Alkaline Phosphatase
DEA (DGKC)

CE

Greiner

Cat.No		Package Size
105 200	5 x 20 mL	2 x 10 mL
105 201	2 x 50 mL	1 x 20 mL
105 202	4 x 100 mL	4 x 20 mL
105 203	Hit I 4 x 50 mL	2 x 20 mL
105 204	Hit II 4 x 100 mL	4 x 20 mL

METHOD
Colorimetric Optimized Kinetic Test according to DGKC ("Deutsche Gesellschaft für Klin.Chemie")

PRINCIPLE
Kinetic determination of the Alkaline phosphatase (ALP) based upon DGKC recommendations:

p-Nitrophenylphosphat + H_2O $\xrightarrow{ALP}$ Phosphate + p-Nitrophenol

REAGENTS COMPOSITION
R1: Diethanolamine (pH 10.4) 1.00 mol/l
Magnesiumchloride 0.50 mmol/l

R2: p-Nitrophenylphosphate 10,0 mmol/l

PRECAUTIONS
- For *in vitro* diagnostic use only.
- The reagents contain < 0,95g/L sodium azide. Avoid contact with skin and/or mucous membranes !
- Use clean or single use glass/plastic material only to avoid contaminations.

STABILITY OF REAGENT
When stored at 2 – 8 °C and protected from light, the reagents are stable until the expiry date printed on the labels.

PREPARATION OF WORKING REAGENT
- For the ***"Start Reagent-procedure"*** the reagents ***R1*** and ***R2*** are ready for use for
- For the ***"Sample Start-procedure"*** with ***monoreagent*** mix R1 + R2 = 5 + 1

Stability : 1 month at 2 – 8 °C
1 week at 18 – 25 °C

SAMPLES
Serum free of hemolysis , plasma (EDTA/heparine)

REFERENCE VALUES

Adults	**37 °C**
	100 - 290 U/L (1.7 – 4,8 µkat/L)

Children	**37 °C**
	180 - 1200 U/L (3,0 –20, µkat/L)

Note: It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

PROCEDURES
Reagents can be used manually (see method below) and on most analyzers. Applications are available on request.

Wavelength : 405 nm (410)
Temperature : 37°C
Cuvette : 1 cm light path
Read against air.

- ***Sample Start Procedure / Monoreagent***

Working reagent	1 mL
Sample	20 µL

Mix and after a 1 minute incubation, measure the change of absorbance per minute (ΔA/min) during 3 minutes.

- ***Start Reagent Procedure / R1-R2***

R1	1 mL
Sample	20 µL

Mix and wait 1 minute

R2	200 µL

Mix and after a 1 minute incubation, measure the change of absorbance per minute (ΔA/min) during 3 minutes.

CALCULATION

Sample Start/Monoreagent procedure :
405 nm : => Activity (U/L) = ΔA/min x 2 757

Start reagent procedure :
405 nm => Activity (U/L) = ΔA/min x 3298

CALIBRATORS & CONTROLS
For the calibration of automated analyzers Greiner Multicalibrator Unical-M is recommended, for quality control use Greiner normal and abnormal control, Unitrol I and Unitrol II.

Greiner Diagnostic GmbH - Unter Gereuth 10 **–** D-79353 Bahlingen – Germany
www.greiner-diagnostic.com

PERFORMANCE DATA (37°C)

- **Analytical range**

The test is linear up to 1500 U/l
At higher values
repeat the test using serum diluted 1/10 with sodium chloride solution (9 g/L). Multiply result by 10.

- Sensitivity

The sensitivity is equal to 1.5 U/L

- Precision

Within-run reproducibility

Within series n = 11	Mean value [U/L]	Standard-deviation [U/L]	CV [%]
Sample 1	182	2.80	1.53
Sample 2	403	2.93	0.73
Sample 3	226	3.33	1.48

Between-run reproducibility

Day to day n = 11	Mean value [U/L]	Standard-deviation [U/L]	CV [%]
Sample 1	179	4.40	2.45
Sample 2	387	3.40	0.87
Sample 3	222	2.26	1.02

- Correlation

A comparative study has been performed between the Greiner method and another commercial reagent on 29 human serum samples. The parameters of linear regression are as follows:

Correlation coefficient r = 0.999
Linear regression: y = 0.997 x – 2.605 U/L

- Ascorbic Acid: no interference until 50 mg/dL
- Bilirubin: no interference until 40 mg/dL,
- Hemoglobin: no interference until 200 mg/dL
- Triglycerides: no interference until 2000 mg/dL

BIBLIOGRAPHY

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 36-46.
2. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617-721.
3. Tietz NW, Rinker D, Shaw LM. IFCC method for alkaline phosphatase. J Clin Chem Clin Biochem 1983;21:731-48.
4. Burtis CA, Ashwood ER. Eds. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company, 1999. p. 1829.
5. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press, 1996. p. 5.

SYMBOLS USED

For *in vitro* diagnostic medical use

Batch code


Use by


Temperature limitation

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