diatron

G-6-PDH

For use on Diatron Pictus® series analyzers
Method: UV Kinetics
Code: 1419-0912
Packaging: 2 x 12 mL (R1) + 2 x 1.5 mL (R2) + 1 x 100 mL (R3)
Store at: 2°– 8°C
For *in vitro* use

INTENDED USE
Ready to use reagents for the quantitative determination of Glucose-6-Phosphate Dehydrogenase activity in human blood, specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
G-6-PDH deficiency may cause hemolysis of varying severity. Hemolytic episodes in patients may be caused during medication (sulfonamides, nitrofurantoin, phenacetin, antipyretics, primacine), by infections, acidosis, stress, or even by intake of specific foods (fava beans). Increased G-6-PDH levels are observed in malignant anaemia, myocardial infarction, hepatic coma, hyperthyroidism, blood loss, megaloblastic anaemia. Diminished levels of G-6-PDH are observed in G-6-PDH deficiency, haemolytic anaemia, infections, septicaemia, diabetic acidosis.

METHOD PRINCIPLE
The method used for the determination of G-6-PDH is UV Kinetic, and is based on the following reaction:

Glucose-6-phosphate + NADP $\xrightarrow{\text{G-6-PDH}}$ 6-Phosphogluconic acid + NADPH

The increase in absorbance at 340 nm due to NADPH production is proportional to the activity of G6PDH 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".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
For *in vitro* diagnostic use only.
Reagent 1 (R1):
Maleimide: 4.3 mM
Glycyl-Glycine: 84 mM
G-6-P: 1.05 mM
Non reactive substances and preservatives.
Reagent 2 (R2):
NADP-Na_2: 7.5 mM
Non reactive substances and preservatives.
Reagent 3 (R3):
Saponin: 0.2%
Non reactive substances and preservatives.

WARNINGS – PRECAUTIONS
- This 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 according to the universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN_3 < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane. NaN_3 may form explosive compounds with copper or lead. To avoid possible build up of azide compounds flush waste pipes with water after the disposal of undiluted reagent.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

PREPARATION
Reagents R1 and R2 are liquid, ready to use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

SHELF LIFE
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, they are stable for 28 days stored in the cooled reagent tray on Pictus® series analyzers.

REAGENT DETERIORATION
The reagent should not be used:
- When there is change in colour of the R1/R2.
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to high temperature.

SAMPLE
Use whole blood with EDTA as specimen. Do not use oxalate or fluoride as anticoagulants. Specimens are stable for more than 20 days at 4°C and for 5 days at 25°C. Add 0.9 ml of red cell lysing reagent (R3) for every 0.1 ml of sample blood. Allow standing at room temperature for 5 – 10 min to ensure complete hemolysis.

CALIBRATION
The protocol of the analyzer contains the appropriate calibration factor. Calibration is not necessary prior to samples analysis under the condition that control results are within the specified ranges. Reagent blank measurement is strongly suggested when the lot of the reagent is changed.

QUALITY CONTROL
Diatron provides Lyophilized controls containing three different levels of G-6-PDH activity (Normal, Intermediate, and Deficient) ref code # 1578-0910.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls should be tested each date patient samples are tested and each time calibration is performed. Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for G-6-PDH should be verified with the corresponding working protocol. Results outside the specified values 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
- Quality control material
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS
Whole blood: 7.0 – 20.5 U/g Hgb
Hgb: 11 – 16 g/dL whole blood
Each laboratory should determine its own expected values as dictated by good laboratory practice.

SPECIFIC PERFORMANCE CHARACTERISTICS
Linearity
The assay is linear up to 3000 U/L. When values exceed this range samples should be diluted accordingly.
Sensitivity
The lowest detectable level of G-6-PDH is estimated at 21 U/L for Pictus® P700/P500 series analyzers.
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

Pictus® P700/P500			Pictus® P400		
Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
710.2	3.33	3.67	405.5	2.85	4.95
1939.5	2.90	3.97	1424	3.25	4.78

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).
Interference: Criterion: recovery within ±20% from target value

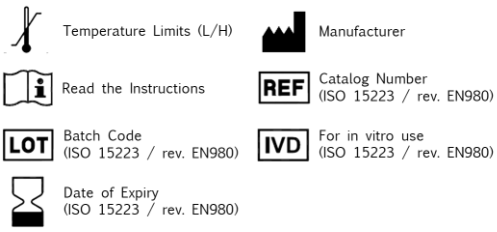
	Pictus® P700/P500	Pictus® P400
Lipemia	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to 1000 mg/dl Intralipid®
Bilirubin	Insignificant up to 40 mg/dl	Insignificant up to 40 mg/dl
Ascorbic acid	Insignificant up to 3 g/dl	Insignificant up to 3 g/dl

Method Comparison
A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P700/P500			
Y=0.995X + 8.084	R=0.9862	N=59	Sample range = 59.4 – 2547 U/L
Pictus® P400			
Y=0,9715X + 78.508	R=0.9950	N=59	Sample range = 151.7 – 2673.8 U/L

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed. Philadelphia: WB Saunders Company, 1995.
2. Burtis CA, Ashwood ER, ed. Tietz textbook of clinical chemistry. 2nd ed. Philadelphia WB Saunders Company, 1994.
3. 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.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press 2000.

SYMBOLS


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MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com
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