Cellex CE

Product Name **Cellex HbA1c Quantitative Test**

REF **Catalog Number：5710**

IVD **In Vitro Diagnostic**

Read this entire insert thoroughly before using the Cellex HbA1c Quantitative test. Only use the Cellex HbA1c Quantitative test with Helios Analyzer（Model:301/303）.

PRODUCT DESCRIPTION

1. Package contents

Specification：25 test units/kit

2. Intended use

This product is for the quantitative determination of HbA1c (Hemoglobin A1c), in human blood, on Helios Analyzer (Model: 301/303).

3. Principle of the assay

The Cellex HbA1c Quantitative test is based on boronate affinity chromatography techonology, including detecting devices of porous membrane filter, pre-rotation test tube with reagent, dilution of reagent and cleaning fluid. To be precise, the reaction reagent and the dilution contains a substance which dissolves red blood cells and precipitates hemoglobin, and a blue boric acid conjugate which can combine with the cis-diol group of glycated hemoglobin. Once the blood dropped into the reaction reagent, the red blood cells will be dissolved immediately, which results in the precipitation of hemoglobin. Then boric acid conjugate will combine with the cis-diol group of glycated hemoglobin. When a portion of the reaction mixture is placed on the test equipment, all the precipitated hemoglobin, whether it is combined by the boric acid conjugate, will remain on the filter. Besides, cleaning fluid will be used to remove additional colored combination. Finally, the color chromatogram for blue(glycated hemoglobin) and red(total hemoglobin) was analyzed by Helios Analyzer 301 or Helios Analyzer 303 to calculate the ratio of the two which represents the concentration of HbA1C in the sample.

□ KIT CONTENTS

The Cellex HbA1c Quantitative test consists of cartridge, R1-A Reagent, R1-B Reagent, R2 Reagent, a user instruction, 10μL Dropper and Capillaries/dropper Comb.

The specifications of all the components of the Cellex HbA1c Quantitative test are as the following:

R1-A Reagent: 1ea/kit, Dye-boronic acid conjugate;

R1-B Reagent: 25ea/kit, 290μL/ea, Conjugate Diluent buffer and surfactant;

R2 Reagent: 1ea/kit, Wash solution;

Cartridge: 25ea/kit, Fiber membrane and absorbing padding;

10μL Dropper: 25ea/kit;

Capillaries/dropper Comb: 25ea/kit.

STORAGE AND EXPIRY DATE

The Cellex HbA1c kit, when stored unopened at 2℃-30℃, will remain stable until the expiration date printed on the kit label.

Once opened, the R1-A reagent and R2 reagent can be stable for 30 days at 2℃-30℃.

The R1-B reagent and the Test cartridge should be used once opened.

□ INDICATION OF PRODUCT FUNCTIONALITY

1. The product of combining hemoglobin and blood glucose is HbA1c, which is non-reversible and proportional to the blood glucose concentration. HbA1c can stay for 120 days; therefore observation of blood glucose concentration before 120 days is feasible. HbA1c tests can usually indicate the blood sugar control in persons in the last 8-12 weeks. For the blood samples close to the reference range limit, judgments should be made considering the clinical symptoms.
2. The Cellex HbA1c Quantitative test can only be used with whole blood sample; please do not use blood serum or blood plasma samples.
3. The following substances were tested and found no interference with Cellex HbA1c Quantitative test: Bilirubin (20mg/dL) and triglyceride (5,000mg/dL).
4. Limit of detection: (LOD)≤3%
5. Linearity range:4%-16%，correlation coefficient is not lower than 0.9900
6. Accuracy

The Accuracy of the Cellex HbA1c Quantitative test system was evaluated at two clinical sites from 207 Patients with replicate measurement. The correlation obtained between Cellex HbA1c Quantitative test system and the reference method was:

N=207,y=1.0083x-0.0006（R2=0.9236）.

7. Precision

The precision of the Cellex HbA1c Quantitative test system was estimated with venous blood samples and control solution in the laboratory.

Within Run Precision (venous blood)

HbA1c concentration (%)	5.5	9.1	11.7
N	10	10	10
Mean	5.6	8.9	11.8
STD	0.15	0.22	0.28
CV(%)	2.7	2.5	2.4

Day to Day Precision (control solution)

HbA1c concentration(%)	6.0	9.7	12.1
N	20	20	20
Mean	5.9	9.9	12.3
STD	0.19	0.31	0.37
CV(%)	3.2	3.1	3.0

TEST PROCEDURE

1. Specimen Storage and Stability

Whole blood samples treated with EDTA can be stored for 3 days at 2℃-8℃. Frozen samples should be thawed only once.

2. Testing Method

Bring all the HbA1C Reagents to room temperature prior to use. Input the calibration curve by using IC card.

a) Add 10μL R1-A Reagent to R1-B Reagent tube with 10μL dropper and mix thoroughly.

b) Use the capillary tube on a composite sampling device (Capillary tube and dropper Comb) to add 10μL blood sample into test tube which contained the mixed solution of R1-A and R1-B Reagent, and then plug the test tube with the base of the composite sampling device. Mix up and down 20 times. Insert it into the incubation hole on desktop of Helios Analyzer; The Analyzer incubates it to react 2 minutes automatically until the incubation light changes from red to green.

c) After the whole blood sample has completed the reaction with R1-A & R1-BReagent, shake the test tube again for thorough mixing. Open the test tube and transfer 1 drop (about 25μL) of mixture from step b) to the cartridge. Please note that do not to touch the filter membrane of the chromatograph, and prevent the formation of air bubbles.

d) When the mixture from step b) has been totally absorbed by the cartridge, add 1 drop (about 25μL) of R2 reagent to the cartridge. Please wait for 10 seconds to dry.

e) Place the cartridge on the tray and use the analyzer to evaluate the sample.

f) The analyzer would run an automatic calibration every time when it is turned on. Tests can only be preceded when the calibration is successful. Experimental labs can also perform quality control by using control HbA1c following the rules and instructions. g) Mathematical formula is: C = B (Ag - A0) = B [log R0 / (Rtest - Rf) - A0].Where C represents the concentration, B represents the absorption proportional constant, Ag represents the reflected light intensity, A0 blank reflection absorbance, R0 represents the blank scattered light intensity, Rtest represents the reflected light intensity measured, and Rf is the nonlinear correction factor

REFERENCE RANGE

By testing on 120 blood samples of healthy individuals, the average value ± 2 S.D. were computed according to the reference range of current available product in the market. The reference range is estimated 4.3% to 6.0%.

ATTENTION

1. This kit is for in vitro diagnosis only.
2. Test kits of different lot number cannot be used together.
3. Since R1-A, R1-B and R2 reagents can be irritant to skin, please do not directly contact the reagents.
4. The R1-B reagent and the cartridge are only for single usage.
5. Change the dropper and capillaries/dropper comb to a new one after every single use.
6. Utilized test kits, equipment and blood samples are considered to be potentially infectious. Suitable precaution and procedure should be performed according to the local or national requirement. Gloves should be worn during the entire procedure.
7. Please do not use this test kit after the expiry date or if the kit is stored not as instructed.

□ REFERENCES

1. Clinical practice advice. (Jan, 2010). American Diabetes Association, 33.

Index of CE Symbols

	Consult instructions for use	REF	Catalog #
EC REP	Authorized Representative	LOT	Lot Number
	Manufacturer	30°C 2°C	Storage temperature
IVD	For in vitro diagnostic use only		Production date
	Expiry date		Cannot be reused
	Caution, consult instructions for use		

Cellex, Inc.

76 TW Alexander Drive,
Research Triangle Park, NC 27709-0002, USA
Tel: 1-919-314-5535
Fax:1-919-314-5336
E-mail: info@cellex.us

EC REP **MedPath GmbH**

Mies-van-der-Rohe-strasse 8, 80807
Munich, Germany

DR5710 Rev. A00 09 April 2019
English version