

PreciControl HbA1c norm



REF 05479207 190

4 x 1 mL Control

REF 05991323 922

4 x 1 mL Control (QCS)

English

System information

For use on Roche/Hitachi **cobas c** analyzers the control code is 208.

For use on COBAS INTEGRA analyzers the system ID is 07 7477 4.

For use on the Roche/Hitachi **cobas c** 513 analyzer the control codes can be found in the following table:

| PCA1N | |
|-------|------------|
| Code | Short name |
| 30001 | PCA1NWS1 |
| 30002 | PCA1NWS2 |
| 30003 | PCA1NHS1 |
| 30004 | PCA1NHS2 |

Different codes have been assigned to distinguish between whole blood (W) and hemolysate (H), and between S1 and S2 sample probe.

Intended use

PreciControl HbA1c norm is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

PreciControl HbA1c norm is a liquid control based on hemolyzed human blood.

The adjusted concentrations of the control components are usually in the normal range or at the normal/pathological threshold.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components in the liquid controls:

Hemolyzed human blood

The concentrations of the components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for COBAS INTEGRA and **cobas c** 111 analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Target values and ranges

The target values were determined using the method stated in the electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator. The target value specified is the mean of all values obtained. The corresponding control range is calculated as the target value \pm 3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.^{1,2}

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

Equilibrate the control to room temperature before use.

The enclosed barcoded labels are intended exclusively for the **cobas c** systems (except for the **cobas c** 513 analyzer) to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within \pm 10 % of initial value.

Stability:

| | |
|----------------|---|
| Unopened: | Up to the stated expiration date at 2-8 °C. |
| After opening: | 28 days at 2-8 °C or 12 weeks at (-15)-(-25) °C, provided that dispensing of the control occurs without microbial contamination, e.g. by pouring out. Freeze only once. |

Store control tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory's requirements.

Follow the applicable government regulations and local guidelines for quality control.

References

- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The Summary of Safety & Performance Report can be found here:
<https://ec.europa.eu/tools/eudamed>

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog. Roche.com for definition of symbols used):

| | |
|--|---------------------------------------|
| | Contents of kit |
| | Volume after reconstitution or mixing |
| | Global Trade Item Number |

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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