Для лабораторий, использующих
Калибратор для автоматических систем (C.f.a.s.),
Универсальные контроли PreciControl ClinChem Multi 1 и Multi 2,
Универсальные контрольные плазмы Precinorm U plus и Precipath U plus
на анализаторе **cobas c** 311,
на модуле **cobas c** 501, **c** 502, **c** 702
и анализаторе COBAS INTEGRA 400 plus

Дата: 08.05.2024 г. Москва
Исх.: 0175/0805/2024
Ref.: QN-RDS-POCoreLab-2024-010

Уведомление по качеству
касательно стабильности для C.f.a.s., PCCC1, PCCC2, Precinorm U plus и Precipath U plus

Название продукта	GMMI / Кат. №	Идентификатор продукта (Номер лота или серийный номер)	Номер РУ, Дата РУ	Производитель
Набор калибраторов для обеспечения правильности определения биохимических параметров на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (C.f.a.s. / Calibrator for automated systems) Набор калибраторов для обеспечения правильности определения биохимических параметров на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (C.f.a.s. / Calibrator for automated systems) в составе: 1. Калибратор C.f.a.s., флакон, 3 мл - 12 шт./уп. 2. Этикетка со штрих-кодами - не более 2 шт. 3. Паспорт присвоенных значений. 4. Инструкция по применению. (C.f.a.s. / Calibrator for automated systems)	10759350190		РЗН 2021/13226 от 20.01.2021	Sandhofer Strasse 116, 68305 Mannheim, Germany
Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4 Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4: I. Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), вариант исполнения 1 (PreciControl ClinChem Multi 1 Roche systems) Состав: 1. Контрольный материал PreciControl ClinChem Multi 1 во флаконе, 5 мл, 4 шт. 2. Этикетка со штрих-	05947626190		РЗН 2022/18277 от 15.09.2022	Sandhofer Strasse 116, 68305 Mannheim, Germany

ООО «Рош Диагностика Рус» Россия, 115114, Москва, ул. Летниковская, дом 2, стр. 3, Бизнес-центр "Вивальди Плаза" Тел.: +7 (495) 229 69 99 Факс: +7 (495) 229 62 64 www.roche.ru

Roche Diagnostics Rus LLC 2, Letnikovskaya street, bld. 3, Business Center "Vivaldi Plaza", 115114, Moscow, Russia Tel.: +7 (495) 229 69 99 Fax: +7 (495) 229 62 64 www.roche.ru

Название продукта	GMMI / Кат. №	Идентификатор продукта (Номер лота или серийный номер)	Номер РУ, Дата РУ	Производитель
кодами, 4 шт. 3. Паспорт ожидаемых значений 4. Инструкция по применению (PreciControl ClinChem Multi 1 Roche systems)				
Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4 Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4: II. Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), вариант исполнения 2 (PreciControl ClinChem Multi 1 Roche systems) Состав: 1. Контрольный материал PreciControl ClinChem Multi 1 во флаконе, 5 мл, 20 шт. 2. Этикетка со штрих-кодами, 20 шт. 3. Паспорт ожидаемых значений 4. Инструкция по применению (PreciControl ClinChem Multi 1 Roche systems)	05117003190		РЗН 2022/18277 от 15.09.2022	Sandhofer Strasse 116, 68305 Mannheim, Germany
Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4 Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4: III. Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), вариант исполнения 3 (PreciControl ClinChem Multi 2 Roche systems) Состав: 1. Контрольный материал PreciControl ClinChem Multi 2 во флаконе, 5 мл, 4 шт. 2. Этикетка со штрих-кодами, 4 шт. 3. Паспорт ожидаемых значений 4. Инструкция по применению (PreciControl ClinChem Multi 2 Roche systems)	05947774190		РЗН 2022/18277 от 15.09.2022	Sandhofer Strasse 116, 68305 Mannheim, Germany
Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4 Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), варианты исполнения 1, 2, 3, 4: IV. Набор контрольных материалов для контроля качества определения множества аналитов клинической химии на анализаторах и модулях Roche/Hitachi cobas c и Cobas Integra (PreciControl ClinChem Multi), вариант исполнения 4 (PreciControl ClinChem Multi 2 Roche systems) Состав: 1. Контрольный материал PreciControl ClinChem Multi 2 во флаконе, 5 мл, 20 шт. 2. Этикетка со штрих-	05117216190		РЗН 2022/18277 от 15.09.2022	Sandhofer Strasse 116, 68305 Mannheim, Germany

Название продукта	GMMI / Кат. №	Идентификатор продукта (Номер лота или серийный номер)	Номер РУ, Дата РУ	Производитель
кодами, 20 шт. 3. Паспорт ожидаемых значений 4. Инструкция по применению (PreciControl ClinChem Multi 2 Roche systems)				
Реагенты, стандарты, калибраторы, контроли и расходные материалы для биохимических анализаторов Hitachi 902, 902 ISE, 912, 912 ISE, 917 ISE, Cobas c 311, Cobas c 111, Cobas c 111 ISE, Cobas Integra 400 Plus/ 800 и платформ модульных MODULAR ANALYTICS, cobas 6000 Прецинорм У плюс (Precinorm U plus)	12149435122		ФСЗ 2010/07525 от 24.03.2021	Sandhofer Strasse 116, D-68305 Mannheim, Germany
Реагенты, стандарты, калибраторы, контроли и расходные материалы для биохимических анализаторов Hitachi 902, 902 ISE, 912, 912 ISE, 917 ISE, Cobas c 311, Cobas c 111, Cobas c 111 ISE, Cobas Integra 400 Plus/ 800 и платформ модульных MODULAR ANALYTICS, cobas 6000 Преципат У плюс (Precipath U plus)	12149443122		ФСЗ 2010/07525 от 24.03.2021	Sandhofer Strasse 116, D-68305 Mannheim, Germany
Инструмент/Система	Анализатор **cobas c** 311 Модуль **cobas c** 501 Модуль **cobas c** 502 Модуль **cobas c** 702 Анализатор COBAS INTEGRA 400 plus			

Уважаемый пользователь,

Сообщаем вам о изменении сроков номинальной стабильности непростатической кислой фосфатазы (NPP2: ACN (8)022 для **cobas c** 311/501/502/702, ACN 20051 для инструментов **cobas c** 503/303; NACP2: идентификатор теста 0-269 на COBAS INTEGRA 400 plus), поскольку целевые значения для NPP2 были заявлены в соответствующих калибраторах и контролях.

Помимо этого, необходимо уменьшить заявленную стабильность реагента после вскрытия упаковки при использовании Калибратора для автоматизированных систем (C.f.a.s.) с 4 часов до 2 при 15-25°C для пакета аналитов ACP2/NPP2/P-ACP2, поскольку NPP2 имеет пониженную стабильность после вскрытия упаковки при 25°C по сравнению с ACP2 и P-ACP2. Для любых контролей, содержащих указанные аналиты, никакого снижения стабильности не требуется. Аналогично, стабильность при других температурах (2-8 °C, –20±5°C)) не снижается.

Кроме того, реализованные обновления, отмеченные в Инструкции по использованию, никак не влияют на производительность.

Описание ситуации

В прошлом NPP2 (= непростатическая кислая фосфатаза) рассматривалась как параметр без уточнения, поскольку сам аналит использовался только для расчета P-ACP2:

$Activity_{P\text{-}ACP}$ [P-ACP2] = $Activity_{ACP}$ [ACP2] - $Activity_{NPP}$ [NPP2]

Пока ACP2 (= общая кислая фосфатаза) и P-ACP2 (= простатическая фосфатаза) соответствуют спецификациям, как показано ниже, в соответствующем калибраторе и контролях, комбинация анализов считается функциональной.

- 4 ч. при 15–25 °C с критерием приемлемости 100 +/-10% в C.f.a.s
- 8 ч. при 15–25 °C с критерием приемлемости 100 +/- 10% в PCCC1/PCCC2

- 4 ч. при 15–25 °C с критерием приемлемости 100 +/- 10 % в PNU+/PPU+)

Поскольку NPP2 является частью пакета ACP2/P-ACP2, целесообразно унифицировать спецификации для ACP2, NPP2 и PACP2. В сыворотках Precicontrol Clinchem Multi 1 (PCCC1), Precicontrol Clinchem Multi 2 (PCCC2), Precinorm U plus (PNU+) и Precipath U plus (PPU+) существующие требования для ACP2 и P-ACP2 сохраняются. Для NPP2 они введены дополнительно.

Для калибратора C.f.a.s. стабильность при 15-25°C должна быть снижена с 4 часов до 2 часов для соответствия новым требованиям для NPP2. Результаты исследований ACP2 и P-ACP2 всегда находились в пределах спецификации.

Электронные Списки целевых значений для C.f.a.s. и контролей для всех анализаторов остаются неизменными.

Далее представлены выдержки из Инструкции по использованию. Новая информация выделена жирным шрифтом:

Стабильность кислой фосфатазы, **непростатической кислой фосфатазы** и простатической кислой фосфатазы в восстановленном калибраторе (критерий: ± 10 % от исходного значения):
- при 15–25 °C **2 ч.**
- при 2–8 °C 1 день
- при -20 °C (± 5 °C) 2 недели (при единоразовой заморозке)

PCCC1
Стабильность общего билирубина, кислой фосфатазы, **непростатической кислой фосфатазы**, простатической кислой фосфатазы и ненасыщенной железосвязывающей способности (UIBC) в восстановленной контрольной сыворотке (хранится в защищенном от света месте):
- при 15–25 °C 8 ч.
- при 2–8 °C 24 ч.
- при -20 °C (± 5 °C) 14 дней (при единоразовой заморозке)

PCCC2
Стабильность общего билирубина, кислой фосфатазы, **непростатической кислой фосфатазы**, простатической кислой фосфатазы и UIBC в восстановленной контрольной сыворотке (хранится в защищенном от света месте):
- при 15–25 °C 8 ч.
- при 2–8 °C 24 ч.
- при -20 °C (± 5 °C) 14 дней (при единоразовой заморозке)

Precinorm U plus
Стабильность кислой фосфатазы, **непростатической кислой фосфатазы** и простатической кислой фосфатазы в восстановленной контрольной сыворотке:
- при 15–25 °C 4 ч.
- при 2–8 °C 24 ч.
- при -20 °C (± 5 °C) 14 дней (при единоразовой заморозке)

Precipath U plus
Стабильность кислой фосфатазы, **непростатической кислой фосфатазы** и простатической кислой фосфатазы в восстановленной контрольной сыворотке:
- при 15–25 °C 4 ч.

- при 2–8 °C 24 ч.
- при -20 °C (± 5 °C) 14 дней (при единоразовой заморозке)

Кроме того, реализованные и отмеченные обновления в Инструкции по использованию не влияют на производительность реагентов.

Причина возникновения

Поскольку для контролей существуют целевые значения калибратора, содержащие аналиты ACP2/NPP2/P-ACP2, заявление о стабильности для NPP2 должно быть указано в целях соблюдения требований.

Поскольку NPP2 является частью пакета ACP2/P-ACP2, целесообразно унифицировать спецификации.

Данные о стабильности калибратора C.f.a.s. после вскрытия упаковки показали заниженные результаты измерений NPP2 в течение 4 часов при 15-25°C. Однако ACP2 и P-ACP2 продолжали работать по назначению. Поскольку Roche намеревается представить заявление о стабильности для ACP2/NPP2/P-ACP2, существующее заявление о стабильности для ACP2/NPP2/P необходимо обновить — сократить с 4 часов при 15–25°C до 2 часов при 15–25°C.

Такая же унификация пакета ACP2/NPP2/P-ACP2 также должна быть реализована для контролей (PCCC1/2, PNU+ и PPU+). Однако по сравнению с калибратором C.f.a.s. нет необходимости уменьшать существующие заявления о стабильности после вскрытия упаковки.

Оценка риска

Частота возникновения

Ни об одном случае не сообщалось.

Вероятность обнаружения

В случае возникновения ошибки результаты калибровки и Контроля Качества будут выходить за пределы допустимого диапазона.

Серьезность последствий

Изменения, описанные для калибратора C.f.a.s. и контролей, не затрагивают результаты пациентов. ACP2 и P-ACP2 всегда функционировали адекватно. Медицинский риск отсутствует.

Важная информация

Обновленная Инструкция по использованию прилагается к настоящему Уведомлению по качеству.
Обновленная электронная документация будет содержать ссылку на настоящее Уведомление по качеству.

Распространение настоящего уведомления по качеству на местах

Настоящее Уведомление по качеству предназначено для всех заинтересованных лиц в Вашей организации или других организациях, которые получали данную продукцию.

Пожалуйста, перешлите данное уведомление другим организациям/лицам, которых она может касаться.

Приносим свои извинения за причиненные неудобства, которые могут быть связаны с данной ситуацией, и надеемся на Ваше понимание и поддержку.

Контакты

В случае возникновения вопросов обратитесь, пожалуйста, в службу поддержки Roche:
Бесплатная линия: 8 800 100-68-96
Время работы: понедельник – пятница с 08:00 до 18:00 по Московскому времени
e-mail: russia.rcsc@roche.com.
С уважением,

Менеджер по продукции
Тел: +7 (916) 922-64-09
Электронная почта: ivan.kargov@roche.com

Иван Каргов

Иван Каргов Digitally signed by Иван Каргов
Date: 2024.05.08 14:42:49 +03'00'

Медицинский менеджер
Тел: + 7 (495) 229-69-99
Электронная почта: maria.kosyakova@roche.com

Мария Косякова

Maria Kosyakova Digitally signed by Maria Kosyakova
Date: 2024.05.08 14:56:14 +03'00'

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Calibrator for automated systems

cobas®

REF 10759350190 —> 12 x 3 mL Calibrator

English

System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

Intended use

Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

C.f.a.s. is a lyophilized calibrator based on human serum.

The concentrations and activities of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

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)	porcine heart
AST (GOT)	human, recombinant
Acid phosphatase	human prostate/potato
Albumin	bovine plasma
Aldolase	rabbit muscle
Alkaline phosphatase	human placenta (recombinant)
Amylase, total	porcine pancreas
Amylase, pancreatic	porcine pancreas
Cholesterol	bovine plasma
Cholinesterase	human serum
Creatine kinase	rabbit muscle
γ-GT	human, recombinant
GLDH	bacterial, recombinant
LD (LDH)	porcine heart
Lipase	human pancreas (recombinant)
Triglycerides	chicken egg yolk

Non-reactive components:

Stabilizers

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

The values are also encoded in the enclosed calibrator 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.

Calibrator values

The calibrator values were determined using the method stated in the electronically available or enclosed value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

The calibrator values were obtained via single determinations performed in different laboratories, in several separate runs. The calibrator value specified is the mean of all values obtained.

Traceability information is given in the respective instructions for use of the system reagents.

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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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 3.0 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 **cobas c** systems (except for the **cobas c** 513 analyzer) to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 5 % of initial value.

Stability of the lyophilized calibrator at 2-8 °C:

Up to the stated expiration date.

Stability of the components in the reconstituted calibrator*:

at 15-25 °C	8 hours
at 2-8 °C	2 days
at -20 °C (± 5 °C)	4 weeks (when frozen once)

*Exceptions: see below

Stability of acid phosphatase, non-prostatic acid phosphatase and prostatic acid phosphatase in the reconstituted calibrator (criterion: ± 10 % of initial value):

at 15-25 °C	2 hours
at 2-8 °C	1 day
at -20 °C (± 5 °C)	2 weeks (when frozen once)

Stability of total bilirubin in the reconstituted calibrator (when stored protected from light):

at 15-25 °C	6 hours
at 2-8 °C	1 day
at -20 °C (± 5 °C)	2 weeks (when frozen once)

Stability of direct bilirubin in the reconstituted calibrator (when stored protected from light):

at 15-25 °C	3 hours
at 2-8 °C	8 hours
at -20 °C (± 5 °C)	2 weeks (when frozen once)

Store calibrator tightly capped (and protected from light) when not in use.

Materials provided

- See “Reagents – working solutions” section

Calibrator for automated systems

cobas®

- Barcoded labels

Materials required (but not provided)

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

Assay

Use C.f.a.s. as specified in the relevant Method Sheet for the system reagents.

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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche

05117020001V8.0

PreciControl ClinChem Multi 1

cobas®

REF 05947626190	→ 4 x 5 mL Control
REF 05117003190	→ 20 x 5 mL Control
REF 05117208922	→ 20 x 5 mL Control (QCS)

English

System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

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 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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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 **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	-20 °C (± 5 °C)	28 days (when frozen once)

*Exceptions: see below

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

at	15-25 °C	8 hours

PreciControl ClinChem Multi 1

cobas®

at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of direct bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	8 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	10 days (when frozen once)

Stability of ALT in reconstituted control serum:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	-20 °C (± 5 °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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Additions, deletions or changes are indicated by a change bar in the margin.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche

05117224001V8.0

PreciControl ClinChem Multi 2

cobas®

REF 05947774190	→ 4 x 5 mL Control
REF 05117216190	→ 20 x 5 mL Control
REF 05117291922	→ 20 x 5 mL Control (QCS)

English

System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

Intended use

PreciControl ClinChem Multi 2 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 2 is a lyophilized control based on human serum. The adjusted concentrations and activities of the control components are usually in the pathological range.

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
Cholesterol	bovine plasma
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 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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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 **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	-20 °C (± 5 °C)	28 days (when frozen once)

*Exceptions: see below

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

at	15-25 °C	8 hours

PreciControl ClinChem Multi 2

cobas®

at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of direct bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	8 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	10 days (when frozen once)

Stability of ALT in reconstituted control serum:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	-20 °C (± 5 °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.

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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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Additions, deletions or changes are indicated by a change bar in the margin.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche

12174316001V13.0

Precinorm U plus

cobas®

REF 12149435122 → 10 x 3 mL Control

English

System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

Intended use

Precinorm U plus is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

Precinorm U plus 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)	porcine heart
AST (GOT)	porcine heart
Albumin	bovine plasma
Aldolase	rabbit muscle
Alkaline phosphatase	placenta (human, recombinant)
Amylase, total	human saliva / porcine pancreas
Amylase, pancreatic	porcine pancreas
Creatine kinase	rabbit muscle
γ-GT	porcine, kidney
GLDH	bacterial, recombinant
LD (LDH)	porcine heart
Lipase	pancreas (human, recombinant)
Acid phosphatase	human prostate / potato
Total protein	bovine plasma

Non-reactive components:

Stabilizers

Reactive components in the diluent:

Sodium carbonate

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 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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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 1, avoiding the loss of lyophilizate, and pipette in exactly 3.0 mL of diluent (bottle 2). Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

Important: When determining **acid phosphatase** and **prostatic phosphatase** dissolve the lyophilizate (bottle 1) with 3.0 mL of **distilled** or **deionized water**.

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 ± 10 % of initial value.

Stability of the lyophilized control serum:

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

Stability of components in reconstituted control*:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	-20 °C (± 5 °C)	28 days (when frozen once)

*Exceptions: see below

Stability of bicarbonate in reconstituted control serum:

closed bottle	at 15-25 °C	24 hours
open bottle	use immediately	

Stability of total bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	8 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Precinorm U plus

Stability of direct bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	4 hours
at	2-8 °C	8 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of UIBC in reconstituted control serum:

at	15-25 °C	4 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of acid phosphatase, non-prostatic acid phosphatase and prostatic acid phosphatase in reconstituted control serum:

at	15-25 °C	4 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Additions, deletions or changes are indicated by a change bar in the margin.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

12174324001V15.0

Precipath U plus

cobas®

REF 12149443122 → 10 x 3 mL Control

English

System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

Intended use

Precipath U plus is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

Precipath U plus is a lyophilized control based on human serum. The adjusted concentrations and activities of the control components are usually in the pathological 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)	porcine heart
AST (GOT)	porcine heart
Aldolase	rabbit muscle
Alkaline phosphatase	placenta (human, recombinant)
Amylase, total	human saliva / porcine pancreas
Amylase, pancreatic	porcine pancreas
Cholesterol	bovine plasma
Creatine kinase	rabbit muscle
γ-GT	porcine, kidney
GLDH	bacterial, recombinant
LD (LDH)	porcine heart
Lipase	pancreas (human, recombinant)
Acid phosphatase	human prostate / potato
Transferrin	human Cohn IV-fraction

Non-reactive components:

Stabilizers

Reactive components in the diluent:

Sodium carbonate

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 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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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 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 1, avoiding the loss of lyophilizate, and pipette in exactly 3.0 mL of diluent (bottle 2). Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

Important: When determining **acid phosphatase** and **prostatic phosphatase** dissolve the lyophilizate (bottle 1) with 3.0 mL of **distilled** or **deionized water**.

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 ± 10 % of initial value.

Stability of the lyophilized control serum:

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

Stability of components in reconstituted control*:

at	15-25 °C	12 hours
at	2-8 °C	5 days
at	-20 °C (± 5 °C)	28 days (when frozen once)

*Exceptions: see below

Stability of bicarbonate in reconstituted control serum:

closed bottle	at 15-25 °C	24 hours
open bottle	use immediately	

Stability of total bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	8 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Precipath U plus

Stability of direct bilirubin in reconstituted control serum (stored protected from light):

at	15-25 °C	4 hours
at	2-8 °C	8 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of UIBC in reconstituted control serum:

at	15-25 °C	4 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

Stability of acid phosphatase, non-prostatic acid phosphatase and prostatic acid phosphatase in reconstituted control serum:

at	15-25 °C	4 hours
at	2-8 °C	24 hours
at	-20 °C (± 5 °C)	14 days (when frozen once)

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 navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Additions, deletions or changes are indicated by a change bar in the margin.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606