BECKMAN COULTER CE

AU/DxC AU

Instructions For Use

LIPASE
Lipase

REF OSR6130 4 x 10 mL R1 Buffer, 4 x R1 Lyo, 4 x 3.3 mL R2, 2 x Calibrator
OSR6230 4 x 30 mL R1 Buffer, 4 x R1 Lyo, 4 x 10 mL R2, 2 x Calibrator

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Kinetic colour test for the quantitative determination of lipase in human serum and plasma on AU Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Reference[1,2]

Lipase is produced in the acinar cells of the pancreas and is responsible for the hydrolysis of water-insoluble long chain fatty acid esters of glycerol. Lipase measurement in serum and plasma is used exclusively for the investigation of pancreatic disorders, usually pancreatitis. Serum lipase may be elevated in acute pancreatitis, acute episodes of chronic pancreatitis and obstructive pancreatitis, with levels up to 80 times the upper reference limit found in acute serious inflammation. However it should be noted that the severe destruction of the acinar cells in the later stages of chronic pancreatitis results in a reduction of the amount of enzyme entering the circulation. Marginal or no increase of lipase is therefore not unusual in this disease. In acute upper quadrant abdominal syndrome, hyperlipasemia of up to 5 times the upper reference limit may be found in penetrating duodenal ulcer, duodenal diverticulum, cholecystitis, and ileus, where there is pancreatic involvement. Lipase levels are also elevated in renal insufficiency, particularly where dialysis is required. Investigation of the biliary tract by endoscopic retrograde pancreatography, or treatment with opiates, may also result in serum lipase elevation. Slight elevations are also frequently present in diabetic ketoacidosis, viral hepatitis, epidemic parotiditis, abdominal typhoid and sarcoidosis, due to involvement of the pancreas.

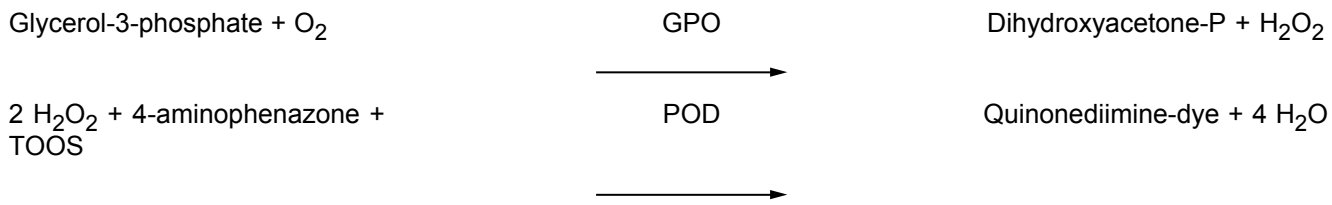
METHODOLOGY

Reference[3]

Pancreatic lipase hydrolyses esters of long chain fatty acids from their triglycerides. The enzyme activity requires the presence of co-lipase. Pancreatic specific 1,2-Diglyceride is hydrolysed to 2-Monoglyceride and fatty acid. The 2-Monoglyceride is then measured by coupled enzyme reactions catalysed by monoglyceride lipase (MGLP), glycerol kinase (GK), glycerol phosphate oxidase (GPO) and peroxidase (POD).

CHEMICAL REACTION SCHEME

1,2-Diglyceride + H_2O	Lipase →	2-Monoglyceride + fatty acid
2-Monoglyceride + H_2O	MGLP →	Glycerol + fatty acid
Glycerol + ATP	GK →	Glycerol-3-phosphate + ADP



SPECIMEN

TYPE OF SPECIMEN

Serum or heparinised plasma.

Stable in serum and plasma for 3 weeks when stored at 2…8°C and 7 days when stored at 15…25°C.[4]

Lipemic and icteric samples should be avoided.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents, this product should be handled as a potentially infectious material.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients

Buffer MES/BES (pH 6.8)	27 mmol/L
1,2-Diglyceride substrate	0.04 mmol/L
Monoglyceride lipase	> 400 U/L
Glycerol kinase	> 100 U/L
POD	> 500 U/L
4-Aminophenazone	0.25 mmol/L
TAPS (pH 8.7)	50 mmol/L
TOOS	1.0 mol/L
Co-lipase	> 15 kU/L
GPO	> 15 kU/L
ATP	> 0.85 mol/L
Preservatives and Surfactants	
Calibrator: Human serum containing porcine lipase.	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Lipase Substrate - R1L

DANGER

H316	Causes mild skin irritation.
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P391	Collect spillage.
	Ethoxylated Nonylphenol 1 - 5%
	MES monohydrate 1 - 5%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

R1: Dissolve the contents of one vial of R1 Lyo completely with the contents of one vial of R1 buffer. Mix gently by inversion and place on board the instrument. R2 is ready for use and can be placed directly on board the instrument.

STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open or prepared, reagents stored on board the instrument are stable for 21 days.

The lipase calibrator is stable, unopened, up to the stated expiry date when stored at 2…8°C. Reconstituted lipase calibrator is stable for 60 days when stored at 2…8°C.

CALIBRATION

CALIBRATOR PREPARATION

1. Carefully remove the cap and rubber stopper from the bottle, avoiding any loss of lyophilised material.
2. Add 3.0 mL of sterile deionised water at 15…25°C to the lyophilised material using a volumetric pipette calibrated to deliver exactly 3.0 mL.
3. With the rubber stopper back in place, dissolve the contents completely by gently mixing for 30 minutes. Avoid foaming.
4. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
5. Record the date the calibrator was reconstituted on the bottle label.

CALIBRATION INFORMATION

Calibrator provided in the kit: For value assigned to the calibrator provided in the kit, please refer to bottle label.

The calibrator value is traceable to a Beckman Coulter master calibrator. Recalibrate the assay every 7 days, or when the following occur:

Change in reagent bottle number or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

Note: System Calibrator Cat. No.: 66300 can also be used. Refer to System Calibrator Cat. No.: 66300 instructions for use for further information.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency.

Good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed. Values obtained for the controls should fall within specified limits as defined by the user. If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

CALCULATIONS

The Beckman Coulter analysers automatically compute the lipase activity of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Adult [5]		< 67 U/L (< 1.12 µkat/L)
Children[6]	< 1y	0 – 8 U/L (0 – 0.13 µkat/L)
	1 – 9y	5 – 31 U/L (0.08 – 0.52 µkat/L)
	10 – 18y	7 – 39 U/L (0.12 – 0.65 µkat/L)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

LIMITATIONS

Carry over from Triglyceride, HDL-Cholesterol and LDL-Cholesterol reagents to Lipase reagent results in elevated lipase values. Please refer to contamination parameters. For AU400/AU480/AU640/AU680/DxC 700 AU customers who use Lipase OSR6x30, HDL-Cholesterol OSR6x87 and LDL-Cholesterol OSR6x83, it is recommended that the programming of these tests is set up such that Lipase is the first test to be run followed by LDL and then HDL.

The release of Lipoprotein Lipase and Hepatic Lipase after the intravenous or subcutaneous administration of heparin may cause an elevation of the measured Lipase activity without any association with pancreatic disorders.[7]

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Ascorbate:	Interference less than 5% or 5.7 U/L up to 20 mg/dL ascorbate
Icterus:	Interference less than 10% or 5.7 U/L up to 12 mg/dL or 205 µmol/L bilirubin
Haemolysis:	Interference less than 10% or 5.7 U/L up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% or 5.7 U/L up to 500 mg/dL intralipid.

Patients treated with N-Acetyl Cysteine (NAC) for a Paracetamol overdose may generate a false low result for lipase.

Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to falsely low results for Lipase. Venipuncture should be performed prior to the administration of Metamizole.

N-acetyl-p-benzoquinone imine (metabolite of Paracetamol) will generate erroneously low results in samples for patients that have taken toxic doses of paracetamol.

In very rare cases gammopathy, especially monoclonal IgM (Waldenström's macroglobulinemia), may cause unreliable results.

Refer to Young[8] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within an enzyme activity range of 3 – 600 U/L (0.05 – 10 µkat/L).

SENSITIVITY

The lowest detectable level in serum on an DxC 700 AU analyser was estimated at 2 U/L.

The lowest detectable level represents the lowest measurable level of lipase that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this assay on the DxC 700 AU against the AU680. Results of linear regression analysis were as follows:

y = 0.993x - 5	r = 1.000	n = 128	Sample range = 11 - 591 U/L

PRECISION

The following data was obtained on an AU680 using 3 serum pools analysed over 20 days.

n = 80	**Within-run**		**Total**	
Mean U/L	**SD**	**CV%**	**SD**	**CV%**
23	0.4	1.8	1.83	8.0
46	0.65	1.4	2.13	4.6
225	1.57	0.7	6.27	2.8

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	**Description**
LIP1N	Lipase (Serum)
LIP2N	Lipase (Serum)

Setting Sheet Footnotes
User defined

DxC 700 AU: † For use in AB mode only, refer to IFU for further instructions. Beckman Coulter System Calibrator Cat No: 66300 (LIP1N) or Calibrator supplied with Kit (LIP2N).

† For use in AB mode only, refer to IFU for further instructions. Beckman Coulter System Calibrator Cat No: 66300.

* Values set for working in U/L. To work in SI units (µkat/L) divide by 60.

REVISION HISTORY

Revised Interferences section.

Preceding version revision history

Added new languages

REFERENCES

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2. Moss DW, Henderson RA. Clinical Enzymology. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999; 698-704.

3. Imamura S, Hirayama T, Arai T, Takao K, Misaki H. An enzymatic method using 1,2-Diglyceride for pancreatic lipase test in serum. Clin Chem 1989; 35:1126.

4. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:36pp.

5. In-house data on file.

6. Lorentz K. Lipase. In:Thomas L, hrsg. Labor und Diagnose. Indikation und bewertung von laborbefunden für die medizinische diagnostik. Frankfurt/Main: TH-Books Verlagsgesellschaft, 2005:113-117.

7. Two automated Fully Enzymatic Assays for Lipase Activity in Serum Compared: Positive Interference from Post-Heparin Lipase Activity. Demanet C, Goedhuys W, Haentjens M et al. Clin Chem 1992:38:288-92.

8. Young DS, Effects of Drugs on CLINICAL Laboratory Tests, AACC, 5th ed. CCPress, 2000.

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