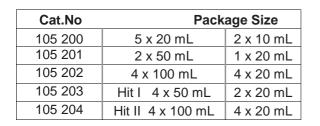
Alkaline Phosphatase DEA (DGKC)



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:

 $p-Nitrophenylphosphat + H_2O \quad \underline{ALP} > Phosphate + p-Nitrophenol$

REAGENTS COMPOSITION

R1:	Diethanolamine (pH 10.4) Magnesiumchloride	1.00 mol/l 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 R	1 + 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	
Children		

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
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	R1 Sample	1 mL 20 μL	
N	lix and wait 1 minute		

R2200 μLMix and after a 1 minute incubation, measurethe change of absorbance per minute (ΔA /min)during 3 minutes.

CALCULATION

Sample Start/Monoreagent procedure :

405 nm : => Activity (U/L) = $\Delta A/min \ge 2757$

Start reagent procedure :

405 nm =>: Activity (U/L) = $\Delta A/\min x$ 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.

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PERFORMANCE DATA (37°C)

- Analytical range

The test is linear up to 1500 U/I 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 = 0.999Linear 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

SYMBOLS USED

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IVD For in vitro diagnostic medical use LOT Batch code Use by Temperature limitation

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