

HbA1c

HC 0040 CH	1 x 40 ml
HC 0080 CH	2 x 40 ml

INTENDED USE

Reagent for quantitative in vitro determination of glycated hemoglobin (HbA1c) in biological fluids.

SUMMARY OF TEST

Glycated hemoglobin (HbA1c) is an important biochemical marker for assessing long-term glycemic control in patients with diabetes. HbA1c is being used not only to guide diabetes treatment but also to assess quality of care, and to predict risk for development and progression of diabetes complications.

PRINCIPLE OF THE METHOD

The test is based on latex immunoagglutination, where HbA1c of the sample is absorbed on latex particles, then anti-HbA1c is added to form an antigen-antibody reaction. The resulting turbidity can be measured at the wavelength of 660 nm.

HbA1c is directly determined without measurement of total hemoglobin.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

HC R1 **0040:** 1 x 30 ml (liquid) white cap
0080: 2 x 30 ml (liquid) white cap

Composition: Latex suspension, stabilizers and preservatives.

HC R2 **0040:** 1 x 10 ml (liquid) red cap
0080: 2 x 10 ml (liquid) red cap

Composition: Anti-HbA1c antibody, stabilizers and preservatives.

Store all components at 2-8°C.

REAGENT PREPARATION

Use separate reagents ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: use preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

SPECIMEN

Whole blood.

Keep specimens away from direct light sources.

Specimens are stable 2 weeks when stored at 2-8°C. Do not freeze.

Preparation of test sample:

10 µl of whole blood have to be diluted with 500 µl of deionized water, in order to hemolyze the sample.

The above procedure does not apply to reconstituted calibrators and controls.

TEST PROCEDURE

Wavelength: 660 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	calibrator	sample
reagent R1	750 µl	750 µl
calibrator	30 µl	-
sample	-	30 µl

Mix, incubate at 37°C for 5 minutes.

dispense:	calibrator	sample
reagent R2	250 µl	250 µl

Mix, incubate at 37°C for 1 minute and record absorbances as A_1 . After exactly 4 minutes, record again absorbances as A_2 .

RESULTS CALCULATION

For calibrators and samples, calculate $\Delta A = A_2 - A_1$. A calibration curve is plotted by the use of a set of standards with increasing HbA1c concentrations. Successively, HbA1c concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Normal values (NGSP) 4.6-6.2%

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control set is available:

HbA1c CONTROL SET

with normal and abnormal control values.

For calibration, use the following product:

HbA1c CALIBRATOR

Please contact Customer Care for further information.

TEST PERFORMANCE

Measuring range

Measure interval depends on the concentration of the highest standard used for calibration.

If such a limit value is exceeded, sample should not be diluted and tested. The result should be reported as "high".

Interferences

No interference was observed by the presence of:

free bilirubin	≤ 20 mg/dl
conjugated bilirubin	≤ 21 mg/dl
ascorbic acid	≤ 50 mg/dl
rheumatoid factor	≤ 1100 IU/ml

Precision

intra-assay (n=10)	mean (%)	SD (%)	CV%
sample 1	5.0	0.01	0.25
sample 2	12.8	0.02	0.17

inter-assay (n=5)	mean (%)	SD (%)	CV%
sample 1	5.0	0.02	0.32
sample 2	12.9	0.06	0.45

Methods comparison

A comparison between CHEMA and HPLC method gave the following results:

HPLC method = x
HbA1c CHEMA = y
n = 142

$$y = 0.99x + 0.02\% \quad r^2 = 0.989$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.








REFERENCES

Little R. R., Rohlfing C. L. *Clinica Chimica Acta* 2013, 418, 63-71.

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SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use