



PHOSPHOROUS LR liquid reagent

REF C3300620 518 Test

CE C3300620A 518 Test

IVD For in vitro medical device

Use

Kit for measurement of inorganic phosphorous in serum or plasma. Colorimetric blue of molybdate method.

Summary

Phosphorous measurements are used in the diagnosis and treatment of disorders characterized by low and elevated levels of inorganic phosphorous.

Principle

End point analysis. Inorganic phosphorous reacts, in acid environment, with ammonium molybdate forming phosphomolybdate complex. The increase in absorbance is proportional to the inorganic phosphorous concentration in the sample.

Reagents

R1 Hydrochloric acid 1.00 mmol/l
ammonium molybdate 0.70 mmol/l
surface-active agents anionic and polyanionic.

Reagent Preparation

Reagents are liquid and ready to use.

Storage and stability

- Store the kit at 15-25°C.
- After opening, the R1 vial is stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or plasma.
- Do not use samples with haemolysis.
- Do not use sodium fluoride as anticoagulant.
- The phosphorous is stable in the samples up to 7 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength λ: 340 (330-360) nm
Working Temperature 37°C
Optical path 1 cm
Reaction "end point"

-- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	--	--
Sample	--	--	10 µl
Standard	--	10 µl	--

Mix, then incubate for 5' at 37°C (15-25°C). Measure the absorbance of the sample (EC) and standard (ESTD) against the reagent blank.

Calculation

Phosphorus [mg/dl] o [mmol/l] = EC/ESTD x Conc. STD

The reagent performances are related to 37°C, 1 cm and 340 nm.

Conversion Factor

Phosphorous [mg/dl] x 0.32 = Phosphorus [mmol/l]

Reference Values

	Sierum or plasma
Adults	2.5 -- 5.5 mg/dl
Childrens	4.0 -- 7.0 mg/dl

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCE

Linearity

Reaction is linear up to a concentration of 20 mg/dl. Samples with values exceeding 20 mg/dl must be diluted with saline solution. Then, multiply, the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 3.85	H = 6.86
S.D.	N = 0.06	H = 0.19
C.V.%	N = 1.62	H = 2.71

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 3.95	H = 6.58
S.D.	N = 0.08	H = 0.15
C.V.%	N = 2.08	H = 2.28

Analytical sensitivity

The test sensitivity in terms of detection limit is: 0.10 mg/dl.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.9956$

$$y = 1.0005x + 0.12$$

Interferences

No interference was observed by the presence of:
Bilirubin ≤ 25 mg/dl.
Triglycerides ≤ 800 mg/dl.
Hemoglobin ≤ 40 mg/dl.

For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, every time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996).
Talke H, Schubert GE: Klin Wchrs., (1965), 43, 174
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed. 2000.

Symbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits

Read instruction for use

Gesam Production srl