05391946001V16.0

SAP Test

cobas®

REF **11820435** 122 Σ **250**

Lot: 190046

Expiration date: 2016-11

English

Intended use

The SAP Test is intended for use by trained Roche personnel only for assay performance checks (APC) of Elecsys and **cobas e** analyzers

Summary

The SAP Test is needed for the Artificial Media test (AM test) and Hot Bead Quench test (HBQ test), which are both part of the APC. In detail, the SAP Test is used to check:

- the absolute signal level of the instrument (AM test)
- potential bead carry over in the measuring cell (AM test)
- the matrix sensitivity of the measuring cell (HBQ test)
- the signal precision (AM and HBQ test)

Reagents - working solutions

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Buffer (gray cap), 1 bottle, 40 mL

R2 Free conjugate (black cap), 1 bottle, 18 mL:
Antibody labeled with biotin and ruthenium complex; phosphate buffer; preservative.

Precautions and warnings

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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear eye protection/ face protection.

P280 Wear protective gloves.

Response:

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

The contents are ready for use. Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation.

Storage and stability

Store at 2-8 °C.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Close tightly after use.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
on all analyzers, open in total	2 weeks

Materials provided

- SAP Test

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers. See operator's manual for additionally required materials.
- For HBQ application: HBQ Sample Set, REF 05118506190 (for additional information, refer to the HBQ Sample Set Method Sheet).

AM test

Consult the respective service manuals for detailed information about the procedure, calculation and interpretation of results.

HBQ test

Consult the service manual for detailed information about the procedure, calculation and interpretation of results. Parameter for lot-calibration of distinct SAP Test and HBQ Sample Set combinations: see table.

Parameter for HBQ lot-calibration

SAP lot	HBQ Sample Set lot	Parameter
190046	181495	SAP factor: 0.76 HBQ BQ slope: 0.888 HBQ BQ offset: 182648 HBQ CQ slope: 1.035 HBQ CQ offset: 83966
190046	188123	SAP factor: 0.76 HBQ BQ slope: 0.907 HBQ BQ offset: 149024 HBQ CQ slope: 1.036 HBQ CQ offset: 75404

Symbols

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

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

SAP Test

cobas®

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