GLUCOSE

Cat. No.	Pack Name	Packaging (Content)
BLT00025	GLU 500	R1: 2 x 250 ml, R2 standard: 2 x 5 ml
BLT00026	GLU 4x250	R1: 4 x 250 ml, R2 standard: 2 x 5 ml
BLT00027	GLU 1000	R1: 1 x 1000 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Glucose in human serum, plasma and urine.

CLINICAL SIGNIFICANCE
Accurate measurement of glucose in body fluid is important in diagnosis and management of diabetes, hypoglycemia, adrenal dysfunction and various other conditions. High levels of serum glucose may be seen in case of Diabetes mellitus, in patients recieving glucose containing fluids intravenously, during severe stress and in cerebrovascular accidents.
Decreased levels of glucose can be due to insulin administration, as a result of insulinoma, inborn errors of carbohydrate metabolism or fasting.

PRINCIPLE
Trinder's method
Glucose in the sample is oxidised to yield gluconic acid and hydrogen peroxide in the presence of Glucose oxidase. The enzyme peroxidase catalyses the oxidative coupling of 4-aminoantipyrine with phenol to yield a coloured quinonemine complex, with absorbance proportional to the concentration of glucose in sample.

$$\beta\text{-D-Glucose} + H_2O + O_2 \xrightarrow{\text{Glucose oxidase}} \text{Gluconic acid} + H_2O_2$$

$$H_2O_2 + \text{phenol} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Red Dye} + 2H_2O$$

REAGENT COMPOSITION
R1	
Phosphate buffer	250 mmol/l
Glucose oxidase	>25 U/ml
Peroxidase	>2 U/ml
Phenol	5 mmol/l
4-aminoantipyrine	0.5 mmol/l
R2 standard	See bottle label

REAGENT PREPARATION
Reagents are liquid, ready to use.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8 °C.

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum, plasma (heparin, EDTA) or urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability after addition of a glycolytic inhibitor (Fluoride, monoiodoacetate, mannose): [4]	2 days	at 20–25°C
	7 days	at 4–8°C
Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor: [2,5]	8 hours	at 25°C
	72 hours	at 4°C
Stability of glucose in urine:	24 hours	at 4–8°C

For the determination in urine dilute the sample using redistilled water in 1 + 10 ratio.
Discard contaminated specimens.

12000048
12000049
12000050

CALIBRATION
Calibration with the standard included in the kit or the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
mg/dl x 0.056 = mmol/l

EXPECTED VALUES [2]
Serum:
Glucose Fasting:

Cord:	45 – 96 mg/dl
Newborn, 1 d:	40 – 60 mg/dl
Newborn, >1 d:	50 – 80 mg/dl
Child:	60 – 100 mg/dl
Adult:	74 – 100 mg/dl
>60 y:	82 – 115 mg/dl
>90 y:	75 – 121 mg/dl
Glucose 2 h Postprandial:	<120 mg/dl
WB (Hep) Adult:	65 – 95 mg/dl
Urine:	1 – 15 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Limit of quantification:	2.34 mg/dl
Linearity:	450 mg/dl
Measuring range:	2.34 – 450 mg/dl

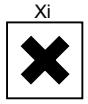
PRECISION
Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	153.75	1.61	1.05
Sample 2	239.64	3.93	1.66

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	97.14	1.61	1.64
Sample 2	258.39	3.04	1.19

COMPARISON
A comparison between XL-Systems Glucose (y) and a commercially available test (x) using 40 samples gave following results:
y = 1.000 x - 0.714 mg/dl
r = 0.999

INTERFERENCES
Following substances do not interfere:
haemoglobin up to 7.5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 750 mg/dl.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
Reagent R1 contains 0.74% NaOH and is classified as irritant and also contains less than 0.05% sodium azide which is classified as very toxic and dangerous substance for the environment.



Irritant

Risk phrases (R):
R 36/38 Irritating to eyes and skin.
Safety phrases (S):
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 28 After contact with skin, wash immediately with plenty of water.
S 37/39 Wear suitable gloves and eye/face protection.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PROCEDURE
Wavelength	(490 – 550) maximum at 500 nm
Cuvette	1 cm

	Reagent blank	Standard (Cal.)	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	-	-	10 µl
Standard (Cal.)	-	10 µl	-
Distilled water	10 µl	-	-

Mix and incubate 5 - 10 min. at 37 °C. Measure absorbance of the sample A_{sam} and standard A_{st} against reagent blank.

CALCULATION
$$\text{Glucose (mg/dl)} = \frac{\Delta A_{sam}}{\Delta A_{st}} \times C_{st}$$

C_{st} = standard (calibrator) concentration

Applications for automatic analysers are available on request.

ASSAY PARAMETERS FOR PHOTOMETERS
Mode	End Point
Wavelength 1 (nm)	505
Wavelength 2 (nm)	670
Sample Volume (µl)	5/10
Reagent Volume (µl)	500/1000
Incubation time (min.)	5
Incubation temp. (°C)	37
Normal Low (mg/dl)	74
Normal High (mg/dl)	100
Linearity Low (mg/dl)	2.34
Linearity High (mg/dl)	450
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	0.2
Units	mg/dl

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REFERENCES

1. Thomas L.: Clinical Laboratory Diagnostics, 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998, p. 131 - 7.
2. Tietz N. W., (Ed.),Textbook of Clinical Chemistry. Burtis CA and Ashwood ER, Fifth Edition, 2012.
3. Barham, D., Trinder, P.: An improved color reagent for the determination of blood glukose by the oxidase system. Analyst, 1972, 97; 142 - 5.
4. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT verlag; 2001;p.30-1.
5. Snacks DB, Bruns DE, Goldstein DE, Mac Laren NK, Mc Donald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chemi 2002; 48:436-72.

SYMBOLS USED ON LABELS

REF Catalogue Number	Manufacturer	See Instruction for Use
LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC	Storage Temperature
Expiry Date	IVD In Vitro Diagnostics	CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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