

For use in quality control only.



Urea Bio

Test kit for the Cedex[®] Bio Analyzer

 **Version: 01**

Content Version: October 2024

Applications URL (082), URB (068), URD (073)

Cat. No. 10 258 829 001 4 x 50 tests

Store the reagent at +2 to +8°C.

1. General Information

1.1. Contents

Vial	Cap	Content	Composition
1 URB R1	white	4 vials, 50 tests each	Reagent 1 (R1): TRIS buffer, 220 mmol/L, pH 8.6; 2-oxoglutarate, 73 mmol/L; NADH, 2.5 mmol/L; ADP, 6.5 mmol/L; urease (jack bean), $\geq 300 \mu\text{kat/L}$; GLDH (bovine liver), $\geq 80 \mu\text{kat/L}$; preservative.

1.2. Storage and Stability

Storage Conditions (Product)

Store at +2 to +8°C and at +2 to +10°C for onboard use.

The reagent is stable at +2 to +8°C until the expiration date printed on the label when stored unopened and kept free of contamination.

Onboard stability: After first use on the analyzer, the reagent is stable for up to 4 weeks.

i Before use on the analyzer, insert a Chimney* into each bottle of R1. The Chimneys* are plastic tubes that protect the reagents onboard by reducing environmental influence and evaporation.

1.3. Additional Equipment and Reagent required

Analyzer and accessories

- Cedex Bio Analyzer*, including accessories and disposables
- Chimneys*
- Standard laboratory equipment

Calibrators and Controls

- Calibrator A Bio*
- Control A Level 1 Bio*
- Control A Level 2 Bio*
- Control A Level 3 Bio*

1.4. Application

This product is intended for quantitative determination of urea in aqueous solutions using the Cedex Bio Analyzer.

2. How to Use this Product

2.1. Protocols

Test protocol

Urea concentrations can be determined in the following ranges, depending on the selected test protocol. Results lower or higher than the valid measuring range will be flagged.

Cedex Bio test definition

Test definition	URL (082)	URB (068)	URD (073)
Measuring range	Low	Standard	High
mmol/L	0.1 – 4.0	1.0 – 40.0	25.0 – 1,000 ⁽¹⁾
mg/L	6.0 – 240	60.0 – 2,400	1,502 – 60,060 ⁽¹⁾
Control level	A 1	A 1, 2, 3	custom
Sample predilution	No	No	1:25
Measuring mode	Absorbance	Absorbance	Absorbance
Abs. calc. mode	Endpoint	Endpoint	Endpoint
Reaction mode	R1-S	R1-S	R1-S
Reaction direction	Decrease	Decrease	Decrease
Wavelength A/B	340/409 nm	340/409 nm	340/409 nm
Calc. first/last	8/20	8/20	8/20
Unit	mmol/L, mg/L	mmol/L, mg/L	mmol/L, mg/L

⁽¹⁾ Up to 10.0 mol/L (600 g/L) with automatic postdilution.

Pipetting parameters

Pipetting parameters	URL (082)	URB (068)	URD (073)
Water Diluent (Sample Predilution) ⁽¹⁾	No	No	8 µL sample + 192 µL water
R1	50 µL + 95 µL water	50 µL + 95 µL water	50 µL + 95 µL water
Sample (S)	20 µL + 80 µL water	2 µL + 98 µL water	2 µL + 98 µL water
Total Volume	245 µL	245 µL	245 µL

⁽¹⁾ Sample predilution is performed in a prior step, after which the reaction mix is prepared in the same way as the unmodified sample.

Calibration

Calibration	
Calibrator	Calibrator A Bio (CAL A, 599)
Calibration mode	Linear regression
Calibration interval	56 days, and if recalibration is required due to QC results.
Consumption, time	Each protocol (URL/URB/URD): 4 tests, 4 cuvettes, 32/9/9 µL Calibrator, ≈10 minutes

2. How to Use this Product

Quality control

Protocol URL

- Control A Level 1 Bio (CONA1, 111)

Protocol URB

- Control A Level 1 Bio (CONA1, 111)
- Control A Level 2 Bio (CONA2, 112)
- Control A Level 3 Bio (CONA3, 113)

Protocol URD

- Prepare a custom control using your typical sample matrix and an urea concentration in the range of 5 to 20 g/L (80 to 333 mmol/L).

Use the recommended control material. Other suitable control material can also be used. Control intervals and acceptance limits should be adapted to each laboratory's individual requirements. If values do not fall within the defined limits, corrective measures and recalibration are required.

Conversion factors

Conversion factors for urea concentration:

- 1 mmol/L = 60.06 mg/L
- 1 g/L = 16.65 mmol/L

Traceability

This method has been standardized against net weight of urea.

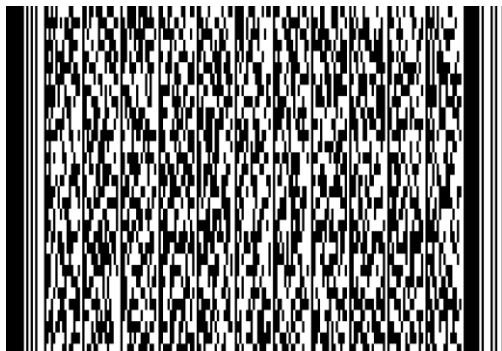
Precision

Representative performance data on Cedex Bio Analyzers are shown. Results obtained in individual laboratories may differ. Precision was determined in samples of three concentration levels. Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 10 days).

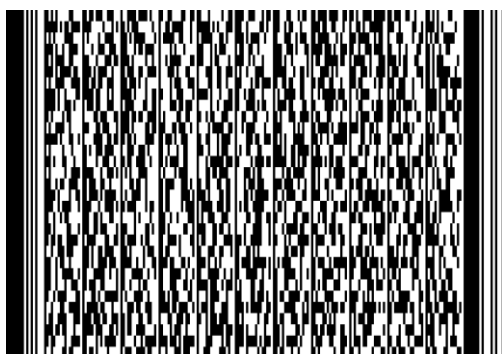
	Level 1	Level 2	Level 3
Mean	2.75 mmol/L (165 mg/L)	14 mmol/L (841 mg/L)	28 mmol/L (1,682 mg/L)
CV in-run [%]	0.95	0.37	0.22
CV inter-run [%]	1.81	1.32	2.15

Test protocol barcodes

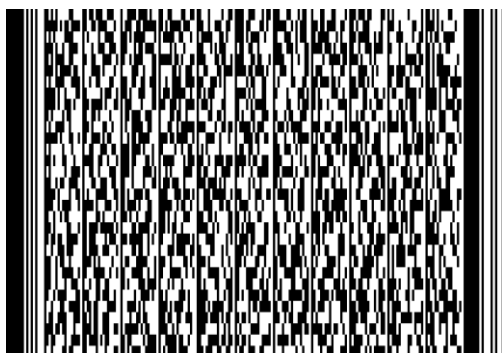
Urea Low Range, URL (ACN 082) v03



Urea, URB (ACN 068) v03



Urea with 1:25 predilution, URD (ACN 073) v03

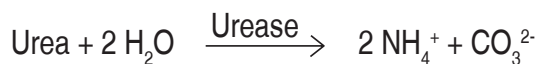


3. Additional Information on this Product

3.1. Test Principle

Urea is hydrolyzed by urease to ammonium and carbonate. The ammonium reacts with 2-oxoglutarate and NADH in the presence of glutamate dehydrogenase (GLDH), producing L-glutamate and NAD⁺.

The consumption of NADH is determined by the decrease of its photometric absorption at 378 nm, which is inversely proportional to the urea concentration of the sample.



4. Supplementary Information

4.1. Conventions

To make information consistent and easier to read, the following text conventions and symbols are used in this document to highlight important information:

Text convention and symbols

i Information Note: Additional information about the current topic or procedure.

! Important Note: Information critical to the success of the current procedure or use of the product.

① ② ③ etc. Stages in a process that usually occur in the order listed.

1 2 3 etc. Steps in a procedure that must be performed in the order listed.

* (Asterisk) The Asterisk denotes a product available from Roche Diagnostics.

4.2. Changes to previous version

First version.

4.3. Ordering Information

Product	Pack Size	Cat. No.
Calibrator		
Calibrator A Bio	6 x 1 mL	06 682 189 001
Consumables		
Chimneys	2 x 48 pieces	06 455 646 001
Controls		
Control A Level 1 Bio	6 x 1 mL	06 682 197 001
Control A Level 2 Bio	6 x 1 mL	06 682 227 001
Control A Level 3 Bio	6 x 1 mL	06 682 545 001
Instruments		
Cedex® Bio Analyzer	1 instrument	06 395 554 001

4.4. Trademarks

CEDEX is a trademark of Roche.

All other product names and trademarks are the property of their respective owners.

4.5. License Disclaimer

Consult product detail pages at custombiotech.roche.com for patent license limitations, if available.

4.6. Regulatory Disclaimer

For use in quality control only.

4.7. Safety Data Sheet

Please follow the instructions in the Safety Data Sheet (SDS).

4.8. Contact and Support

For additional documentation such as certificates and safety data sheets, please visit documentation.roche.com.

Your Roche CustomBiotech Customer Service:

Europe, Middle East, Africa and Latin America

Roche Diagnostics Deutschland GmbH
Phone +49 621 759 8580
Fax +49 621 759 6385
mannheim.custombiotech@roche.com

United States

Roche Diagnostics Corporation
Phone +1 800 428 5433 (toll free)
Fax +1 317 521 4065
custombiotech.ussales@roche.com

Canada

Roche Diagnostics
Phone +1 450 686 7050
Fax +1 450 686 7012
custombiotech.can@roche.com

Japan

Roche Diagnostics K.K.
Phone +81 3 6634 1046
Fax +81 3 5479 0585
japan.custombiotech@roche.com

Asia Pacific

Roche Diagnostics Asia Pacific Pte. Ltd.
Phone +65 6371 6638
Fax +65 6371 6601
apac.custombiotech@roche.com

