

ISD Sample Pretreatment

REF	Σ	SYSTEM
05889073 190	100	Elecsys 2010 MODULAR ANALYTICS E170 cobas e 411 cobas e 601 cobas e 602

English

Intended use

ISD Sample Pretreatment is an in vitro diagnostic reagent intended for the extraction of specific analytes from specimens. It is used together with specified immunoassays on Elecsys and **cobas e** analyzers.

Summary

ISD Sample Pretreatment is used to extract cyclosporine, tacrolimus, everolimus and sirolimus from specimens (human whole blood samples, PreciControl ISD, PreciControl Everolimus, Cyclosporine CalSet, Tacrolimus CalSet, Everolimus CalSet and Sirolimus CalSet) in order to determine the analyte concentration. It is used together with the Elecsys Cyclosporine, Elecsys Tacrolimus, Elecsys Everolimus and Elecsys Sirolimus assays.

Test principle

For detailed information please refer to the respective section in the assay Method Sheet.

Reagents - working solutions

ISD Sample Pretreatment is labeled as ISD Sample PT.

1 bottle containing 30 mL

Contents: zinc sulfate solution in methanol and ethylene glycol.

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.

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



Danger

H225 Highly flammable liquid and vapour.

H301 + H311 Toxic if swallowed, in contact with skin or if inhaled.
+ H331

H318 Causes serious eye damage.

H370 Causes damage to organs.

H410 Very toxic to aquatic life with long lasting effects.

Prevention:

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
+ P330

P305 + P351 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
+ P338 + P310 Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

P308 + P311 IF exposed or concerned: Call a POISON CENTER or doctor/physician.

P361 + P364 Take off immediately all contaminated clothing and wash it before reuse.

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

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

ISD Sample Pretreatment is ready for use. Keep the bottle tightly capped when not in use.

Storage and stability

Store at 15-25 °C. Keep away from sources of ignition. The reagent is stable up to the expiration date printed on the label if stored as directed. Discard after the expiration date. Improper reagent storage can affect assay performance.

Stability:	
after first opening	84 days
open	total of 2 hours

Materials provided

- ISD Sample Pretreatment

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** analyzer
- See the appropriate assay Method Sheet and the operator's manual for additionally required material.

Assay

For pretreatment procedure refer to the respective section in the assay Method Sheet.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

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
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ISD Sample Pretreatment

cobas[®]

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

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