PreciControl ClinChem Multi 1

cobas®

REF **05947626** 190	→ 4 x 5 mL Control
REF **05117003** 190	→ 20 x 5 mL Control
REF **05117208** 922	→ 20 x 5 mL Control (QCS)

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 391 (PCCC1).

For use on Roche/Hitachi **cobas c** 513 analyzers the control code is 30391 (PCCC1).

For use on COBAS INTEGRA analyzers the system ID is 07 7469 3.

Intended use

PreciControl ClinChem Multi 1 is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

PreciControl ClinChem Multi 1 is a lyophilized control based on human serum. The adjusted concentrations and activities 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 lyophilizate:

Human serum with chemical additives and material of biological origin as specified.

The origin of the biological additives is as follows:

Analyte	*Origin*
ALT (GPT)	human, recombinant
AST (GOT)	human, recombinant
Aldolase	rabbit muscle
Alkaline phosphatase	human placenta (recombinant)
Amylase, total	human saliva / porcine pancreas
Amylase, pancreatic	porcine pancreas
Creatine kinase	human CK-MM / human CK-MB (recombinant)
CK-MB	human CK-MB (recombinant)
γ-GT	human, recombinant
GLDH	bacterial, recombinant
LDH	porcine heart
Lipase	human pancreas (recombinant)
Acid phosphatase	human prostate / potato
ASLO	sheep
CRP	human
Transferrin	human
Ferritin	human

Non-reactive components in the lyophilizate:

Stabilizers

The concentrations and activities 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 Roche/Hitachi MODULAR, 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 ± 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.

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

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 5.0 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.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR analyzers and **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 ± 10 % of initial value.

Stability of the lyophilized control serum:

Up to the stated expiration date at 2-8 °C.

Stability of components after reconstitution*:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	(-15)-(-25) °C	28 days (when frozen once)

*Exceptions: see below

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Stability of total bilirubin, direct bilirubin, acid phosphatase, prostatic acid phosphatase and UIBC in reconstituted control serum (stored protected from light):

at	15-25 °C	8 hours
at	2-8 °C	24 hours
at	(-15)-(-25) °C	14 days (when frozen once)

Stability of ALT in reconstituted control serum:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	(-15)-(-25) °C	14 days (when frozen once)

The possible appearance of a slight green coloration has no effect on the recovery of the values.

Store control tightly capped and protected from light 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

1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 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.

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):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE 0123

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