

# Diluent Universal

REF 03183971122

2 x 36 mL

For USA: Elecsys Diluent Universal

## 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 411	cobas e 601, cobas e 602
Prolactin II	03203093	•	•
Cortisol	11875116	•	•
HCG STAT	03300811	•	•
Troponin T STAT	04660307	•	•
Troponin T	04491815	•	•
Myoglobin	12178214	•	•
Myoglobin STAT	11820788	•	•
proBNP II	04842464	•	•
proBNP II STAT	05390109	—	•
CEA	11731629	•	•
CEA	04491777	—	•
AFP	04481798	•	•
AFP	04491742	—	•
total PSA	04641655	•	•
total PSA	04491734	—	•
CA 15-3 II	03045838	•	•
CA 125 II	11776223	•	•
CA 19-9	11776193	•	•
Elecsys CYFRA 21-1	11820966	•	•
Ferritin	03737551	•	•
Ferritin	04491785	•	•
Anti-HBs	11820524	•	•
Anti-HBc IgM	11820567	•	•
Anti-HAV IgM	11820591	•	•
Rubella IgM	04618831	•	•
Digoxin	11820796	•	•
IgE II	04827031	•	•
N-MID Osteocalcin	12149133	•	•
HCG+β	03271749	•	•
Anti-TPO*	06368590	•	•
CMV IgM	04784618	•	•
Folate*	04476433	•	•
Folate III*	07559992	•	•
Vitamin B12*	04745736	•	•
Vitamin B12 II*	07212771	•	•
Vitamin D*	06506780	•	•
Vitamin D total II*	07464215	•	•

Assay	REF	cobas e 411	cobas e 601, cobas e 602
Elecsys Vitamin D total III	09038078	•	•
Toxo IgM	04618858	•	•
Elecsys Tacrolimus*	05889057	•	•
Elecsys Anti-SARS-CoV-2 S	09289267	•	•
Elecsys total PSA	08791686	•	•
Elecsys total PSA	08791716	•	•

- Dilution possible

— Assay not available on analyzer

- \* Manual dilution only

### Reagents - working solutions

Diluent Universal is labeled as Dil. Uni.

2 bottles each containing a usable volume of 36 mL

Contents: Protein matrix; preservative ≤ 0.1 %

### 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 dust/fume/gas/mist/vapours/spray.

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).

# Diluent Universal

## Reagent handling

Diluent Universal is ready for use.

Bring the cooled diluent to approximately 20 °C and place on the reagent disk of the analyzer.

Opening and closing of the bottle is performed automatically by the analyzer.

## Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers at 20-25 °C	12 weeks

## Materials provided

- Diluent Universal

## Materials required (but not provided)

- **cobas e** immunoassay analyzers and assay reagents

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

## Assay

The general predilution which is required for some Elecsys assays is triggered by the system software.

For analyte concentrations above the measuring range, see dilution recommendation in the respective Elecsys Method Sheet.

Dilutions can be performed either manually by the operator or, if requested, automatically by the analyzers via the instruments' 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.

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).

## 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](http://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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