



12177447001V9.0

SDR II

COBAS FP Sample Dilution Reagent II

REF 20720720 322

1 x 200 mL

cobas[®]

English

Intended use

The COBAS FP Sample Dilution Reagent II is an aqueous solution intended for use as a generic diluent for all COBAS TDM assays performed on COBAS INTEGRA chemistry systems.

Test principle

Please refer to the method sheets provided with your COBAS TDM reagents for a complete description of the COBAS FP test principle.

Reagents – working solutions

Reactive components:

The COBAS FP Sample Dilution Reagent II is a buffered aqueous solution containing surfactant.

Non-reactive components:

Preservative

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.

Reagent handling

Ready for use

Storage and stability

Shelf life at 15-25 °C

See expiration date on reagent label

COBAS INTEGRA 400 plus/800 systems

On-board in use

7 days

Store protected from light by storing in the original shipment cardboard box. Keep bottle tightly capped to prevent evaporation. The reagent should appear clear to slightly yellow. Do not use the reagent after the expiration date marked on the bottle.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

COBAS INTEGRA Vial & Cap Kit, Cat. No. 03261689 190

General laboratory equipment

Instructions for reagent use

Please refer to the method sheet provided with your COBAS TDM reagents for a complete explanation of the COBAS FP Test System including the use of this reagent.

- Recommended empty bottles for use with SDR II:
 - 11 mL (supplied in COBAS INTEGRA Vial & Cap Kit, Cat. No. 03261689 190), or
 - 22.6 mL (supplied in COBAS INTEGRA Vial & Cap Kit, Cat. No. 03261689 190)
- Please use a new bottle each time when the reagent is being replaced on the instrument.
 - Do not pour over two different reagent lots
 - Do not top over the reagent bottle in use
 - Do not pool reagent residuals from other bottles even if they have the same lot numbers
- For use on *COBAS INTEGRA 800 analyzers* the bottle must be filled up to the neck before placing on the reagent rack.
- Reagent placement
 - COBAS INTEGRA 400 plus analyzers*: uncapped on ISE or sample rack
 - COBAS INTEGRA 800 analyzers*: capped on ISE rack

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

Volume after reconstitution or mixing

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