04665244001V7.0

Activator

cobas®

Order information

REF	CONTENT	Analyzer(s) on which kit(s) can be used
04663632 190	Activator (9 × 12 mL)	COBAS INTEGRA systems **cobas c** systems **cobas c** 111 system

English

Intended use

The Activator is an auxiliary maintenance reagent recommended during the daily service tasks for the conditioning of the ISE electrodes, tubing and samples probes. After the Activator is placed on the system it is pipetted automatically when required for service actions. The primary purpose of the Activator is to activate the ISE electrodes, to coat the ISE tubing and the sample probes which ensures correct handling and pipetting of sample material after the daily cleaning procedures.

Summary

Activator is a lyophilized human serum.

Reagents - working solutions

Lyophilized human serum without chemical additives.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
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 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 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]

For USA: For prescription use only.

Reagent handling

Carefully open one bottle containing the lyophilized Activator, avoid the loss of lyophilisate and pipette in 12.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by gentle swirling within 30 minutes. Avoid the formation of foam. The final volume of reconstituted material will be 13 mL. Then proceed according to the weekly handling recommendation.

Weekly handling recommendation

COBAS INTEGRA systems

1st day:
Transfer approximately 6.5 mL of reconstituted material to a new 11 mL plastic vial supplied in the Activator Bottle Set. Place the freshly filled 11 mL vial on the ISE rack in the position reserved for the Activator. Return the unused material to storage at 2-8 °C.

4th day:
Discard the 11 mL vial and remaining contents regardless of residual volume. Transfer the remaining reconstituted material from the originally prepared bottle into a new 11 mL vial and place on the ISE rack in the position reserved for the Activator.

Roche/Hitachi cobas c systems

1st week:
Firstly transfer approximately 6.5 mL of reconstituted material to a new adequate plastic or glass vial with stopper. Store the freshly filled vial tightly capped at (-15)-(-25) °C for use during the second week.

Keep the remaining material in the original glass bottle and decant sufficient material daily for service tasks (750 µL Activator per Cobas sample cup). Use fresh material each day and return the unused material to storage at 2-8 °C.

2nd week:
Thaw the frozen material and gently swirl the contents until mixed and at room temperature. Use this material for daily service tasks (750 µL Activator per Cobas sample cup). Use fresh material each day and return the unused material to storage at 2-8 °C.

Roche/Hitachi cobas c 111 system (without ISE unit)

1st week:
Firstly transfer three aliquots of 3 mL of reconstituted material to new adequate plastic or glass vials with stoppers. Store these vials tightly capped at (-15)-(-25) °C for use during second, third and fourth week.

Keep the remaining material in the original glass bottle for use as required during weekly service tasks. Return the unused material to storage at 2-8 °C.

2nd, 3rd and 4th week:
Thaw the frozen material weekly and gently swirl the contents until mixed and at room temperature. Use this material as required during weekly service tasks. Return the unused material to storage at 2-8 °C.

Discard the original glass bottle as well as the vials and remaining contents regardless of residual volume after weekly usage.

Roche/Hitachi cobas c 111 system (with ISE unit)

1st week:
Firstly transfer approximately 6.5 mL of reconstituted material to a new adequate plastic or glass vial with stopper. Store the freshly filled vial tightly capped at (-15)-(-25) °C for use during the second week.

Keep the remaining material in the original glass bottle for use as required during weekly service tasks. Return the unused material to storage at 2-8 °C.

2nd week:
Thaw the frozen material and gently swirl the contents until mixed and at room temperature. Use this material as required during weekly service tasks. Return the unused material to storage at 2-8 °C.

Discard the original glass bottle as well as the vials and remaining contents regardless of residual volume after weekly usage.

Note

The reconstituted material must be kept stoppered and stored at adequate temperature. Do not pool Activator from different stored vials due to clotting effects. Do not use a lid for the 11 mL vial of the Activator when placed on the ISE rack for COBAS INTEGRA systems.

The on-board stability for the Activator material in a new 11 mL vial is 4 days maximum for all COBAS INTEGRA systems.

Excessive use of plasma samples will invoke additional service procedures on COBAS INTEGRA systems. These procedures will use additional Activator material. In some cases more material will be required than recommended in the weekly handling.

Bacterial contamination of the Activator will lead to system contamination and have a negative impact on pipetting and ISE function. To avoid this possibility please make sure that only new 11 mL vials are used, and that the recommended protocol is followed.

Storage and stability

Stability of the lyophilized Activator:

at 15-25 °C	5 days
at 2-8 °C	up to the stated expiry date

Stability of the reconstituted Activator:

at 15-32 °C	4 days
at 2-8 °C	7 days
at (-15)-(-25) °C	28 days (when frozen once)

The possible cloudy appearance of the reconstituted material has no effect on the functionality of the Activator. Store the Activator tightly capped when not in use.

Materials provided

See “Reagents – working solutions” section for reagents.

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Materials required (but not provided)

- Activator Bottle Set (50 x 11 mL), Cat. no. 04745086 (for COBAS INTEGRA systems)
- Adequate plastic or glass vials with stopper
- Cobas sample cup, Cat.no. 10394246 (Roche/Hitachi **cobas c** systems)
- Distilled or deionized water
- Roche system reagents and clinical chemistry analyzer
- General laboratory equipment

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.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets and method sheets of all necessary components.

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
REAGENT	Reagent
→	Volume after reconstitution or mixing
GTIN	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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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336

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