

# Diluent Universal

REF 07299001190

07299001501

36 mL

## English

### For use in the USA only

### Intended use

Diluent Universal is used as a sample diluent in conjunction with Elecsys assay reagents.

### Summary

Dilution of samples is necessary when the analyte concentrations exceed the measuring range of the respective Elecsys test method. In addition, general predilution of samples is specified for some Elecsys assays.

Assay	REF	cobas e 801	cobas e 402
Elecsys AFP	07026706190	•	•
Elecsys AFP	09015124190	•	•
Elecsys AMH	07026714190	•	•
Elecsys AMH	08819378190	•	•
Elecsys Androstenedione	07679840190	•	•
Elecsys Anti-HAV IgM	07026773190	•	•
Elecsys Anti-HBc IgM	07026811160	•	•
Elecsys Anti-HBs	08343594160	•	•
Elecsys Anti-SARS-CoV-2 S	09289275190	•	•
Elecsys Anti-TPO*	07026935190	•	•
Elecsys CA 15-3 II	07027001190	•	•
Elecsys CA 19-9	07027028190	•	•
Elecsys CA 125 II	07026986190	•	•
Elecsys CEA	07027079190	•	•
Elecsys CMV IgM	07027133190	•	•
Elecsys Cortisol II	07027150190	•	•
Elecsys CYFRA 21-1	07299966190	•	•
Elecsys Digoxin	07027214190	•	•
Elecsys Ferritin	07027273190	•	•
Elecsys Folate	07027290190	•	•
Elecsys HBsAg II Auto Confirm	08741034190	•	•
Elecsys HCG STAT	07229569190	•	•
Elecsys HCG STAT	08890595190	•	•
Elecsys HCG+β	07251025190	•	•
Elecsys hGH	07027486190	•	•
Elecsys IgE II	07027516190	•	•
Elecsys IGF-1	07475918190	•	•
Elecsys Myoglobin	07027583190	•	•
Elecsys N-MID Osteocalcin	07027591190	•	•
Elecsys proBNP II	07027664190	•	•
Elecsys proBNP II	09315284190	•	•
Elecsys Prolactin II	07027737190	•	•
Elecsys Tacrolimus	07251254190	•	•
Elecsys total PSA	07027966190	•	•
Elecsys total PSA	08791732190	•	•
Elecsys Toxo IgG	07028008190	•	•
Elecsys Toxo IgM	07028024190	•	•
Elecsys Rubella IgM	07027796190	•	•
Elecsys Vitamin B12 II	07028121190	•	•

Assay	REF	cobas e 801	cobas e 402
Elecsys Vitamin D total II	07028148190	•	•
Elecsys Vitamin D total III	09038086190	•	•

\* Manual dilution only

### Reagents - working solutions

Diluent Universal is labeled as Dil Uni.

3 bottles containing a total usable volume of 36 mL

Contents: Protein matrix; preservative

### 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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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



### Warning

H317 May cause an allergic skin reaction.

### Prevention:

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

### Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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

### Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: 1-800-428-2336

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

### Reagent handling

Diluent Universal is ready for use.

Place the cooled (stored at 2-8 °C) diluent on the reagent manager. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

### Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date

# Diluent Universal

cobas®

Stability:	
on the <b>cobas e 402</b> and <b>cobas e 801</b> analyzers	16 weeks



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## Materials provided

- Diluent Universal

## Materials required (but not provided)

**cobas e 402** and **cobas e 801** immunoassay analyzers and Elecsys assay reagents

See the appropriate Elecsys assay Method Sheet and the operator's manual for additionally required materials.

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

## Assay

For general predilution and for analyte concentrations above the measuring range, see dilution recommendation in the respective Elecsys assay Method Sheet.

Dilutions can be performed either manually by the operator or, if requested, automatically by the analyzer via the instrument's software.

## Elecsys test results

The analyte content of the diluent is in the vicinity of the lower detection limit for the Elecsys assays and can be ignored.

For manual dilutions, the measured concentration must be multiplied by the dilution factor to obtain the actual value in the sample. When dilution is performed by the analyzer, this factor is automatically included in the calculation of the sample concentration.

The concentration in the diluted sample may not be less than the stated minimum concentration in the respective Elecsys assay Method Sheet.

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

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.

## Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume for reconstitution
	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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