

# HbA1c Control P



20764841 322

for 4 x 0.5 mL Control

05174406 922

for 4 x 0.5 mL Control (QCS)

## English

### System information

For use with Roche reagents on COBAS chemistry systems.  
For use on Roche/Hitachi **cobas c** analyzers the control code is 358.  
For use on COBAS INTEGRA analyzers the system ID is 07 6484 1.

### Intended use

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

### Summary

HbA1c Control P is a lyophilized control based on hemolyzed human blood. The adjusted concentrations of the control components are usually in the pathological range.

### Reagents – working solutions

*Reactive components in the lyophilizate:*

Hemolyzed human blood

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

For the **cobas c** 501 system the values are encoded in electronic files sent via cobas link to the analyzer.

### Target values and ranges

The target values were determined using the method stated in the value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

The traceability of the target values is given in the respective instructions for use of the system reagents to be used in combination with the recommended calibrator.

### Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

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 applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.<sup>1,2</sup>

Safety data sheet for professional user available on request.

Disposal of all waste material should be in accordance with local guidelines.

### Handling

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 0.5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam. Pretreat reconstituted control in the same way as samples.

The enclosed barcoded labels are intended exclusively for the **cobas c** systems 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 of the lyophilized control at 2–8°C:

Up to the stated expiration date.

Stability of the components in the reconstituted control:

at 2–8°C

4 weeks

at (-15)–(-25)°C

3 months (only freeze once in aliquots of no less than 0.1 mL)

Store control tightly capped when not in use.

### Materials provided

- HbA1c Control P
- Barcoded labels

### Materials required (but not provided)

- Distilled or deionized water
- Roche system reagents and clinical chemistry analyzer
- General laboratory equipment

### Assay

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

The control should be run daily in parallel with the patient samples and after every calibration. The control intervals should be adapted to each laboratory's individual requirements. Each laboratory should establish QC procedures that conform with pertinent regulations or accreditation requirements.

### References

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001;17:260–273.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

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