

**REF** A11A01646

**REAGENT** 2 x 25 mL

**IVD** **CE**



**HORIBA ABX SAS**  
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FRANCE

# ABX Pentra Magnesium RTU

Bi-reagent

- Pentra C400

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

## Application Release

**Serum, plasma: Magn-bi (not for use in the USA)**

1.xx

**Intended Use (not for use in the USA) <sup>a</sup>**

**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 xylydyl 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 xylydyl blue. Magnesium ions form a purple colored complex with xylydyl 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 (Glycoetherdiamine-tetraacetic acid)	60 µmol/L
Xylydyl blue	110 µmol/L

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

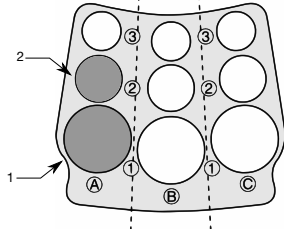
## Handling in Rack

1. Place one volume of reagent on position 1.

<sup>a</sup>Modification: new leaflet form.

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2. Place one volume of reagent on position 2.



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 Pentra C400 reagent compartment.

## Calibrator

For calibration, use:

- **ABX Pentra Multical** (A11A01652) (not included)  
10 x 3 mL (lyophilisate)

## Control <sup>b</sup>

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 <sup>b</sup>

- 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 <sup>c</sup>

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) <sup>d</sup>

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

<sup>b</sup>Modification: control removed.

<sup>c</sup>Modification: modification of "Specimen".

<sup>d</sup>Modification: information added.

# ABX Pentra Magnesium RTU

## Storage and Stability <sup>e</sup>

### 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 Pentra C400". 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 <sup>f</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.
- **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 Pentra C400

### Lot to Lot Variability <sup>g</sup>

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 (not for use in the USA)

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

**Number of tests:** approximately 200 tests

### On Board Reagent Stability

Once opened, the reagent in open container placed in the refrigerated Pentra C400 compartment is stable for 1 day.

**Sample volume:** 2.5 µL/test

### Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.12 mmol/L (0.29 mg/dL).

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (7) and equals 0.34 mmol/L (0.83 mg/dL).

<sup>e</sup>Modification: modification of storage and stability.

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

<sup>g</sup>Modification: chapter added.

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## 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	0.87	2.12	1.35
Control specimen 2	1.39	3.38	1.05
Specimen 1	0.49	1.18	2.40
Specimen 2	0.84	2.05	1.36
Specimen 3	1.59	3.86	1.22

### Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	0.93	2.26	2.4
Control specimen 2	1.47	3.57	2.1
Specimen 1	0.46	1.12	3.7
Specimen 2	0.63	1.53	3.2
Specimen 3	0.96	2.33	2.4
Specimen 4	1.79	4.35	2.4

### Measuring Range <sup>h</sup>

The assay confirmed a measuring range from 0.34 mmol/L (0.83 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 <sup>i</sup>

Patient samples: Serum

Number of patient samples: 110

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 0.53 mmol/L (1.29 mg/dL) to 1.61 mmol/L (3.91 mg/dL).

The equation for the allometric line obtained using Passing-Bablok regression procedure (12) is:

$$Y = 1 X + 0 \text{ (mmol/L)}$$

$$Y = 1 X + 0 \text{ (mg/dL)}$$

with a correlation coefficient  $r^2 = 0.962$ .

### Interferences

Haemoglobin: No significant influence is observed up to 145 µmol/L (250 mg/dL).

Triglycerides: No significant influence is observed up to a triglyceride concentration of 5.35 mmol/L (468.1 mg/dL).

Total Bilirubin: No significant influence is observed up to 412 µmol/L (24.1 mg/dL).

Direct Bilirubin: No significant influence is observed up to 324 µmol/L (18.95 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).

Calcium: No significant influence is observed up to 3.40 mmol/L (13.61 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

$$\text{mmol/L} \times 2.43 = \text{mg/dL}$$

<sup>h</sup>Modification: modification of measuring range.

<sup>i</sup>Modification: modification of correlation.

# ABX Pentra Magnesium RTU

## Reference

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3. Burcar PJ, Boyle AJ. Spectrophotometric determination of magnesium in blood Serum Using Magon. Clin. Chem. (1964) **10**: 1028-1038.
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9. Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline, CLSI (NCCLS) document EP05-A3 (2014) **24** (25).
10. Evaluation of Linearity of Quantitative Measurement Procedures. 2<sup>nd</sup> Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).
11. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3<sup>rd</sup> 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.
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