SỐ 2

HbA1c 2R

Cat. No.	Pack Name	Packaging (Content)
XSYS0096	HbA1c 2R	R1: 2 × 21 ml, R2: 2 × 8 ml, R3: 3 × 50 ml

EN

CE IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of glycated hemoglobin HbA1c in whole blood on photometric systems.

CLINICAL SIGNIFICANCE
Hemoglobin A1c (HbA1c) is a glycated hemoglobin which is formed by the non-enzymatic reaction of glucose with native hemoglobin. This process runs continuously throughout the circulatory life of the red cell (average life time 100–120 days). The rate of glycation is directly proportional to the concentration of glucose in the blood. The blood level of HbA1c represents the average blood glucose level over the preceding 6 to 8 weeks (due to the kinetics of erythrocyte turnover this period is more affected by the blood glucose level than the preceding weeks). Therefore, HbA1c is suitable for retrospective long-term monitoring of blood glucose concentration in individuals with diabetes mellitus. Clinical studies have shown that lowering of HbA1c level can help to prevent or delay the incidence of late diabetic complications.
As the amount of HbA1c also depends on the total quantity of hemoglobin the reported HbA1c value is indicated as a percentage of the total hemoglobin concentration.
Falsely low values (low HbA1c despite high blood glucose) may occur in people with conditions with shortened red blood cell survival (hemolytic diseases) or significant recent blood loss (higher fraction of young erythrocytes). Falsely high values (high HbA1c despite normal blood glucose) have been reported in iron deficiency anemia (high proportion of old erythrocytes). These circumstances have to be considered in clinical interpretation of HbA1c values.

PRINCIPLE
Particle enhanced immunoturbidimetric test.
HbA1c is determined directly without measurement of total hemoglobin.
This test is based on latex immunoagglutination where HbA1c in the test sample is absorbed onto latex particles, and then Cross-linked anti-HbA1c is added to form an Antigen-Antibody reaction. The measured absorbance is proportional to the HbA1c bound to particles, which in turn is proportional to the percentage of HbA1c in the sample.

STANDARDIZATION
The assay is standardized according to the approved IFCC reference method [3]. Calibration according to DCCT/NGSP is also possible. Corresponding calibrator values are listed in the package insert of the calibrator set HbA1c liquid. DCCT/NGSP and IFCC values show a linear relationship and can therefore be calculated from each other. Also new IFCC recommended units mmol/mol (mmol HbA1c / mol Hb) can be easily calculated from IFCC values. Recalculation equations are following:
IFCC = (NGSP – 2.15) / 0.915
NGSP = 0.915 x IFCC + 2.15
mmol/mol = 10 x IFCC
IFCC: International Federation of Clinical Chemistry [3,4]
DCCT: Diabetes Control and Complications Trial [5]
NGSP: National Glycohemoglobin Standardization Program [6]

REAGENT COMPOSITION
R1: Latex 0.1 %
R2: Anti-HbA1c Cross linked anti-human hemoglobin HbA1c mouse monoclonal antibody
Buffer
NaCl 2 %
R3: Hemolyzing solution

REAGENT PREPARATION
All reagents are ready for use. Mix each reagent well before use.

STABILITY AND STORAGE
The reagents are stable until expiry date when kept at 2–8 °C. Stability after opening and installation to the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

SPECIMEN COLLECTION
Whole blood collected with EDTA.
Sample preparation:
Hemolyzing solution (R3) 500 µl
Sample 10 µl
Mix and allow to stand for 5 minutes or until complete lysis is apparent.
Sample preparation on-board is not recommended.
Specimen stability:

Whole blood	1 week	at 2–8 °C
Hemolysate	10 hours	at 15–25 °C
Hemolysate	10 days	at 2–8 °C

ASSAY PROCEDURE
Application sheets for automated systems are available on request.

Wavelength	660 nm
Optical path	1 cm
Temperature	37 °C
Measurement	Against air

Sample or calibrator	36 µl
Reagent 1	900 µl
Mix, incubate for 5 min., read absorbance 1, then add:	
Reagent 2	300 µl
Mix, read absorbance 2 after exactly 5 min.	

MATERIAL REQUIRED BUT NOT PROVIDED
General laboratory equipment.

CALIBRATION
The concentration of HbA1c in unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at different levels, where the first calibrator with zero value is used as blank.
Stability of calibration: 4 weeks
For calibration us the HbA1c 2R CALIBRATOR SET (XSYS0097).

CONTROLS
For internal quality control use the HbA1c 2R CONTROL LOW (XSYS0098) and HbA1c 2R CONTROL HIGH (XSYS0099).

CALCULATION
Results are calculated automatically by the instrument.

EXPECTED VALUES [7]
Reference intervals should be established or verified by the laboratory based on an appropriate non-diabetic patient population.

	% NGSP	% IFCC	mmol/mol
Non-diabetics	4–6	3–4	30–40
Target of therapy	< 7	< 5	< 50
Change of therapy	> 8	> 6	> 60

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 detection: 0.24 % NGSP
Limit of quantification: 0.73 % NGSP
Linearity: 15.6 % NGSP
Measuring range: 0.73–15.6 % NGSP

Erba Mannheim
XL SysPack

Accuracy:

	Target (% NGSP)	Result (% NGSP)	bias (%)
CONTROL LOW	5.7	5.42	-4.9
CONTROL HIGH	13.3	14.19	+6.7

Precision:

Intra-assay n = 20	Mean (% NGSP)	SD (% NGSP)	CV (% NGSP)
Sample 1	6.72	0.04	0.65
Sample 2	11.08	0.06	0.58

Inter-assay n = 20	Mean (% NGSP)	SD (% NGSP)	CV (% NGSP)
Sample 1	6.67	0.05	0.81
Sample 2	11.07	0.26	2.39

Method Comparison:
A comparison between XL-Systems HbA1c (y) and commercially available test (x) using 70 samples were carried. Whole blood samples were assayed in parallel and the results compared by linear regression analysis according to Passing-Bablok. The following statistics were obtained:
y = 0.9828 x - 0.048
r = 0.972
Specificity/Interferences:
Due to its antibodies, HbA1c 2R is a specific immunoassay for human HbA1c.
No interference was observed by ascorbic acid up to 50 mg/dl, bilirubin F up to 19.6 mg/dl, bilirubin C up to 20.6 mg/dl, chyle up to 1590 FTU, rheumatoid factor up to 1100 IU/ml and high lipid up to 1400 formazine turbidity units.
Testing of interferences was performed on Hitachi 7180.

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagents R1 and R2 are not classified as dangerous.
Supplemental information:
EUH 208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction

Reagent R3 is not classified as dangerous.

Immediately after HbA1c measurement cleaning of cuvettes is necessary. Use the alkaline cuvette washing solution which is recommended by the analyzer manufacturer.
Take necessary precautions for use of laboratory reagent.

WASTE MANAGEMENT
Please refer to local legal requirements.

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