

REF A11A01691

REAGENT 1 x 5 mL

IVD **CE**



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ABX Pentra Kappa

- **ABX Pentra 400**

Diagnostic reagent for quantitative *in vitro* determination of Light Kappa Chains in serum by immunoturbidimetry.

Application Release ^a

Serum: Kappa (not for use in the USA)

4.xx

Intended Use (not for use in the USA) ^a

ABX Pentra Kappa reagent is intended for the quantitative *in vitro* diagnostic determination of Light Kappa Chains in serum by turbidimetry.

Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

Clinical Interest

Finding the change in the ratio of light kappa chains to lambda chains can be used as one of the tests to detect for monoclonal gammopathies, myeloma, and Waldenström macroglobulinemia.

Method

Human serum is mixed with the antibody solution. The resulting immune complexes are measured by turbidimetry. The signal generated is in direct correlation with the concentration of light kappa chains in the sample.

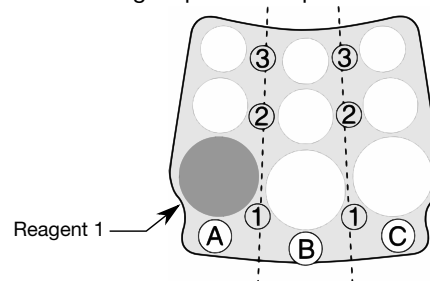
The concentration of light kappa chains in the sample is calculated by comparison of the results on a standard curve.

Reagents

- **ABX Pentra Kappa** is ready-to-use. It is a fraction of purified immunoglobulins from rabbit serum. It contains 15 mM NaN₃ as stabiliser.
- **Immunogen:** Polyclonal light chains of kappa type are isolated from human serum.
- **ABX Pentra Kappa** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Place the reagent directly in position 1 of one available sector using a specific adapter.



2. If present, remove foam by using a plastic pipette.
3. Place the reagent rack into the refrigerated ABX Pentra 400 reagent compartment. After the tests, recap immediately the reagent vial and place it in a refrigerator.

^aModification: chapter added.

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4. Place the **ABX Pentra Accelerator I CP** (A11A01655) and **ABX Pentra Sample Diluent CP** (A11A01662) cassettes in the refrigerated ABX Pentra 400 reagent compartment.

Calibrator

For calibration, use:

ABX Pentra Protein Cal (A11A01698) (not included)
4 x 1 mL

Control ^b

For internal quality control, use:

- **ABX Pentra Protein Control L/H** (A11A01700) (not included)
2 x 1 mL + 2 x 1 mL (Only the low control is titrated)
or
- **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 Protein Cal** (A11A01698)
- Controls:
 - ABX Pentra Protein Control L/H** (A11A01700)
or
 - ABX Pentra N MultiControl** (1300054414)
 - ABX Pentra P MultiControl** (1300054415)
- **ABX Pentra Sample diluent CP** (A11A01662), 99 mL
- **ABX Pentra Accelerator I CP** (A11A01655), 99 mL
- Standard laboratory equipment.

^bModification: new control.

^cModification: general precautions modification.

Specimen

- Serum.

Reference Range (1)

2.0 - 4.1 g/L based on CRM 470.

Kappa/Lambda ratio: 1.35 - 2.69.

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

Storage and Stability

Stability before opening:

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

Stability after opening:

Stable up to the expiry date on the label if stored at 2-8°C, closed immediately and contamination is avoided.

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 prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **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 (2).
- 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.

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- 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.
- It is the user's responsibility to verify that this document is applicable to the reagent used.

Performance on ABX Pentra 400

Serum

The performance data listed below have been obtained on the ABX Pentra 400 analyzer.

Number of tests: approximately 300 tests

Sample volume: 5 µL/test

Detection Limit

The detection limit is determined according to the Valtec protocol (3) and equals 0.69 g/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (3) with samples tested 20 times:

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

	Mean value g/L	CV %
Control specimen 1	2.36	1.75
Control specimen 2	5.80	1.40
Specimen 1	1.60	2.81
Specimen 2	3.26	1.90
Specimen 3	6.09	2.78

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A protocol (4) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value g/L	CV %
Control specimen 1	2.20	8.42
Control specimen 2	5.59	7.61
Specimen 1	2.71	6.98
Specimen 2	5.87	4.00

Measuring Range

The assay confirmed a measuring range from 0.69 g/L to the highest calibration point.

The reagent linearity has been assessed up to 12 g/L according to the recommendations found in the CLSI (NCCLS), EP6-P protocol (5).

Correlation

Number of patient samples: 98

Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (6).

The equation for the allometric line obtained using Passing-Bablok regression procedure (7) is:

$$Y = 1.06 X - 0.11 \text{ (g/L)}$$

with a correlation coefficient $r^2 = 0.9887$.

Interferences

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

Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 7 mmol/L (612.5 mg/dL).

Total Bilirubin: No significant influence is observed up to 705 µmol/L (41.3 mg/dL).

Direct Bilirubin: No significant influence is observed up to 736 µmol/L (43.1 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (8, 9).

Prozone Effect

No antigen excess has been detected up to a concentration of 81 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 30 days.

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

Reference

1. Lievens MM. Medical and technical usefulness of measurement of kappa and lambda immunoglobulin light chains in serum with an M-component. J. Clin. Chem. Clin. Biochem. (1989) **27**: 519-523.

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2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
4. Evaluation of Precision Performance of Clinical Chemistry Devices. Approved Guideline, CLSI (NCCLS) document EP5-A (1999) **19** (2).
5. Evaluation of the Linearity of Quantitative Analytical Methods. Proposed Guideline, CLSI (NCCLS) document EP6-P (1986) **6** (18).
6. Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) **22** (19).
7. Passing H, Bablock W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-20.
8. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
9. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.