CALCIUM

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

2°C – 8°C

REF 1419-0201 **Packaging:** 8 x 21 mL

Σ 840

INTENDED USE
Reagents for In Vitro quantitative automated determination of Calcium in samples of human serum or urine from the general patient population. Measurements of Calcium are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis and management of several comorbidities involving bone, liver and thyroid disorders.

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
Calcium tests may be ordered to screen for, diagnose, and monitor a range of conditions relating to the bones, heart, nerves, kidneys, and teeth. Licensed physicians may request the test to help them assess a patient's health status.

METHOD PRINCIPLE
Calcium ions react with Arsenazo III dye in acidic pH, to form a violet complex. The absorbance at 650/750 nm is proportional to the concentration of calcium 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

MES buffer (pH 6.5):	100 mmol/l
Arsenazo III:	1.5 mmol/l
Non-reactive ingredients, preservative	

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.
- The reagent contains Arsenazo III. Avoid swallowing and contact of the reagent with 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
Reagent ready to use when placed in the corresponding position 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 cloudy or decolorized.
- After prolonged exposure to sunlight or high temperature.

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

SAMPLE Serum, or 24-hour urine may be used as specimen. Precipitation of calcium has also been reported with fibrinogen or lipids in heparinized plasma during storage or refrigeration. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Plastic or glass test tubes may absorb calcium during storage. Calcium excretion fluctuates during the day, declining at night. Obtain blood sample with minimal venous occlusion, avoiding patient exercise, or after restoring circulation for more than 1 min, since the pressure from the tourniquet may lead to increased total calcium concentration due to water diffusion from the vein pores. Upright position for 15 min causes a 4 – 7% increase in calcium levels. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Calcium is stable for several days at 2 – 8°C, and for 6 months when stored at –20°C. Do not freeze thawed samples. Collect 24 hours urine sample in a bottle containing 10 mL HCl 6M, or acidify after collection to pH < 2 and wait for at least 1 hour before analysis to allow any calcium salts to dissolve.
Urine samples should be diluted in a 1:5 ratio with deionized water. Calcium concentration should be corrected for the added volume of HCl.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 909b NIST for serum calibration. Calibrate the assay when a new lot of reagent is installed. Perform a Reagent Blank measurement every 2 weeks. 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. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

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

REFERENCE INTERVALS
Serum, plasma: 8.1 – 10.4 mg/dL
Urine: 100 – 300 mg/24h. In low calcium diet the reference interval for urine is 50 – 150 mg/24h. In calcium free diet the reference interval for urine is 5 – 40 mg/24h. 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
The reagent contains Arsenazo III. Flush waste pipes with water after the disposal of 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	Serum: Up to 20 mg/dL	Urine: Up to 40 mg/dL
Lowest detection limit:	Serum: 0.13 mg/dL	Urine: 0.1 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			
SERUM		**URINE**	
Level (mg/dL)	**%CV**	**Level (mg/dL)**	**%CV**
5.70	2.40	7.76	0.87
14.3	2.10	11.5	0.47
Level (mg/dL)	**Total CV%**	**Level (mg/dL)**	**Total CV%**
5.70	3.10	7.76	1.34
14.3	3.50	11.5	1.40

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

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Triglycerides	3000 mg/dL	Bilirubin	20 mg/dL
Hemoglobin	500 g/dL	Ascorbic Acid	3 g/L
Bilirubin	20 mg/dL	Glucose	10 g/dL
Conj. Bilirubin	20 mg/dL	Creatinine	10 gr/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:

Serum:	Y = 1,0697X – 0,809	R=0.979 N=40	Sample Range = 5.4 – 11.5 mg/dL
Urine:	Y = 1,053X – 0,429	R=0.999 N=26	Sample Range = 0.3 – 25.4 mg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 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 Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

SYMBOLS

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

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

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