Clinical Chemistry

2023/04/28
A93A00232SEN

REF A11A01646

REAGENT 2 x 25 mL

IVD CE

HORIBA ABX SAS
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FRANCE

ABX Pentra Magnesium RTU

- **ABX Pentra 400**

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

Application Release

Serum, plasma: Magn

World wide except the USA: 10.xx
For the USA only: 5.xx

Intended Use [a]

ABX Pentra Magnesium RTU reagent is intended for the quantitative *in vitro* diagnostic determination of magnesium in human serum and plasma based on a photometric test using xylidyl blue. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

Clinical Interest (1, 2)

Deficiency of magnesium is a quite common disorder which can be caused by malnutrition, malabsorption, renal loss and endocrinological disturbances. Complications associated with decreased magnesium concentrations are neuromuscular irritability (e.g. tremor, seizures) and cardiac symptoms (e.g. tachycardia, arrhythmia). Decreased magnesium concentrations are often related to decreased calcium and potassium levels, taking into account that hypomagnesemia may be the primary cause of hypocalcemia. Elevated magnesium values can be observed in dehydration, renal disorders and after intake of excessive amounts of antacids and can be associated with weakness of reflexes and low blood pressure.

Method (3)

Photometric test using xylidyl blue.
Magnesium ions form a purple colored complex with xylidyl blue in alkaline solution. In presence of GEDTA, which complexes calcium ions, the reaction is specific. The intensity of the purple color is proportional to the magnesium concentration.

Reagents

ABX Pentra Magnesium RTU is ready-to-use.

Reagent:	
Ethanolamine pH 11.0	750 mmol/L
GEDTA (Glycoletherdiamine-tetraacetic acid)	60 µmol/L
Xylidyl blue	110 µmol/L

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

Handling

1. Transfer the necessary reagent volume for a daily workload into a 15, 10 or 4 mL reagent vial.

[a]Modification: new leaflet form.

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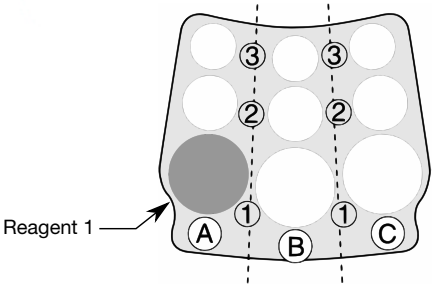
2. Place the vial in position 1 of one of the available areas.
   Please use one of the following:
   - a 15 mL reagent vial
   - a 10 mL reagent vial + a specific adaptor
   - a 4 mL reagent vial + a specific adaptor



3. If present, remove foam by using a plastic pipette.
4. Place the reagent rack into the refrigerated ABX Pentra 400 reagent compartment.

Calibrator

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

Control [b]

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 [b]

- Automated clinical chemistry analyzer: ABX Pentra 400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen [c]

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.

Do not use EDTA plasma.
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: 7 days
- At 4-8°C: 7 days
- At -20°C: 1 year

Reference Range (5, 6) [d]

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

Neonates: 1.2 - 2.6 mg/dL (0.48 - 1.05 mmol/L)
Children: 1.5 - 2.3 mg/dL (0.60 - 0.95 mmol/L)
Women: 1.9 - 2.5 mg/dL (0.77 - 1.03 mmol/L)
Men: 1.8 - 2.6 mg/dL (0.73 - 1.06 mmol/L)

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

[b]Modification: control removed.
[c]Modification: modification of "Specimen".
[d]Modification: information added.

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attending health-care professional's evaluation of the patient's condition.

Storage and Stability [e]

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 ABX Pentra 400".
Stable up to the expiry date on the label if stored at 2-8°C, closed immediately and contamination is avoided. Store protected from light.

Do not freeze.

Waste Management

Please refer to local legal requirements.

General Precautions [f]

- 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.
- **Danger**
  H315: Causes skin irritation.
  H318: Causes serious eye damage.
  P264: Wash hands thoroughly after handling.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P310: Immediately call a POISON CENTER or doctor/ physician.
  P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  Contains: 2-aminoethanol.
- Observe the standard laboratory precautions for use.
- The reagent vials 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 ABX Pentra 400

Lot to Lot Variability [g]

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 ABX Pentra 400 analyzer.

Number of tests: approximately 200 tests

On Board Reagent Stability

Once opened, the reagent in open container placed in the refrigerated ABX Pentra 400 compartment is stable for 1 day.

Sample volume: 2.5 µL/test

Detection Limit [h]

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.10 mmol/L (0.24 mg/dL).

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[e]Modification: modification of storage and stability.
[f]Modification: general precautions modification.
[g]Modification: chapter added.
[h]Modification: modification of detection limit.

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Limit of Quantitation [i]

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.13 mmol/L (0.32 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (8) with samples tested 20 times:

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.00	2.44	2.02
Control specimen 2	1.72	4.19	1.28
Specimen 1	0.65	1.58	2.28
Specimen 2	0.93	2.27	1.92
Specimen 3	1.18	2.86	1.98

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.03	2.50	3.2
Control specimen 2	1.76	4.27	2.8
Specimen 1	0.90	2.20	2.6
Specimen 2	1.31	3.19	2.8

Measuring Range [j]

The assay confirmed a measuring range from 0.13 mmol/L (0.32 mg/dL) to 1.90 mmol/L (4.62 mg/dL).
The measuring range is extended up to 5.70 mmol/L (13.85 mg/dL) with the automatic post-dilution.

The reagent linearity has been assessed up to 1.90 mmol/L (4.62 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (10).

Correlation [k]

Patient samples: Serum
Number of patient samples: 82
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (11).
Values ranged from 0.14 mmol/L (0.34 mg/dL) to 1.83 mmol/L (4.45 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:
Y = 1.214 X - 0.09662 (mmol/L)
Y = 1.214 X - 0.23479 (mg/dL)
with a correlation coefficient r^2 = 0.961.

Interferences [l]

Haemoglobin:	No significant influence is observed up to 195 µmol/L (336 mg/dL).
Triglycerides:	No significant influence is observed up to a triglyceride concentration of 6.61 mmol/L (578.38 mg/dL).
Total Bilirubin:	No significant influence is observed up to 290 µmol/L (17.0 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 520 µmol/L (30.4 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (13, 14).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 1 day.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

mmol/L x 2.43 = mg/dL

[i]Modification: data added.
[j]Modification: modification of measuring range.
[k]Modification: modification of correlation.
[l]Modification: modification of interferences.

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Reference

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft (1998): 231-241.
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: WB Saunders Company (1999): 1395-1457.
3. Burcar PJ, Boyle AJ. Spectrophotometric determination of magnesium in blood Serum Using Magon. Clin. Chem. (1964) **10**: 1028-1038.
4. Guder WG, Zawta B. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag (2001): 38-39.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft (1998): 339-340.
6. Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH (1986): 166.
7. Evaluation of detection capability for clinical laboratory measurement procedures. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP17-A2 (2012) **32** (8).
8. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
9. Evaluation of Precision Performance of Quantitative Measurement Method. Approved Guideline, CLSI (NCCLS) document EP5-A2 (2004) **24** (25).
10. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).
11. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP09c (2018) **38** (12).
12. 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.
13. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
14. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.