

DIRECT BILIRUBIN

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

REF 1419-0152

Packaging: 6 x 35 mL (R1) + 6 x 1.82 mL (R2)

840



INTENDED USE

Reagents for In Vitro quantitative automated measurement of the concentration of Direct Bilirubin in samples of human serum from the general patient population. Measurements of Direct 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. Due to its very low solubility in water, unconjugated bilirubin (indirect bilirubin) is bound with albumin and transported to the liver, where it is conjugated with glucuronic acid (direct bilirubin) and then it is excreted in the bile. Direct bilirubin increases in intra or extrahepatic obstruction of the biliary tree, in hepatocellular damage (hepatitis, cirrhosis and cancer in advanced stages), Dubin-Johnson syndrome, Rotor syndrome and due to the administration of drugs that cause cholestasis. Theoretically bilirubin should increase in hemolytic anemias. When there are no complications, increase in bilirubin is expected only for the non-conjugated fraction. However, in hemolytic anemias without proven complications, some increase in direct bilirubin may be detected.

METHOD PRINCIPLE

The modified Malloy-Evelyn method is applied. Direct (bound) bilirubin reacts with diazotized sulfanilic acid in acidic pH to form azobilirubin, a colored chromophore. The free (unbound) bilirubin fraction does not react. Reaction is end-point.

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)	
Sulfanilic acid:	32 mM	Sodium nitrite:	60 mM
Hydrochloric acid:	165 mM		



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 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

Reagents R1 and R2 are ready-to-use when placed in the corresponding positions of the analyzer. The vials bear bar codes 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, the reagents are 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. Direct 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 (code 1578-0891), traceable to Medicon Master Lot for 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

- Direct Bilirubin calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum-plasma: 0 – 0.4 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 20 mg/dL

Lowest detection limit: 0.11 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
0.40	2.80
6.90	2.40
Level (mg/dL)	Total CV%
0.40	3.10
6.90	3.60

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

(Insignificant up to)

Triglycerides 2400 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 analyzer and another commercially available product. The results were as follows:

Y = 1.054X – 0.078 R=0.9878 N=48 Sample range = 0.00 – 7.54 mg/dL

BIBLIOGRAPHY

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- Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
- Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
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LABEL ELEMENTS

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P260: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.	H272: May intensify fire; oxidizer.
P280: Wear protective gloves/protective clothing/eye protection/face protection.	H290: May be corrosive to metals.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.	H301: Toxic if swallowed
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.	H314: Causes severe skin burns and eye damage.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	H315: Causes skin irritation.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	H317: May cause an allergic skin reaction.
	H319: Causes serious eye irritation.
	H335: May cause respiratory irritation.
	H400: Very toxic to aquatic life.

SYMBOLS

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

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