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ABX Pentra Ig M CP

REF A11A01925
REAGENT 1 28 mL
REAGENT 2 6 mL

IVD CE

HORIBA ABX SAS
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FRANCE

- Pentra C200

Diagnostic reagent for quantitative *in vitro* determination of Immunoglobulin M (IgM) in serum or plasma by immunoturbidimetry.

Application Release

Serum, plasma: IGM (not for use in the USA)

01.xx

Intended Use (not for use in the USA)

ABX Pentra Ig M CP reagent is intended for the quantitative *in vitro* diagnostic determination of Immunoglobulin M (IgM) in serum and plasma by turbidimetry.
Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Clinical Interest (1, 2, 3)

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgM has a molecular weight of about 970 000 daltons and consists of five Y-shaped molecules which are bound together by a joining peptide. Each of the five Y-shaped units consists of two identical heavy chains and two identical light chains which are bound together by disulfide bonds. IgM is produced by plasma cells (B-cells) and represents about 5% of all soluble immmunoglobulin classes. The main function of IgM is to bind to antigens, initiating complement activation and trigger further catabolism of the antigen. IgM is the immunoglobulin class synthesized first after initial contact with a new antigen.
Decreased IgM concentrations occur in primary as well as in secondary immunodeficiency syndromes. Increased loss of proteins due to severe inflammation of the bowel may result in a decreased IgM concentration. A high increase in one immunoglobulin class due to multiple myeloma may result in a decrease in other immunoglobulin classes like IgM.
Increased IgM concentrations can be observed in severe infections and autoimmune diseases. Many forms of Myeloma and especially Waldenström's macroglobulinemia, produce high amounts of monoclonal or polyclonal IgM. Quantitative IgM determination is necessary for differential diagnosis of these diseases.
All methods for IgM quantitation are calibrated for polyclonal IgM. The quantitation of monoclonal IgM is not standardized and values may differ for different reagents and methods. Values should only be used for follow up studies. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigation in addition to the quantitative determination.

Method

Immunoturbidimetric test.
Endpoint determination of the concentration of IgM done by photometric measurement. It is an antigen-antibody-reaction of the antibodies of IgM with the IgM that is present in the sample.

Reagents

ABX Pentra Ig M CP is ready-to-use.

Reagent 1 (R1):

TRIS pH 7.5	100 mmol/L
NaCl	150 mmol/L

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Reagent 2 (R2):	
TRIS pH 8.0	100 mmol/L
NaCl	1150 mmol/L
Anti-human IgM antibody (goat) < 1%	

ABX Pentra Ig M 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. Place the cassette into the refrigerated Pentra C200 reagent compartment.

Calibrator

For calibration, use:
ABX Pentra SP Cal (A11A01927) (not included)
5 x 1 mL (5 levels)
This calibrator is traceable against CRM 470-CAP/IFCC.
Calibration is carried out by using:

- NaCl solution 9 g/L for Cal 0 (concentration 0 mg/L).
- **ABX Pentra SP Cal**, which contains five calibrator levels at different concentrations. Each vial is labelled from 1 to 5. The relation level/calibrator concentration is mentioned in the annex.

Control [a]

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 [a]

- Automated clinical chemistry analyzer: Pentra C200
- Calibrator: **ABX Pentra SP Cal** (A11A01927)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- NaCl solution: 9 g/L
- Standard laboratory equipment.

Specimen

This device intended testing population is general population.

- Serum.
- Plasma in lithium heparin or EDTA.

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

Stability (4)

- At 20 - 25°C: 2 months
- At 4 - 8°C: 4 months
- At -20°C: 6 months

Freeze only once!

Reference Range [b]

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

Adults (5): 0.40 - 2.30 g/L (40 - 230 mg/dL)

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

[a]Modification: control removed.
[b]Modification: information added.

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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 C200".

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 [c]

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 2 (R2):**
  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 (6).
- Do not pipette by mouth.
- Do not replenish the reagents.
- 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 C200

Lot to Lot Variability [d]

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: < 10%.

Serum, plasma

The performance data listed below have been obtained on the Pentra C200 analyzer.

Number of tests: approximately 78 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 28 days.

Sample volume: 2 µL/test

Detection Capability [e]

The detection limit is determined according to the Valtec protocol (7) and equals 0.052 g/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
- 3 specimens (low / medium / high levels)

[c]Modification: general precautions modification.
[d]Modification: chapter added.
[e]Modification: data added.

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	Mean value g/L	CV %
Control specimen 1	0.94	2.30
Control specimen 2	3.05	0.99
Specimen 1	1.09	2.56
Specimen 2	2.10	1.19
Specimen 3	4.12	1.98

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
- 3 specimens (low / medium / high levels)

	Mean value g/L	CV %
Control specimen 1	0.89	3.86
Control specimen 2	2.96	3.57
Specimen 1	0.96	4.51
Specimen 2	1.87	4.80
Specimen 3	3.57	4.42

Measuring Range

The assay confirmed a measuring range from 0.05 g/L to 8.0 g/L.
The measuring range is extended up to 24 g/L with the automatic post-dilution.
The reagent linearity has been assessed up to 8.00 g/L according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (9).

Correlation [f]

Patient samples: Serum
Number of patient samples: 106
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 0.17 g/L to 6.80 g/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:
Y = 1.043 X - 0.1243 (g/L)
with a correlation coefficient r^2 = 0.988.

Interferences

Haemoglobin: No significant influence is observed up to 290 µmol/L (500 mg/dL).

Triglycerides: No significant influence is observed up to a triglyceride concentration of 5.9 mmol/L (518.9 mg/dL).

Total Bilirubin: No significant influence is observed up to 400 µmol/L (23.4 mg/dL).

Direct Bilirubin: No significant influence is observed up to 400 µmol/L (23.4 mg/dL).

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

Prozone Effect

No antigen excess has been detected up to a concentration of 50 g/L.

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 15 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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[f]Modification: modification of correlation.

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