Kalstein

HbA1c Quantitative Test

Model YR05129

Instruction Manual

Thank you very much for purchasing our Kalstein´s HbA1c Analyzer Model YR05129

Please read the “Operating Instructions” and “Warranty” before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the “Warranty” at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

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Product Name HbA1c Quantitative Test

REF Catalog Number: 5710

IVD In Vitro Diagnostic

Read this entire insert thoroughly before using the HbA1c Quantitative Test. Only use the HbA1c Quantitative test with HbA1c Analyzer (Model:YR05129).

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 HbA1c Analyzer (Model: YR05129).

3. Principle of the assay

The HbA1c Quantitative test is based on boronated affinity chromatography technology, including detecting devices of porous membrane filter, pre-rotaton 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 acdi 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 HbA1c Analyzer YR05129 to calculate the ratio of

The two which represents the concentration of HbA1c in the sample.

KIT CONTENTS

The HbA1c Quantitative test consists of cartridge,R1 Reagent,R2 Reagent,R3 Reagent,a user instruction,5uL Dropper Comb.

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

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

R2 Reagent: 1 tube/kit, solution.

R3 Reagent: 25 tube/kit, 200ul/tube, Conjugate Diluent buffer and surfactant;

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

5ul Dropper: 25 pcs/kit.

STORAGE AND EXPIRY DATE

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

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

The R3 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; 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 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 HbA1c Quantitative test :(20mg/dL)and triglyceride(5000mg/dL).

4. Limit of detection:(LOD) ≤3%

5. Linearity range:4%-16%, correlation coefficient is not lower than0.9900

6. Accuracy

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

N=207,y=1.0083*-0.006(R2=0.9236).

7. Precision

The precision of the Quantitative test system was evaluated 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
Wean	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
Wean	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 5ul R1 Reagent to R3 Reagent tube with 5ul pipette and mix thoroughly.

Use the 5ul dropper to add 5ul blood sample into test tube which contained the mixed solution of R1 and R3 Reagent, and thenmix thoroughly.Insert it into the incubation hole on desktop of HbA1c Analyzer; The Analyzer incubates it to react 2 minutes automatically until the incubation light changes from red lo green.

c）After the whole blood sample has completed the reaction with R1&R3 Reagent, place the pipette in the mixture and repeatedly suck and spit for 5 times to fully mix. Use a pipette to take 25ul of the 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, Use a pipette to take 25ul 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) Mathematical formula is:C=B(Ag-A0)=B[log RO/(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±2S.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 vitro diagnosis only.
2. Test kits of different lot number cannot be used together.
3. Since R1, R2 and R3 reagents can be irritant to skin, please do not directly contact the reagents.
4. The R3 reagent and the cartridge are only for single usage.
5. Change the dropper and capillaries/dropper comb to a new after every contact the reagents.
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. Should be worn during the entire procedure.
7. Please do not use this test after 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	catalog#
Authorized Representative	Lot Number
Manufacturer	storage temperature
For in vitro diagnostic use only	Production date
Expiry date	Cannot be reused

Caution, consult instructions for use

EC REP MedPath GmbH