ASO

ANTISTREPTOLYSIN O

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

2°C – 8°C

REF 1419-1066 **Packaging:** 4 x 30 mL (R1) + 4 x 6 mL (R2) Σ 480

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of Antistreptolysin-O (ASO) in samples of human serum or plasma from the general patient population. Measurements of ASO are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the diagnosis of post-streptococcal infection complications.

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
Streptococcus pyogenes is a gram-positive bacterium and is associated with many important diseases that result from the release of its toxin like: pharyngitis, sinusitis, pneumonia, septic scarlet fever and lymphangitis. It can also cause diseases by the reaction of the immune system against it, such as rheumatic fever and glomerulonephritis. Streptolysin O, a hemolysin produced by streptococci, can cause an immune response and the detection of Antistreptolysin O (ASO) antibodies can be clinically used to confirm a recent infection. ASO antibodies can be detected 1 – 3 weeks after infection and they sustain at maximum levels for 3 – 6 weeks.

METHOD PRINCIPLE
The turbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and a solution (R2) of Latex particles covered with streptolysin, anti-streptolysin-O antibodies in the sample react specifically with streptolysin, leading to agglutination of latex particles. This agglutination is detected as a change in turbidity at 590 nm, which is proportional to the concentration of ASO 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)
Tris buffer (pH 8.4):80 mM Polyethylene glycol:5% Non-reactive components and preservatives.	Streptolysin O from Streptococcus Pyogenes colony, bound on polysterene particles. Non-reactive components 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 streptolysin, which is a hemolyzing agent that may be dangerous if it enters the bloodstream. Avoid contact with the skin.
- The reagent contains sodium azide (NaN_3 < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
Reagent 1 (R1) is ready to use when placed in the appropriate position of the analyzer. R2 has to be mixed by inversion 5 – 10 times before it is placed on the analyzer. Repeat mixing of R2 weekly. Avoid foaming. Vials bear barcode for recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

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

⚠ **SAMPLE** Serum or Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. ASO is stable in serum or plasma samples for 2 days when stored at 2 – 8°C, and for 6 months when stored at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON EASO Calibrator (1478-1062), traceable to NIBSC 64/2 for calibration. Calibrate the assay every 2 weeks 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 Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) for quality control. Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for ASO 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
- ASO calibrator
- Quality control material
- Diatron Pictus® analyzer
- Usual laboratory equipment

REFERENCE INTERVALS
Newborns: similar to the mother
Children: ≤ 150 IU/ml
Adults: ≤ 200 IU/ml
Each laboratory should determine its own expected values as dictated by good laboratory practice.

⚠ **WASTE DISPOSAL**
This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

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 1000 IU/mL
Hook effect > 5000 IU/mL
Lowest detection limit 10.9 IU/mL
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 EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (IU/mL)	**%CV**
140	2.22
409	0.96
Level (IU/mL)	**TOTAL %CV**
140	2.25
409	1.08

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	400 mg/dL
Bilirubin	20 mg/dL
Ascorbate	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 = 0.964X - 0.077 R=0.9945 N=30 Sample range = 5.6 – 497 IU/mL

BIBLIOGRAPHY

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SYMBOLS

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

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