0108062986190c503V4.0

PYP

cobas®

Pyridoxal phosphate

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08062986190	Pyridoxal phosphate (950 tests)	System-ID 2012 001	**cobas c** 303, **cobas c** 503

English

System information

PYP: ACN 20120

Intended use

For the modification of alanine aminotransferase/glutamic pyruvic transaminase (ALT/GPT) or aspartate aminotransferase/glutamic oxaloacetic transaminase (AST/GOT) reagents to include pyridoxal-5-phosphate.

Summary

Measurements of ALT/GPT and AST/GOT enzymes are used in the diagnosis and treatment of certain liver diseases (e.g. viral hepatitis, cirrhosis) and heart disease.

Vitamin B_6 occurs in three natural forms: pyridoxine, pyridoxal and pyridoxamine. All three of these moieties are converted to pyridoxal-5-phosphate (P-5-P or PYP) in the body by an enzymatic reaction with ATP.[1] P-5-P serves as a highly versatile coenzyme for many types of reaction: decarboxylation, racemization, transamination and other metabolic functions. P-5-P undergoes amination to pyridoxamine phosphate. The amino group is then transferred to an α-keto acid, returning pyridoxamine phosphate to its pyridoxal-5-phosphate form.[2]

Pyridoxal-5-phosphate is essential to these aminotransferase reactions. In normal individuals, part of the aminotransferase enzymes are not saturated with P-5-P. In some hepatic disorders, in vitamin B_6 deficiency, and following renal dialysis, the aminotransferase enzymes may be significantly stripped of P-5-P, thus rendering the enzymes inactive. The apoenzyme (enzyme without coenzyme) is activated by the addition of P-5-P. The addition of pyridoxal-5-phosphate to reaction media for catalytic determinations is widely accepted (IFCC/DGKC/SFBC).[3,4,5]

Test principle

Refer to appropriate insert or application sheet for analyzer-specific information.

Reagents – working solutions

PYP Pyridoxal phosphate: 730 µmol/L; additives; preservative

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

For details see method sheet for ALTP or ASTP.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- ALTP, Cat. No. 08056773190
- ASTP, Cat. No. 08056838190

See appropriate method sheets for additional required materials.

Assay

For optimum performance of the assay follow the directions given in the method sheets for ALTP and ASTP. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Performance data

See method sheet for ALTP or ASTP.

References

1 Greengard P. The Pharmacological Basis of Therapeutics. 5th ed. Goodman, Gilman, eds. New York, NY: Macmillan 1975:1556-1558.

2 Lehninger AL. Biochemistry. 2nd ed. Worth. 1975:344-345/562-565.

3 Plebani M, Bonvicini P, De Besi T, et al. Reference values for alanine and aspartate aminotransferase (ALT and AST) optimized by addition of pyridoxal phosphate. Enzyme 1980;25(5):346-352.

4 Rej R. Review: the role of coenzymes in clinical enzymology. Ann Clin Lab Sci 1977;7(6):455-468.

5 Euro J Clin Chem Clin Biochem 1993;31:901-909.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

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