Clinical Chemistry

2024/04/08
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REF 1300017438

CONTROL 1 x 15 mL

IVD CE Rx Only

HORIBA ABX SAS
Parc Euromédecine
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ABX Pentra Precitest Solution

- **Pentra C200**
- **Pentra C400**
- **ABX Pentra 400**

Quality control solution for the pipetting precision of HORIBA Medical clinical chemistry analyzers.

Intended Use

ABX Pentra Precitest Solution is a control solution used on HORIBA Medical clinical chemistry analyzers to check the pipetting precision of the instrument.

Reagents

ABX Pentra Precitest Solution is a ready-to-use solution.
This control contains naphtol green blue (~0.44%).
ABX Pentra Precitest Solution should be used according to this control notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling on Pentra C200

Please refer to the "Precision Test" procedure developed in Pentra C200 User Manual for a detailed information.

Test P1:

1. Fill the 30 mL compartment of the 30/10 cassette labelled with reagent code n°700 with 25 mL of distilled water.
2. Configure and place the cassette in the reagent compartment.
   Target value: 600 ΔA +/- 100
3. Transfer 500 µL of **ABX Pentra Precitest Solution** in a sample cup.
4. Configure and place the sample cup with adaptor on the sample tray.
5. Create the request for Test P1 with 15 replicates.
6. When all the ordered test analysis are performed (15), use the results to calculate the mean and the coefficient of variation (CV). The expected CV is ≤2.0%.

Application release: **01.xx**

Handling on Pentra C400 in cassette

Please refer to the "Precision Test" procedure developed in Pentra C400 User Manual for a detailed information.

Test P1:

1. Fill the 30 mL compartment of the 30/10 cassette labelled with T1 barcode (reagent code n°600) with 25 mL of distilled water.
2. Configure and place the cassette in the reagent compartment.
   Target value: 600 ΔA +/- 100
3. Transfer 500 µL of **ABX Pentra Precitest Solution** in a sample cup.
4. Configure and physically position **ABX Pentra Precitest Solution** as a control.
5. Create the calibration request for Test P1.
6. Once the calibration is validated, perform the control request for **ABX Pentra Precitest Solution** with 15 replicates.
7. Once the 15 replicates are performed, check the results. CV should be ≤1.0%.

Application release: **1.xx**

QUAL-QA-WORI-5543 Rev.2

ABX Pentra Precitest Solution

Handling on ABX Pentra 400 and Pentra C400 in rack

Please refer to the "Precision Test" procedure developed in ABX Pentra 400 User Manual and Pentra C400 User Manual for a detailed information.

Test P1:

1. Transfer 500 µL of **ABX Pentra Precitest Solution** in a sample cup.
2. Configure and physically position **ABX Pentra Precitest Solution** as a control.
   Target value: 600 ΔA +/- 100
3. Configure and physically position a 15 mL vial of distilled water as reagent (R1).
4. Create the calibration request for Test P1.
5. Once the calibration is validated, perform the control request for **ABX Pentra Precitest Solution** with 15 replicates.
6. Once the 15 replicates are performed, check the results. CV should be ≤1.0%.

Application release (P400): **2.xx**
Application release (PC400): **1.xx**

Materials Required but not Provided

- Automated clinical chemistry analyzer.
- Standard laboratory equipment.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-35°C.

Stability after opening:

Stable up to the expiry date on the label if stored at 2-35°C, closed immediately and contamination is avoided.
Stable for 1 hour if installed on the instrument.

Do not freeze.

Waste Management

Please refer to local legal requirements.

General Precautions [a]

- **ABX Pentra Precitest Solution** should be used for quality control purpose only.
- This quality control 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.
- **EUH208:** May produce an allergic reaction. Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2Hisothiazol-3-one (3:1).
- Do not pipette by mouth.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The quality control vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the SDS associated with the control.
- 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 control 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.

[a]Modification: general precautions modification.