglobin	100 g/dL
Ascorbic acid	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 0.934X – 0.072 R=0.9734 N=69 Sample range = 0.25 – 1.80 mg/dL

BIBLIOGRAPHY

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⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P260: Do not breathe dust/ fumes/ gas/ mist/ vapors/ spray.	**H290**: May be corrosive to metals.
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H314**: Causes severe skin burns and eye damage.
P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.	**H335**: May cause respiratory irritation.
P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.	
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	

SYMBOLS

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests

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