

**REF** 1300023858

**REAGENT 1** 6 x 32 mL

**REAGENT 2** 6 x 11 mL

**IVD**  **Rx Only**

**HORIBA ABX SAS**  
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FRANCE

# Yumizen C1200 Lipase

- Yumizen C1200
- Yumizen C230
- Yumizen C240
- Yumizen C560

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

## Application Release

**Serum, plasma: Lipase**

1.xx

## Intended Use

**Yumizen C1200 Lipase** reagent is intended for the quantitative *in vitro* diagnostic determination of lipase in serum or lithium heparin 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

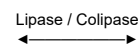
Enzymatic colorimetric test.

A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycerol-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.

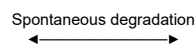
Lipase catalyses the reaction:

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



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

Glutaric acid-(6-methylresorufin)-ester



Glutaric acid + Methylresorufin

## Reagents

**Yumizen C1200 Lipase** 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

**Yumizen C1200 Lipase** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

## Handling on Yumizen C1200

1. Remove the caps of the cassettes.
2. If present, remove foam by using a plastic pipette.
3. Place the cassettes into the refrigerated reagent compartment.

## Handling on Yumizen C230 / Yumizen C240 / Yumizen C560

Transfer the required volume of reagents for the day in 20 mL bottle.

**Warning:** To prevent carry over we recommend you to perform this test in batch mode.

## Calibrator for Yumizen C1200

For calibration, use:

**Yumizen C1200 Multi Cal** (1300023891 / 1300023890)  
(not included)  
20 x 3 mL / 6 x 3 mL (lyophilisate)

## Calibrator for Yumizen C230 / Yumizen C240 / Yumizen C560

For calibration, use:

**Pointe Chemistry Calibrator C7506-50** (5390012500)  
(not included)

## Control for Yumizen C1200

For internal quality control, use:

- **Yumizen C1200 N Multi Control** (1300023938 / 1300023939) (not included)  
6 x 5 mL / 20 x 5 mL (lyophilisate)

- **Yumizen C1200 P Multi Control** (1300023940 / 1300023941) (not included)  
6 x 5 mL / 20 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.

## Control for Yumizen C230 / Yumizen C240 / Yumizen C560

For internal quality control, use:

**Pointe Chemistry Controls C7592-100** (5390012531)  
(not included)

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: Yumizen C1200 / Yumizen C230 / Yumizen C240 / Yumizen C560
- Calibrator:  
For Yumizen C1200: **Yumizen C1200 Multi Cal** (1300023891 / 1300023890)  
For Yumizen C230 / Yumizen C240 / Yumizen C560: **Pointe Chemistry Calibrator C7506-50** (5390012500)
- Controls:  
For Yumizen C1200:  
**Yumizen C1200 N Multi Control** (1300023938 / 1300023939)  
**Yumizen C1200 P Multi Control** (1300023940 / 1300023941)  
For Yumizen C230 / Yumizen C240 / Yumizen C560: **Pointe Chemistry Controls C7592-100** (5390012531)
- Standard laboratory equipment.

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## 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. Store protected from light.

### Stability after opening:

Refer to the paragraph "Performance on Yumizen C1200".

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 <sup>a</sup>

- 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.

<sup>a</sup>Modification: general precautions modification.

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- 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 Yumizen C1200

### Serum, plasma

The performance data listed below have been obtained on the Yumizen C1200 analyzer.

**Number of tests:** approximately 6 x 315 tests

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated compartment is stable for 12 weeks.

**Sample volume:** 2 µL/test

### Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 1.45 U/L.

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 4.00 U/L.

### 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
- 5 specimens (low / medium / high levels)

	Mean value U/L	CV %
Control specimen 1	58.58	0.45
Control specimen 2	100.93	0.37
Specimen 1	16.22	1.35
Specimen 2	56.53	2.12

	Mean value U/L	CV %
Specimen 3	80.93	1.36
Specimen 4	220.76	0.68
Specimen 5	303.08	0.58

#### Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (8) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value U/L	CV %
Control specimen 1	60.39	3.2
Control specimen 2	106.20	2.0
Specimen 1	19.30	6.0
Specimen 2	58.73	2.6
Specimen 3	88.49	3.0
Specimen 4	212.08	1.9
Specimen 5	314.92	1.9

### Measuring Range

The assay confirmed a measuring range from 4.6 U/L to 321 U/L.

The measuring range is extended up to 963 U/L with the automatic post-dilution.

The reagent linearity has been assessed up to 321 U/L according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (9).

### Correlation

Patient samples: Serum

Number of patient samples: 177

Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09-A3 protocol (10).

Values ranged from 7.47 U/L to 312.3 U/L.

The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:

$$Y = 0.9283 X + 2.276 \text{ (U/L)}$$

with a correlation coefficient  $r^2 = 0.998$ .

### Interferences

Haemoglobin: No significant influence is observed up to 218 µmol/L (375 mg/dL).

Triglycerides: No significant influence is observed up to a triglyceride concentration of 1.46 mmol/L (127 mg/dL).

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Total Bilirubin:	No significant influence is observed up to 392 µmol/L (22.92 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 309 µmol/L (18.05 mg/dL).
Ascorbic Acid:	No significant influence is observed up to 340 µmol/L (5.98 mg/dL).
Ibuprofen:	No significant influence is observed up to 2.43 mmol/L (50.1 mg/dL).
Acetaminophen:	No significant influence is observed up to 1324 µmol/L (20 mg/dL).
Acetylsalicylic Acid:	No significant influence is observed up to 3.62 mmol/L (65.16 mg/dL).

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

## Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.

The calibration stability is 12 weeks.

*Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.*

## Conversion Factor

U/L x 0.0167 = µkat/L

## Reference

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3. Guder WG, Zawta B. The Quality of Diagnostics Samples. Samples: From the Patient to the Laboratory. 1<sup>st</sup> Ed. Guder WG, Narayanan S, Zawta B. (WILEY-VCH, Darmstadt, Germany) (2001): 36.
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7. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
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11. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-720.
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