Lipase – method Enzymatic – Colorimetric
Instruction for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB NDIKO	REF B75182536	n° 4 flaconi x 20 mL n°4 flaconi x 5 mL
CHEMILAB	REF B81180281	n° 1 flaconi x 25 mL n° 1 flaconi x 7 mL

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of the Lipase in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE
Lipase is an enzyme that hydrolyzes glycerol esters and long-chain fatty acids. Enzyme and its cofactor colipase are produced in the pancreas, lipase is also secreted in small amounts by the salivary glands, pulmonary and intestinal mucosa. Bile acids and colipase are hidden in them to form complexes with lipids and lipase will bind on the substrate/water. Lipase is used for the investigation of disorders of the pancreas. In acute pancreatitis, lipase concentrations exceed the maximum reference limit by 20-50 times within 4-8 hours after the onset of abdominal pain with a peak in the 24 hours and a decrease in the following 8 to 14 days. Elevated lipase values can also be observed in chronic pancreatitis and obstructions of the pancreatic duct.

PRINCIPLE OF THE METHOD
Enzymatic colorimetric method.

Storage and stability
= storage temperature 2-8°C
stored at 2-8 ° C avoiding direct light, the reagents are stable until the expiration date printed on the label.

Concentrations

Reagent A			
	Conc.	U.M.	
Good's Buffer pH 8,0	50	mmol/L	
Taurodeoxyholate	4.3	mmol/L	
Deoxycholate	8.0	mmol/L	
Calcium chloride	15	mmol/L	
Colipase	2.2	mg/L	
Reagent B			
Tartrate buffer pH 4,0	7.5	mmol/L	 *GHS05
Taurodoxycholate	17.2	mmol/L	
Colored substrate	0.65	mmol/L	

* *Warning*: **DANGER**
H318 – Causes serious eye damage
P280 - Wear eye protection / face protection
P305+P351+P338 - IN CASE OF CONTACT WITH EYES: rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do so. Keep rinsing.
P310 - Contact a POISON CENTER/doctor immediately.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls, calibrators and pipettes with adequate volume.

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles)
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements.
Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

PROCEDURE
Quality control
Control sera with a known titer of Lipase are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration
For calibration use the "Calibrator serum Sclavo" Code B35181702

Traceability
The Lipase traceability is reported in the package insert supplied with the calibrator serum.

SAMPLE
Type of sample and storage
Serum or heparinised plasma samples should be used.
Samples can be kept for 7 days at 4 - 8°C, 7 giorni a 20-25°C or for 12 months at -20°C.

REAGENT PREPARATION
Reagents are ready-to-use liquids. Don't shake!
After opening, the reagents are stable until their expiry date if maintained under the conditions indicated in "Storage and stability". Their slight variation in coloring, from batch to batch, does not affect the test results.

Automation
The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1/R2/C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD
The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:
Reaction conditions
Wavelength (primary): 580 nm
Temperature 37°C
Reaction End-point (increasing reaction)

Technical – bireagent procedure
Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Blank	Calibrator Serum	Sample
Reagent A	µL	1000	1000	1000
Calibrator Serum	µL	-	20	-
Sample	µL	-	-	20
Water	µL	20	-	-
Mix gently and incubate for 1 - 5 min. and add 37°C				
Reagent B	µL	250	250	250

Mix, then incubate at 37°C. Measure the absorbance values of first reading after 30 seconds for a sample adding, read a second time after 60 seconds.
The reaction volumes can be altered proportionately without alteration of results.

Results:
Manual Method
Calculation of Urea concentration:

$$\frac{\Delta \text{D.O.Sample}}{\Delta \text{D.O.Calibration Serum}} \times \text{Calibration Serum Conc. (U/L)} = \text{U/L Lipase}$$

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Automation
The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different instruments.

REFERENCE RANGE
Serum/Plasma ≤ 60 U/L
Each laboratory should establish its own normal values according to the population in which it operates.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The method is linear up to 300 U/L.

Trueness
The Trueness of the analytical results has been determined accordingly to the CLSI guidelines, using commercial control sera. The data obtained are shown in the following table.

Level	Replicates	Mean	SD	CV%	Recovery
Low	5	50,7	0,87	1,72	92,5 %
High	5	81,0	1,21	1,51	89,4 %

Interferences

Interference	Limits
Ascorbic Acid	**30 mg/dL**
Bilirubin	**60 mg/dL**
Hemoglobin	**500 mg/dL**
Lipids	**1000 mg/dL**

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	13,4	0,24	1,81	20
High	U/L	103	1,50	1,45	20
Total Precision (Within-Lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	13,4	0,24	1,81	20
High	U/L	103	0,65	0,63	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is of about 3 U/dL of Lipase.

Comparison between methods
The method was compared with a similar commercially available method, analyzing 67 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	-1.15
Slope	0.96
Correlation Coeff. (R)	0,999

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

REFERENCES

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2. **Wroblewsky F., Ladue J.S.,** (1965). Proc. Soc. Exper. Biol and Med, 91:569
3. **NCCLS Document,** "Procedures for the collection of arterial blood specimens", Approved Standard, 3rd Ed. (1999).
4. **EU-Dir 1999/11** Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC.
5. **Clinical Laboratory Standards Institute (CLSI). User Verification of Performance for Precision and Trueness**; Approved Guideline – Second Edition. EP15-A2.
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7. **Clinical Laboratory Standards Institute (CLSI).** Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. EP09-A3.
8. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition – EP17
9. **Clinical Laboratory Standards Institute (CLSI).** Interference Testing in Clinical Chemistry, – Third Edition. - EP07.
10. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition - EP06.

REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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