Clinical Chemistry

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REF A11A01631
REAGENT 1 24 mL
REAGENT 2 7 mL

IVD CE

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FRANCE

ABX Pentra Lipase CP

- **Pentra C400**

Diagnostic reagent for quantitative *in vitro* determination of Lipase in serum or plasma by colorimetry.

Application Release

Serum, plasma: Lipase
1.xx

Intended Use

ABX Pentra Lipase CP reagent is intended for the quantitative *in vitro* diagnostic determination of lipase in serum or plasma.
Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

Clinical Interest (1, 2)

Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase is produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate / water interface. Determination of lipase is used for investigation of pancreatic disorders. In acute pancreatitis the lipase concentrations rise to 2-50 fold the upper reference limit within 4-8 hours after begin of abdominal pain peaking at 24 hours and decreasing within 8 to 14 days. Elevated lipase values can also be observed in chronic pancreatitis and obstruction of the pancreatic duct.

Method

Enzymatic colorimetric test.
A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester) is added to a microemulsion which is specifically split by lipase in the presence of colipase and bile acids. The combination of lipase and bile acids make this specific and reliable for pancreatic lipase without any reaction due to lipolytic enzymes or esterases. The reagent composition has been thoroughly optimised so there is no serum matrix effects. The generated methylresorufin-ester is spontaneously degraded to methylresorufin. The absorbance by this red dye is directly proportional to the lipase activity in the sample.
Lipase catalyses the reaction:

1,2-o-Dilauryl-rac-glycero-3-glutaric acid (6-methylresorufin) ester

Lipase / Colipase ⟷

1,2-o-Dilauryl-rac-glycerin + Glutaric acid-(6-methylresorufin)-ester

Glutaric acid-(6-methylresorufin)-ester

Spontaneous degradation ⟷

Glutaric acid + Methylresorufin

Reagents

ABX Pentra Lipase CP is ready-to-use.

Reagent 1 (R1):	
Good's buffer pH 8.0	50 mmol/L
Taurodesoxycholate	4.3 mmol/L
Desoxycholate	8.0 mmol/L
Calcium chloride	15 mmol/L
Colipase	2.2 mg/L

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Reagent 2 (R2):	
Tartrate buffer pH 4.0	7.5 mmol/L
Taurodesoxycholate	17.2 mmol/L
Color substrate	≤0.65 mmol/L

ABX Pentra Lipase CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove both caps of the cassette.
2. If present, remove foam by using a plastic pipette.
3. Position a protective cap ref. GBM0969 on Reagent 1 and on Reagent 2.
4. Place the cassette into the refrigerated Pentra C400 reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided

- Automated clinical chemistry analyzer: Pentra C400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen (3)

This device intended testing population is general population.

- Serum.
- Plasma in lithium heparin.

Anticoagulants other than those listed have not been tested by HORIBA Medical and are therefore not recommended for use with this assay.

Stability:

- At 20-25°C: 7 days
- At 4-8°C: 7 days
- At -20°C: 1 year

Reference Range (4)

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

≤ 38 U/L (37°C).

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after opening:

Refer to the paragraph "Performance on Pentra C400".

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Do not freeze.

Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

General Precautions

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 1 (R1):**
  Warning: This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (5).
- **Reagent 2 (R2):**
  Warning
  H319: Cause serious eye irritation.
  P264: Wash hands thoroughly after handling.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P337 + P313: If eye irritation persists: Get medical advice/attention.
  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  EUH208: May produce an allergic reaction. Contains: 2-Chloracetamide.
- As many other clinical reagents contain lipase or high concentrations of detergents, avoid carry over! Special care should be taken in combination with triglycerides, HDL and LDL reagents. Glassware must be cleaned thoroughly after being used for other assays. In case of automated measurement, refer to the instrument manual for special washing programs
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Pentra C400

Lot to Lot Variability [a]

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification:

Sample value	Specification
< 60 U/L	< 10 U/L
> 60 U/L	< 10%

Serum, plasma

The performance data listed below are representative of performance on HORIBA Medical Systems.

Number of tests: 100 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C400 compartment is stable for 40 days.

Sample volume: 5.0 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 7.80 U/L.

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 8 U/L.

[a]Modification: lot to lot variability specification added.

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Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (7) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value U/L	CV %
Control specimen 1	64.68	2.28
Control specimen 2	76.06	1.94
Specimen 1	42.62	4.77
Specimen 2	91.39	3.75
Specimen 3	213.53	1.71

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (8) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 2 specimens (medium / high levels)

	Mean value U/L	CV %
Control specimen 1	60.3	5.27
Control specimen 2	77.0	5.54
Specimen 1	54.7	5.98
Specimen 2	165.2	4.82

Measuring Range

The assay confirmed a measuring range from 8.0 U/L to 321.0 U/L.
The measuring range is extended up to 963.0 U/L with the automatic post-dilution.
The reagent linearity has been assessed up to 321.0 U/L according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (9).

Correlation

Patient samples: Serum
Number of patient samples: 103
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (10).
Values ranged from 11.8 U/L to 273.3 U/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:
Y = 1.011 X - 3.909 (U/L)
with a correlation coefficient r^2 = 0.987.

Interferences

Haemoglobin: No significant influence is observed up to 278 µmol/L (480 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 6.36 mmol/L (556.5 mg/dL).
Total Bilirubin: No significant influence is observed up to 289 µmol/L (16.9 mg/dL).
Direct Bilirubin: No significant influence is observed up to 321 µmol/L (18.8 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (12, 13).

Positive interferences may appear when the lipase test is performed after using ABX Pentra Triglycerides CP (A11A01640 / 1220001640) or ABX Pentra Cholesterol CP (A11A01634 / 1220001634). Even with the incompatibility protocol, in some rare cases, the interference could persist.
If your lipase result is > 38 U/L (or the reference value of your laboratory) rerun lipase alone:

- *If result is still > 38 U/L (or the reference value of your laboratory), report the result as a pathologic.*
- *If result is ≤ 38 U/L (or the reference value of your laboratory), report the result as a normal.*

To avoid rerun, another option is to perform lipase test in batch mode (all lipase tests executed consecutively in a same run).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 10 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

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