ALP

Alkaline Phosphatase
RX SERIES

INTENDED USE

An Alkaline Phosphatase test system is a device intended for the quantitative *in vitro* determination of Alkaline Phosphatase (ALP) activity in serum and plasma. This product is suitable for use on RX **series** instruments which includes the RX **daytona** and the RX **imola**.

Cat. No.		
AP 3803	R1. Buffer	6 x 51 ml
	R2. Substrate	6 x 14 ml

GTIN: 05055273200355

CLINICAL SIGNIFICANCE

Measurements of alkaline phosphatase are of use in the diagnosis, treatment and investigation of hepatobilary disease and in bone disease associated with increased osteoblastic activity. Alkaline phosphatase is also used in the diagnosis of parathyroid and intestinal disease.

COLORIMETRIC METHOD[1]

This is an optimized standard method according to the recommendations of the Deutsche Gesellschaft Für Klinische Chemie.

PRINCIPLE

p-nitrophenyl phosphate + H_2O $\xrightarrow{AP}$ phosphate + p-nitrophenol

SAMPLE COLLECTION AND PREPARATION[2]

Serum or heparinized plasma.
Alkaline phosphatase is stable in serum for 5 days when stored at +2 to +8°C

REAGENT COMPOSITION

Contents	Concentrations in the Test
R1. Buffer	
Diethanolamine	1 mol/l, pH 9.8
$MgCl_2$	0.5 mmol/l
R2. Substrate	
p-nitrophenylphosphate	10 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise- the normal precautions required for handling laboratory reagents.

Solution R1 contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Solution R1 contains diethanolamine which may cause serious damage to eyes and which is harmful if swallowed. Avoid ingestion and wear suitable eye protection.

Health and Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. Buffer
Contents ready for use. Stable up to the expiry date when stored at +2 to +8°C.

R2. Substrate
Contents ready for use. Stable up to the expiry date when stored at +2 to +8°C.

MATERIALS PROVIDED

Buffer
Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Saline (Cat. No. SA 3854)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

CALIBRATION

The use of Saline and Randox Calibration Serum Level 3 is recommended for calibration. A 2 point calibration is recommended with change of reagent lot or as indicated by quality control procedures.

This assay uses a **Linear** calculation and **no reagent blank**.

Ensure that on the [Calibration] [Checks (F10)] screen the following are selected for this test:

Sampling Method for Standards

- **Duplicate**

Reagent Blank measurement

- **Disable reagent blank and S1 blank**

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland + 44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCE

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	250 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	800 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [4]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES IN SERUM[3]

	25°C	30°C	37°C
Adults	60-170 U/l	73-207 U/l	98-279 U/l

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

LINEARITY

This method is linear up to 2183 U/l. In the event of a rerun, the linearity is extended to 3274 U/l.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance data was obtained using an RX **daytona** analyser at 37°C.

SENSITIVITY

The minimum detectable activity of Alkaline Phosphatase with an acceptable level of precision was determined as 34.7 U/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (U/l)	85.0	161	539
SD	1.81	2.47	8.86
CV(%)	2.13	1.53	1.64
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (U/l)	87.4	156	510
SD	2.80	3.59	4.68
CV(%)	3.20	2.30	0.92
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 1.01 X - 2

and a correlation coefficient of r = 1.00

40 patient samples were analyzed spanning the range 95 to 665 U/l.

REFERENCES

1. Rec. GSCC (DGKC); J. Clin. Chem. Clin. Biochem. 1972; **10**: 182.
2. Englehardt A., *et al*, Aerztl Labor 1970; **16**: 42.
3. Hausamen, T.U. *et al,* Clin. Chim. Acta 1967; **15**: 241.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

Revised 27 Jun 23 bm