Clinical Chemistry

2025/07/31
A98A00099CUS

REF 1300023946

CONTROL 6 x 5 mL

IVD CE Rx Only

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Yumizen C Urine Level 1 Control

- **Pentra C200**
- **Pentra C400**
- **ABX Pentra 400**
- **Yumizen C1200**
- **Yumizen C230/C240**
- **Yumizen C560**

Control urine for the quality control of HORIBA methods.

Intended Use [a]

The **Yumizen C Urine Level 1 Control** is for use in quality control by monitoring accuracy and precision of HORIBA methods, listed in the annex, on clinical chemistry analyzers.

Characteristics

- **Yumizen C Urine Level 1 Control** is a liquid stable control based human control urine. **Yumizen C Urine Level 1 Control** is spiked with human salivary amylase, hCG derived from human urine, and human and bovine serum albumin. The control contain stabilizers and preservatives.
- **Yumizen C Urine Level 1 Control** is ready-to-use. The kit consist of 6 vials of 5 mL.
- **Yumizen C Urine Level 1 Control** should be used according to this notice and as specified in the respective instructions for use of the reagent. The manufacturer cannot guarantee its performance if used otherwise.

Handling [b]

1. Thoroughly mix the content of the vial before each use by gently inverting for approximately 5 minutes.
2. Remove the cap of the vial, use a pipette to transfer the required volume into a sample cup.
3. Place the sample cup on the instrument:
   - For **Pentra C200**: Place the sample cup in the correct position on the instrument sample tray.
   - For **Pentra C400**: Place the sample cup on the appropriate rack of the instrument.
   - For **ABX Pentra 400**: Place the sample cup on the appropriate rack of the instrument.
   - For **Yumizen C1200**: Place the sample cup on the appropriate rack of the instrument.
   - For **Yumizen C230/C240/C560**: Place the sample cup in the correct position on the instrument sample tray.
4. Treat the **Yumizen C Urine Level 1 Control** as a patient specimen.

An analysis of the control urine must be carried out on a daily basis at the same time as the patient samples, including each time a calibration is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

Materials Required but not Provided

- HORIBA reagents and automated clinical chemistry analyzer.
- Standard laboratory equipment.

Assigned Values [c]

The target value is the median of all values obtained. Determinations were performed under strictly standardized conditions on HORIBA analyzers using HORIBA reagents and HORIBA master calibrator.

[a]Modification: instrument added.
[b]Modification: § handling changed.
[c]Modification: information added.

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Yumizen C Urine Level 1 Control

Results must be within the range of the defined confidence limits. Each laboratory must establish the procedure to be followed in case the results are outside of the confidence interval given.
The concentration of the constituent(s) is lot specific.
Assigned values and confidence interval are indicated in the enclosed annex.
These target values can also be downloaded from our web site www.horiba.com.

Note: Creatinine values may gradually decrease over the product shelf life. Individual laboratory means may eventually fall outside of the corresponding ranges printed in the enclosed annex.

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 for 3 months at 2-8°C if closed immediately and contamination is avoided.

Do not freeze.

Waste Management

Please refer to local legal requirements.

General Precautions [d]

- **Yumizen C Urine Level 1 Control** 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.
- **Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the control should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).
- **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 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 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.

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory workers from Occupationally Acquired Infections. Approved Guideline, Third Edition (2005), document M29-A3, Clinical and Laboratory Standards Institute (CLSI).

[d]Modification: general precautions modification.