HbA1c Reagent Kits (HPLC)

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【Symbol Explanation】

Symbol	Title of Symbol
	Manufacturer
	Authorized representative in the European Community
	Use-by date
	Batch code
	Date of Manufacture
	Temperature limit
	Consult instructions for use
	In vitro diagnostic medical device
	Caution
	Contains sufficient for <n> tests
	Keep dry
	This way up
	Transport package should not be rolled
	Stacking limit by number

【Product Name】

HbA1c Reagent Kits (HPLC)

【Package Specification】

100T, 200T, 400T.

【Intended Use】

The kit is used to quantitative determination of HbA1c content in the whole blood of human body with Lifotronic HbA1c/Hemoglobin Analyzer by high performance liquid chromatography (HPLC) method.

HbA1c has a stable structure, of which in vivo synthesis process is slow and irreversible. The synthesis rate of HbA1c is proportional to the concentration of blood glucose. It accumulates in the erythrocytes of 120 days lifetime. Therefore, the level of HbA1c reflects the average level of blood glucose in the past 2~3 months. It's a reliable biomarker to indicate blood glucose levels.

【Principle】

Ion Exchange Chromatography: When passing through cation-exchange column, the hemoglobin will be absorbed by resin which was balanced by acidic buffer. Since the charges of different glycated hemoglobin and un-glycated hemoglobin, absorbing forces will be different. The less cation of glycated hemoglobin means the less absorbing force. On the contrary, the cation level of un-glycated hemoglobin is high. Elute those glycated hemoglobin with different buffer solutions in sequence, as HbA1a, HbA1b, HbF,LA1c and HbA1c. The strongest absorbing force of HbA0 and variant will be eluted in the end. Finally, the content of HbA1c in whole blood could be calculated in the hemoglobin analyzer.

【Components】

Different lots of components can not be used at the same time or mixed up together.

Reagent Component	Main Ingredients	Volume (100T)	Volume (200T)	Volume (400T)
Eluent A	Phosphate buffer solution	800 mL	800 mL×2	900 mL×2
Eluent B	Phosphate buffer solution	400 mL	700 mL	750 mL
Eluent C	Phosphate buffer solution	/	800 mL	850 mL
Hemolytic Agent L	De-ionized water	2500 mL	5000 mL	5000 mL
Applicable Instrument		GH-900Plus	H8, H9	H8, H9

【Storage and Shelf Life】

Stored the reagent kits at 4~30°C.

Shelf life is 24 months, and open-vial shelf life is 3 months.

Use the reagent kit before valid date marked on the box.

【Applicable Instrument】

Lifotronic HbA1c/Hemoglobin Analyzer, GH-900 Plus, H8, H9

【Specimen Collection, Handling and Storage】

1．Require fasting blood, and use EDTA-K_2 for anti-coagulation.

2．Recommend fresh blood samples.

3．If the sample needs store, refrigerate it at 2 ~ 8°C for 7 days without direct illumination.

【Assay Procedure】

1. Place samples on sample loader.
2. Once complete assay, the content of HbA1c will present on the screen
3. Print the result out if necessary..

【Reference Range】

Reference range: 4.0%~6.1%.

The reference value is calculated by measuring HbA1c content of whole blood in a number of seemingly healthy population. Recommend each laboratory to establish its own reference range according to groups of patients.

【Result Explanation】

If the result of a certain sample exceeds the maximum measurement range, the system will prompt further dilution tip of sample for re-test. Then multiply by the appropriate dilution factor.

1. Please follow below instructions to obtain acceptable accurate results.
   a) For each test, total area of all peaks should be within normal range according to user manual of instruments, otherwise, the test result needs discard;
   b) QC value should be within targeted range;
   c) Reportable value range: The reagent kit's linearity range is 3%~18%, once the test result extend this range, Lifotroinc HbA1c/Hemoglobin Analyzer will mark it with (*), and should not report.
2. Glycated hemoglobin concentration presents in NGSP units (%) and IFCC unit (mmol/mol), conversion formula: IFCC=（NGSP-2.15）×10.929.
3. The level of HbA1c reflects the average level of blood glucose in the past 120 days, the test results are only for assisting diagnosis, and it needs to be combined with clinical presentation, medical history and other diagnostic results before taking appropriate clinical management.

【Limitations】

1. The test results are only for aided diagnosis, and it needs to be combined with clinical presentation, medical history and other diagnostic results before taking appropriate clinical management.
2. This product can only be used for measuring EDTA-K_2 anticoagulated whole blood sample, and can not be used for other body fluid samples.
3. To avoid interference, it's suggested to pre-treat high blood lipids sample before testing. Obviously contaminated sample would lead to erroneous results, so it's required to avoid using that type of sample.
4. Dilution ration effect.

Lifotronic HbA1c/Hemoglobin Analyzer will automatically dilute the sample according to preset dilution ration. For each acceptable test, the total area of all peaks range should be within normal range according to user manual of machine. otherwise, the test result was affected; Please manually dilute the sample according to instrument user manual and test it again.

5. Abnormal red blood cell survival time.

Hemolytic anemia patient sample has shorter red blood cell life than normal patient's, thus, the HbA1c test result will be lower according to hemolysis degree. Sick cell disease patient and patient after splenectomy sample results will be higher since their red blood cell life are longer than normal patient's.

6.Interfering substance

The bilirubin levels up to 60 mg/dL, glucose levels up to 1000mg/dL, triglyceride levels up to 5680 mg/dL and HBF up to 10% have no clinically significant effect on HbA1c determination.

【Analytical Performance】

1. Sensitivity: Limit of detection ＜3%
2. Measurement Range: 3%～18%
3. Accuracy: Test a known concentration calibrator, the measured concentration and the concentration of the calibrator relative deviation (Bias%)should be in the range of ± 6%.
4. Intra-assay imprecision: CV≤3%
5. Inter-assay iprecision: CV≤3%

【Precautions】

1. Only for in vitro diagnostics.
2. Please strictly follow the instructions in use manual.
3. All the used blood raw materials have been inactivated at 60 ℃ during the preparation process, and has been proven negative for HBsAg, anti-HCV, anti-HIV, anti-TP tests. But there is no test method to be absolutely safe. All the samples that are taken from human blood, samples and kits, should be regard as potentially infectious

source.

4. Wear personal protective equipment when operate the sample and reagents.
5. The reagents use NaN_3 in very low concentrations as the preservatives. In case of skin and eye contact, immediately cleanse the affected skin areas with soap under running water. Remove contaminated clothing and shoes.

【Reference】

[1] Hoelzel W,Weykamp C,Jeppsson JO, et al.IFCC reference system for measurement of hemoglobin A1c in human blood and the national standardization schemes in the United States,Japan,and Sweden:a method-comparison study. Clin Chem, 2004, 50(1): 166-174.

[2] Tu Guohua, Jiang Xunjin *etc*. The build and evaluation of HPLC in HbA1c test. J Jiangsu Univ (MEDICINE), 2011, 21(2): 147-150.

【Version and Revision】

Version: A1

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