LabonaCheck™ A1c HbA1c Test Kit

Read this entire insert thoroughly before using the LabonaCheck™ A1c HbA1c Test Kit. Only use the LabonaCheck™ A1c HbA1c Test Kit with the LabonaCheck™ A1c HbA1c Analyzer. Keep this insert for future reference. If you have any inquiry or question, please contact your local distributor.

Product description

● Intended use

The LabonaCheck™ A1c HbA1c Test kit is intended for the quantitative determination of glycated hemoglobin in human blood.

● Test principle

The LabonaCheck™ A1c is a boronate affinity assay. The LabonaCheck™ A1c HbA1c Test kit consists of the cartridges, the R1/Reagent and the R2/Reagent. The R1/Reagent contains the agents that lyse erythrocytes and precipitate hemoglobin specifically, as well as a blue boronic acid conjugate that binds cis-diol of glycated hemoglobin. When blood is added to the R1/Reagent, the erythrocytes are lysed and all hemoglobin precipitates, as well as the boronic acid conjugate binds to the cis-diol configuration of glycated hemoglobin. An aliquot of the reaction mixture is added to the cartridge and all the precipitated hemoglobin, conjugate-bound and unbound, remains on top of the filter. Any unbound boronate is removed with the R2/Reagent. The precipitate is evaluated by measuring the blue (glycated hemoglobin) and the red (total hemoglobin) color intensity respectively with the LabonaCheck™ A1c HbA1c Analyzer, the ratio between them being proportional to the percentage of glycated hemoglobin in the sample.

● Test Kit contents

- Cartridge(with the membrane filter) ·····1 x 24 units
- R1/Reagent ·····1 x 24 x 0.2ml
- R2/Reagent ·····1 x 2.0ml
- Insert Paper

● Reagent composition

R1/Reagent
- Boronate derivative ····· 0.030±0.015mg
- Organic solvent ····· 6.2 %
- Lysing agent ····· 0.15 %

R2/Reagent
- Detergent ····· 0.5%

Cartridge
- Filter(Glass Fiber)
- Membrane(Nylon)
- Absorption pad(Glass Fiber)

● Material needed (not supplied with the kit)
- Capillary tubes
- Capillary tube holder
- Volume fixed pipette and pipette tips
- LabonaCheck™ A1c HbA1c Analyzer

● Warnings and precautions
- For in vitro diagnostic use only.
- Do not transfer components from or to any different kit lots.
- Do not use the kit after the expiration date.
- The R1/Reagent and R2/Reagent contain a toxic agent(0.05%). Avoid direct contacts to the skin.
- Do not drink the R1/Reagent and R2/Reagent.
- The R1/Reagent and cartridge are single use only.
- Dispose of used reagents and cartridges according to the local guidelines.
- Exercise the normal precautions required for handling all laboratory reagents.
- Blood specimens, used reagents, pipette tips and tubes should be considered potentially infectious.
- This LabonaCheck™ A1c HbA1c Test Kit shall be used with the Labona Check™ A1c HbA1c Analyzer only. Do not use it with other brands' analyzers.
- Change the pipette tip between each pipetting step.
- The test will be applied on a routine basis and not in emergency situation.

Test characteristics

● Measuring range
- Measuring range: 4.0 ~ 15.0% or 20 ~ 140mmol/mol
- Measuring interval: 0.1% or 1mmol/mol

● Reference range [1)]

	NGSP	IFCC
Prediabetes	5.7~6.4%	39~46mmol/mol
Presence of diabetes	≥6.5%	≥48mmol/mol
Target in diabetes	<7.0%	<53mmol/mol

● Accuracy

The Accuracy of the LabonaCheck™ A1c HbA1c system was evaluated at clinical sites from 100 patients with replicate.
In the Labonacheck™ A1c HbA1c system accuracy test, 100 of the 100 samples with HbA1c concentrations 4~15% were within ±20% of the reference values. Therefore, 100 of 100 samples (100%) were within the minimum acceptable performance criteria. The Accuracy test result satisfies the acceptance criteria to prove that LabonaCheck™ A1c HbA1c Monitoring System is qualified in terms of system accuracy.

● Precision

The precision of the LabonaCheck™ A1c HbA1c system was estimated with venous blood samples and control solution in the laboratory. Readings obtained with the LabonaCheck™ A1c HbA1c system were compared to those obtained using Tosoh HLC-723 GHb G7(Tosoh Bioscience).

Within Run Precision(venous blood)

HbA1c concentration(%)	5.3	8.7	11.1
Mean	5.4	8.7	11.2
STD	0.14	0.25	0.25
CV(%)	2.5	2.3	2.2

Day to Day Precision(control solution)

HbA1c concentration(%)	5.6	8.6	11.5
Mean	5.7	8.7	11.4
STD	0.16	0.24	0.31
CV(%)	2.9	2.8	2.7

● Limitations of the test
- Operation temperature and humidity
  Temperature Range: 15~35°C (59~95°F) the recommened is 20~25°C (68~77°F)
  Humidity Range: 15~75% RH
- The reagent must be stored in the designated temperature range (2~8°C). If the reagents are stored in the temperature out of the designated temperature range(2~8°C), the test result can be inaccurate.
- Do not keep the reagents for more than 3 hours in room temperature.
- Use only fresh capillary whole blood or venous blood. Do not use serum or plasma.
- Interference substances
  1) The venous blood collected with an anticoagulant (e.g.: K3 EDTA, Heparin, NaF) using aseptic technique is available for testing.
  2) The Hb-concentration lower than 10g/dL or higher than 20g/dL can cause inaccurate test results.

3) The test results are not affected by albumin, ascorbic acid, bilirubin, glucose, lipid.

Stability and storage

● Unopened kits

The unopened LabonaCheck™ A1c HbA1c Test Kit shall be stable until the expiration date if it is stored in the designated condition (2~8°C and 15~75 % relative humidity).

Storing out of the designated condition might affect the expiry date and quality. The expiry date of the unopened is one year from the manufacturing date.

● Opened kits

- The R1/Reagent has to be stored in its original pouch and the low temperature(2~8°C). Before using the R1/Reagent, grab it for more than 30 seconds in order to equilibrate to room temperature. Avoid direct sunlight and do not leave it at room temperature for more than 3 hours.
- The cartridge has to be stored in the temperature range (2~25°C). Keep it in its original pouch and maintain the humidity between 15 and 75%. Before using the cartridge, it shall be equilibrated to room temperature.
- The R2/Reagent has to be stored in the temperature range (2~25°C). Before using the R2/Reagent, it shall be equilibrated to the room temperature. The expiry date is one year from the manufacturing date at room temperature.

● Sample material

Anticoagulant added Blood samples can be stored up to 7 days at 2~8°C. Avoid measuring hemolysed samples. Do not freeze.

Test procedure

● Important procedural notes

- Do not interchange components from different kit lots.
- It shall be equilibrated to room temperature before using the R1/Reagent, R2/Reagent and cartridge.
- Do not touch the membrane with the pipette tip
- Change the pipette tip between each pipetting step.

● Sample material

- Capillary blood and venous blood with or without anticoagulants (EDTA, heparin and NaF) can be used.

● Test procedure

1. Add 5㎕ whole blood to the test tube pre-filled with the R1/Reagent. Mix well. Leave the tube for minimum 2 minutes, maximum 3 minutes. Do not leave it more than 3 minutes.

NOTE

Make sure that the R1/Reagent shall be equilibrated to room temperature before using.

2. Once the reaction mixture completed, shake the test tube once again for the components to be blended well. Open the tube and collect 25㎕. Apply that 25㎕ to the cartridge. Leave it for 10 seconds so as the applied sample to soak enough into the membrane.

NOTE

Do not touch the membrane with the pipette tip.

NOTE

Avoid bubbling during applying the mixture on the membrane filter of the cartridge.

3. When the sample is absorbed completely, apply 25㎕ of the R2/Reagent to the cartridge. Allow the sample to soak into the membrane for about 10 seconds.

NOTE

Avoid bubbling during applying the R2/Reagent on the membrane filter of the cartridge.

4. Once the sample is absorbed completely, place the cartridge on the tray and then select “Analyze” on the display. The tra shall be inserted into the LabonaCheck™ A1c HbA1c Analyzer.

NOTE

Review the User Manual of the LabonaCheck™ A1c HbA1c Analyzer for operation.

References

1. American Diabetes Association Clinical Practice Recommendation, January 2010; 33 (supplement 1)

Symbol information

IVD	In vitro disgnostic medical device
LOT	Batch code
REF	Reference No.
	Temperature limitation
	Use by
	Caution, consult accompanying documents
	Consult instructions For use
	Manufacturer
	Data of manufacture
	Do not reuse
EC REP	Authorized representative in the European Community
#	Model Number
CC	Country of manufacture
UDI	Unique Device Identifier
CE	This product fulfils the requirements for directive on In Vitro Diagnostic Medical Device.
Σ	Contains sufficient for <n> tests.

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