For use in quality control/manufacturing process only.

Print

Glucose Bio

Cedex Bio

REF 06 343 732 001 2 × 100 tests

Applications GLC2B (932), GLC2D (901)

Version 06
Content version: January 2015

Store at +2 to +8°C

Intended Use

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

Test Principle

Glucose is phosphorylated by ATP in presence of hexokinase (HK) to glucose-6-phosphate (G-6-P), which is oxidized by NADH in presence of glucose-6-phosphat dehydrogenase (G-6-PDH). The rate of NADPH formation is measured UV-photometrically and is directly proportional to the glucose concentration

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{G-6-P} + \text{ADP}$$

$$\text{G-6-P} + \text{NADP}^+ \xrightarrow{\text{G-6-PDH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^+$$

Contents

Vial/Cap	Content	Function / Composition
1 R1 white cap	2 vials, 100 tests each	Reagent 1: TRIS, 100 mmol/L; Mg^{2+}, 4 mmol/L; ATP, 1.7 mmol/L; NADP, ≥1 mmol/L; preservative; pH 7.8
2 SR black cap	2 vials, 100 tests each	Start Reagent: HEPES, 30 mmol/L; Mg^{2+},4 mmol/L; HK (yeast), ≥130 µkat/L; G-6-PDH (*E. coli*), ≥250 µkat/L; preservative; pH 7.0

Storage and Stability

Store at +2 to + 8°C and at +2 to +10°C for on-board use.

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

On-board stability: After first use on the instrument, the reagents are stable for up to 4 weeks.

Additional Materials Required

- Cedex Bio Instrument, Cat. No. 06 395 554 001, with general accessories and disposables
- Standard laboratory equipment
- Calibrator A Bio, Cat. No. 06 682 189 001
- Control A Level 1 Bio, Cat. No. 06 682 197 001
- Control A Level 2 Bio, Cat. No. 06 682 227 001
- Control A Level 3 Bio, Cat. No. 06 682 545 001

Test Protocol

GLC2B is the standard protocol for glucose determination. If the glucose concentration of samples is expected higher than 7.5 g/L (41.6 mmol/L), then protocol GLC2D shall be used (same protocol with preset 1:10 sample predilution).

Results higher than the valid measuring range will be flagged and a rerun with an automatic 1:10 predilution will be recommended by the software.

Cedex Bio test definition:

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction direction	Increase
Wavelength A/B	340/409 nm
Calc. first/last	16/37
Unit	mmol/L, mg/L
Reaction mode	R1-S-SR

Pipetting parameters:

R1	150 µl
Sample	2 µl + 20 µl Diluent (H_2O)
SR	30 µl
Total volume	202 µl

Calibration:

Calibrator	Calibrator A Bio (CAL A, 599)
Calibration mode	Linear regression
Calibration intervall	Each new lot, and if recalibration is required due to QC results

Quality control:

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

Use the recommended control material. Other suitable control material can be used in addition.

Intervals / limits	Control intervals and acceptance limits should be adapted to each laboratory's individual requirements.

If values do not fall into the defined limits, corrective measures and recalibration are required

Measuring Range

Glucose concentration can be determined in following ranges:

- GLC2B: 0.02 - 7.50 g/L (0.111 - 41.6 mmol/L)
- GLC2D: 0.2 - 75.0 g/L (1.11 - 416.0 mmol/L), up to maximal solubility with postdilution

Conversion Factors

Conversion factors for glucose concentration:

- 1 mmol/L = 180.2 mg/L
- 1 g/L = 5.550 mmol/L

Traceability

This method has been standardized against Isotope dilution mass spectrometry (ID-MS).

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).

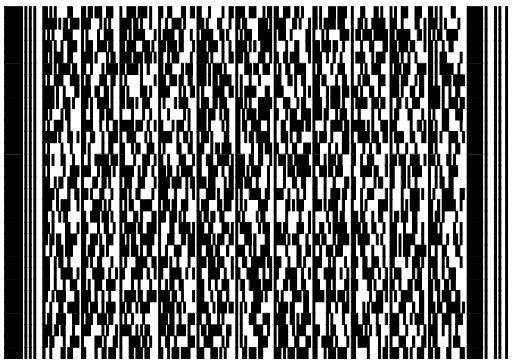
	Level 1	Level 2	Level 3
Mean	2.52 mmol/L (1.14 mg/L)	9.89 mmol/L (1.75 mg/L)	14.1 mmol/L (4.86 mg/L)
CV in-run	1.1%	0.8%	0.5%
CV inter-run	0.5%	0.6%	0.5%

Changes to Previous Version

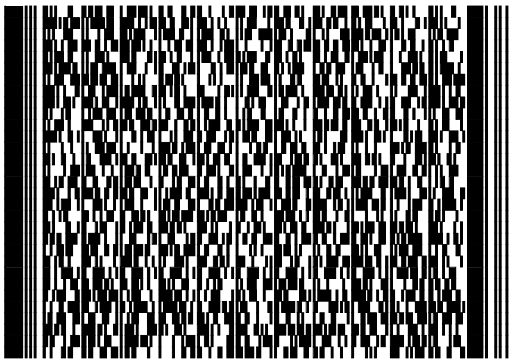
- Editorial Changes
- Correction of "Calc. first/last" Value

Test Protocol Barcodes

Glucose, GLC2B (ACN 932) v02



Glucose with 1:10 predilution, GLC2D (ACN 901) v02



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