diatron

ACP

For use on Diatron Pictus® series analyzers
Method: α-Naphthylphosphate – Fast Red
Product code: 1519-0234
Package: 6 x 6 ml (R1) + 1 x 5 ml (R2) + 1 x 5 ml (R3)
Store at: 2 – 8°C
For *in vitro* use only

INTENDED USE
Reagent for the quantitative determination of total and prostatic acid phosphatase in human serum specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
The α-napthylphosphate – Fast Red method is applied. Acid phosphatase activity is increased in prostate cancer and especially but not always with metastases, multiple myeloma, Paget's disease, sickle cell crisis, Gaucher disease, cirrhosis, hyperparathyroidism, thrombocytosis.

METHOD PRINCIPLE
The determination of acid phosphatase is based on the following reactions:

α-napthylphosphate + H_2O ⟷ α-naphtol + inorganic Phosphate

α-naphtol + Fast Red TR ⟶ Diazo Dye

The a-Naphtol / Fast Red TR formed complex absorbs light at 405/750 nm.

For the determination of prostatic acid phosphatase, the prostatic fraction is specifically inhibited by L-Tartrate, leaving the non prostatic fraction active. The activity of the prostatic fraction is calculated by extracting the activity of non prostatic from total acid phosphatase.

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
Reagent 1 (ACP):
Citrate buffer (pH 5.3±0.1): 60 mM
a-naphthyl phosphate: 3 mM
Reagent 2 (Buffer):
Acetate buffer (pH 5.0): 5 M
Reagent 3 (L-Tartrate):
Sodium L-Tartrate: 2 mM
Citric Acid: 70 mM
Sodium Citrate: 10 mM

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 with special caution.
- Avoid swallowing and contact with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION
Reconstitute the ACP reagent R1 by adding exactly 6 ml deionized H_2O. Shake gently. Avoid foaming.
Reconstitute reagent R3 (L-Tartrate) with exactly 5 ml deionized H_2O. If needed, warm the reagent at 40 – 50°C to completely dissolve the material.
Reagent R2 (Acetate Buffer) is ready to use. Transfer contents of all vials to analyzer-specific reagent containers supplied with barcodes for recognition by Pictus® series analyzers.
- For the determination of ACP use reconstituted reagent R1 (ACP).
- For the determination of NP-ACP use a vial of reagent R1 (ACP), in which 60 µl of reagent R3 (L-Tartrate) have been added.
- Reagent R2 (Acetate Buffer) is used for the stabilization of ACP in serum.

REAGENT DETERIORATION
The reagent should not be used
- When the blank measurement of the reconstituted reagent of ACP is greater than 0.4 when measured against H_2O at 405 nm.
- When the L-Tartrate has precipitated. Warm the L-Tartrate solution at 40°– 50°C to redissolve it.

SHELF LIFE
Unopened, the reagents are stable up to the expiry date stated on the label when stored at 2°– 8°C. The reconstituted ACP reagent is stable for 1 day at room temperature and for 7 days stored in the cooled reagent tray of Pictus® series analyzers. The reconstituted L-Tartrate reagent is stable up to the expiry date stated on the label when stored at 2°– 8°C. If recrystalization occurs warm the solution at 40°– 50°C to redissolve the content.
The acetate buffer is stable up to the expiry date stated on the label when stored at 2°– 8°C.

SAMPLE
Specimens of non-hemolyzed serum must be used. Acid phosphatase in serum is particularly unstable. It is necessary to stabilize the ACP in the sample by adding 20 µL Acetate buffer for every 1 mL serum. ACP in control sera is more unstable. Do not omit, whenever ACP/NP-ACP is to be measured, to add Acetate Buffer in control sera at the same volume ratio as for serum. NOTE: The strongly acidic environment this will create may affect the determination of other analytes, (urea, enzymes, etc.) therefore the samples for ACP/NP-ACP determination should be aliquoted immediately after centrifugation and prior to Acetate buffer addition.

CALIBRATION
Diatron provides MEDI-CAL (1578-0891) for calibration of ACP. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 14 days. Calibration should be repeated when a new lot of reagent is used, after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. The calibration factor of NP-ACP is set automatically from the ACP calibration factor.

QUALITY CONTROL
Diatron provides 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 SUPPLIED WITH THE KIT
- ACP Calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

CALCULATION
Total ACP (U/L) = ΔA/min x 853
Non Prostatic ACP (U/L) = ΔA/min x 860
(Prostatic ACP) = (Total ACP) – (Non prostatic ACP)
ΔA/min: Change of Optical Density / min
Results are automatically calculated by all automated biochemistry analyzers, based on the Calibration Factor and ΔA/min.

REFERENCE INTERVALS
Total ACP up to 9 U/L
Prostatic ACP up to 3 U/L

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® series 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

	Pictus® P400		Pictus® P700/P500	
Linearity	Total:	0.4 – 65 U/L	Total:	0.4 – 65 U/L
	Prostatic:	0.4 – 40 U/L	Prostatic:	0.4 – 40 U/L
Lowest Detection Limit:	Total:	0.3 U/L	Total:	0.3 U/L
	Prostatic:	0.3 U/L	Prostatic:	0.4 U/L

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 in one run 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 400			Pictus 700 / P500		
	Within Run			Within Run		
	Level (U/L)	CV%	Total CV%	Level (U/L)	CV%	Total CV%
Total ACP	10.2	1.55	3.75	8.6	2.79	4.29
	29.1	2.30	3.38	20.0	2.13	4.68
Prostatic ACP	6.3	2.41	3.52	4.6	5.14	5.35
	14.9	1.72	3.02	9.5	3.83	4.53

Interferences Criterion: recovery within ±20% from target value

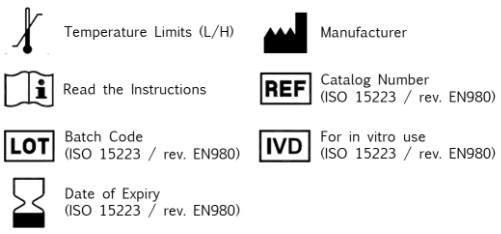
	Pictus® P400	Pictus® P700/P500
Total ACP		
Lipemia	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to Intralipid® 1000 mg/dl
Heamoglobin	Insignificant up to 75 mg/dL	Insignificant up to 200 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 2.5 mg/dL	
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 8 mg/dL
Prostatic ACP		
Lipemia	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to Intralipid® 1000 mg/dl
Heamoglobin	Insignificant up to 75 mg/dL	Insignificant up to 150 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 2,5 mg/dL	
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 8 mg/dL

Correlation 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® P400				
Total	Y = 0.975X + 0.32	R=0.969	N=90	Sample range: 0.55 – 52.40U/L
Prostatic	Y = 0.968X + 0.21	R=0.975	N=90	Sample range: 0.15 – 3.49U/L
Pictus® P700/P500				
Total	Y = 0.983X + 0.22	R=0.974	N=90	Sample range: 0.55 – 52.40U/L
Prostatic	Y = 0.975X + 0.14	R=0.982	N=90	Sample range: 0.15 – 3.49U/L

BIBLIOGRAPHY

1. Bergmeyer, H.V., Methods of Enzymatic analysis. Weinheim, Verlag chemie, 3rd p. 92 (1984)
2. Tietz, N.W., Fundamentals of Clincal Chemistry, Philadelphia: W.B. Saunders Company Ltd., p. 614 (1976)
3. Amador, E et al, Am. J. Clin. Path. 51:202
4. Hillman, G.Z., Klin. Chem. Klin. Biochem 3:323 (1971)
5. Shaw, L.M., et al, Am. J. Clin. Path. 68:57 (1977)

SYMBOLS


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