

Finccare™ HbA1c Control

Control lot Kit lot

F87317701B F20719204AD

The Finccare™ HbA1c Controls are supplied at 2 levels: Level 1 and Level 2.

INTENDED USE

The Finccare™ HbA1c control is intended for monitoring the precision of HbA1c in laboratory testing procedures for Finccare™ HbA1c Rapid Quantitative Test.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY AND PRINCIPLE

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. The test is based on the fluorescence immunoassay technology using a sandwich immuno-detection method. **PRECAUTIONS**

1. This product is for *in vitro* diagnostic use only.
2. Do not swallow.
3. The target values and ranges are specific for this lot of control, do not mix.
4. Do not use the control beyond the expiration date.
5. Tests should be applied by professionally trained staff working in certified laboratories.
6. Do not use the control if the vial is damaged or not well sealed.
7. The operation should be conducted strictly according to the instruction.
8. The control is supplied lyophilized. Carefully dissolve each vial exactly with 0.5ml of distilled water. The control should be returned to room temperature before dissolved.
9. If an expected value is not obtained, please check whether the test device is expired or the operation is improper. If not, please use another new control to retest.
10. If there is agglutination or floccule after dissolved, the product may be over-treated or frozen. Discard it and use another new control.
11. Control, used test devices, pipette tips, and buffer vials are biomedical waste. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
12. If you have any questions or need help, please contact the local distributor to solve problems timely.

MATERIAL

Material Provided

1. Control (lyophilized): 0.5ml x2. The controls mainly contain HbA1c concentrate.
2. Leaflet with instructions for use.

TEST PROCEDURE

1. Finccare™ FIA instruments (Model No. FS-112, FS-113, FS-114, FS-205)
2. Finccare™ HbA1c Rapid Quantitative Test
3. Transfer pipette set
4. Distilled water
5. Timer

STORAGE AND STABILITY

1. Store at 2°C - 8°C and keep away from sunlight.
2. Dissolved controls are stable for 8 hours at 2°C - 30°C.

TEST PROCEDURE

1. Take out the control from refrigerator and balance it at room temperature for 15 minutes before dissolved.
2. Open the vial very carefully, avoiding any loss of materials.
3. Dissolve each vial exactly with 0.5ml of distilled water.
4. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam.
5. The dissolved control should be treated the same as patient specimens, and conduct the test procedures including preparation and test, in accordance with the instructions accompanying the instrument or kit being used. **Note:** When test the control on the Finccare™ FIA instruments, please select "QC" item on the Sample Type field.

VALUE ASSIGNMENT

The target value and range are derived from replicate analyses and are specific for this lot of product. ¹Value:

Lot No.	Level	Target value (%)	Range (%)
F87317701B	1	6.42	5.13-7.70
F87317701B	2	10.05	8.04-12.06

The test values must be within the target ranges. Those outside the range may indicate unsatisfactory performance. The causes for such discrepancy may be variation in techniques, instruments, reagents etc., which should be evaluated by the laboratory. It is recommended that each laboratory establishes its own target ranges.

LIMITATIONS OF PROCEDURE

1. This product is applicable for Finccare™ HbA1c Rapid

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2. Quantitative Test only.
3. The target ranges given are intended only as guidelines and laboratories should determine the target ranges based on in-vitro test system.

PERFORMANCE CHARACTERISTICS

Intra-Vial Precision

Precision

Intra-vial precision has been determined by using 10 replicates of one vial control for each of three lots on the Finccare™ HbA1c Rapid Quantitative Test. CV is $\leq 10\%$.

Inter-Vial Precision

Inter-vial precision has been determined by using 10 different vials of controls for each of three lots on the Finccare™ HbA1c Rapid Quantitative Test. CV is $\leq 10\%$.

BIBLIOGRAPHY OF SUGGESTED READING

1. Little R. R., Rohlfing C., Sacks D. B. The National Glycohemoglobin Standardization Program: Over 20 Years of Improving Hemoglobin A1c Measurement. *J Clin Chem*, 2013; 65(7): 839-848.
2. Schnell O., Crocker J. B., Wang J. Impact of HbA1c Testing at Point of Care on Diabetes Management. *J Diabetes Sci Technol*, 2017; 11(3): 611-617.
3. Marthel D. M., Weesener N., Twarkowski D., et al. Retrospective Accuracy Study of Point-of-Care Hemoglobin A1c in Field Conditions. *J Clin Chem*, 2017; 65(3): 780-783.
4. Pakrider S., Samra R., Sivaganesan L., et al. Long-Term Performance of Point-of-Care Hemoglobin A1c Assays. *J Diabetes Sci Technol*, 2016; 10(6): 1308-1315.
5. Nagae M. F., Nassar C. Hemoglobin A1c testing in an emergency department. *J Diabetes Sci Technol*, 2011; 5(6): 1437-1443.
6. O'Brien M., Sacks D. B. Point-of-Care Hemoglobin A1c. *JAMA*, 2019.
7. Gestel E. The start of something good: the discovery of HbA1c and the American Diabetes Association's (ADA) Rainbow Outstanding Discovery Award. *J Diabetes Care*, 2012; 35(12): 2429-2431.

Keep dry

LOT Batch number

REF Catalog number

8. Korns, H.P. Item 5, Housley Diet, all internal quality control best practice[1] Clin Pathol. 2013;66(12):1.

 Consult instructions for

 Control

 Manufacturing date

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IFU-WB7301-01
Version 02
2002/01/17

INTERPRETATION OF RESULTS

Use

 Manufacturer

IVD In vitro diagnostic use

 Expiry date

INDEX OF SYMBOLS

 Authorized representative

 Store between 2-8°C

 Keep away from sunlight

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