archem

CE IVD

LIPASE

Diagnostic reagent for determination of Lipase concentration.

Liquid, 2 Reagents — Store at 2°C - 8°C
For in Vitro Diagnostic Use — Do not freeze

Cat. No.
AD2270 LIPASE 6X10ML

TEST PRINCIPLE

The colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3- glutaric acid-(6'methyl-resorufi n)-ester is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the alkaline test conditions to yield the chromophore methylresorufi ne. The kinetic of colour formation at 580 nm is monitored and it is proportional to lipase activity in sample.

REAGENTS COMPOSITION

Reagent 1:
Composition: Tris buffer 40 mM pH 8.30, colipase ≥ 1 mg/l, desoxycholate ≥ 1.8 mM, taurodesoxycholate ≥ 7.0 mM.
Reagent 2:
Tartrate buffer 15 mM pH 4.00, lipase substrate ≥ 0.70 mM, calcium ions ≥ 1 mM.
Calibrator: lyophilized (value on label) - 3 ml

REAGENTS PREPARATION

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C;
Stability since fi rst opening of vials: ≥ 90 days at 2-8°C. Caution: reagent B is a micro-emulsion. Therefore, a slight apparent precipitation could occur, showing a light red deposit on the bottom of vial. It is a normal behaviour and it is recommended to resuspend solution before analysis, with a mild shaking.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Some commercial reagents for triglycerides determination could contain microbial lipases, whose could stick on surface of instrument plastic cuvettes. It is recommended to program a "wash" procedure before lipase determination, if a contamination is suspected.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

TEST PROCEDURE

Wavelength: 580 nm (allowed 570 ÷ 590 nm)
Light path: 1 cm
Temperature: 37°C

Pipette into test tubes	Reagent Blank Tube	Standard Tube	Sample Tube
Reagent 1	1000 µl	1000 µl	1000 µl
Reagent 2	200 µl	200 µl	200 µl
Sample	-	-	10 µl
Standard	-	10 µl	-
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the □A/min.			

CALCULATION

ΔA/min(calibrator-net) = ΔA/min(calibrator) - ΔA/min(blank)
ΔA/min(sample-net) = ΔA/min(sample) - ΔA/min(blank)
Serum/plasma sample:

$$\frac{\Delta A/min\ (sample\text{-}net)}{\Delta A/min\ (calibrator\text{-}net)} \times \text{Concentration of STD}$$

= U/l (methylresorufine 37°C) for urine multiplies result by 10.

LINEARITY

the method is linear up to 250 U/l.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.
Sensitivity/limit of detection (LOD)
the limit of detection is 5 U/l.

INTERFERENCES

no interference was observed by the presence of:
Hemoglobin ≤ 150 mg/dl
bilirubin ≤ 20 mg/dl
Lipids ≤ 300 mg/dl
(Lipids at concentration more elevated than 300 mg/dl give a -6% negative interference)

Precision

intra-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	11.80	2.63	22.27
sample 2	119.20	4.14	3.47
sample 3	215.35	6.11	2.84
inter-assay	mean (U/l)	SD (U/l)	CV%
sample 1	11.65	2.80	24.06
sample 2	119.55	6.82	5.71
sample 3	215.03	12.33	5.73

Methods comparison
a comparison between Archem and a commercially available product gave the following results:
Lipase Archem = y
Lipase competitor = x
n = 101
y = 0.50054x + 3.9443 U/l r2 = 0.997

EXPECTED VALUES*

Normal subjects: ≤ 63 U/l (methylresorufi ne 37°C)
Each laboratory should establish appropriate reference intervals related to its population.
*It is recommended that each laboratory establish its own normal range.

WASTE DISPOSAL

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. Refer to special instructions/ safety data sheets.

QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following human based control serums are available:
"ARCON N", Assayed Control Serum Normal
Cat.No. A3910
"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

CALIBRATION

Any commercially available Standard or Calibrator suitable for this method may be used.

AUTOMATION

Special adaptations for automatic analyzers can be made on request.

REFERENCES

1. Kaplan, L.A., Pesce, A,J.: "Clinical Chemistry", Mosby Ed. (1996).
2. Jakobs, D.S., Kasten, Jr., BL., Demmott, W.R., Wolfson, W.L.: "Laboratory Test Handbook", Lexi-Comp and Williams & Wilkins Ed. (2nd Edition - 1990).
3. Neumann, U. et al.: "New substrates for the optical determination of lipase". EP 207252 (1987).

ARCHEM CO. Isteks San Sit. B-2 Blok No:4 Ikitelli/Istanbul/TURKEY www.archem.com.tr / archem@archem.com.tr