Eclipse A1c™

Hemoglobin A1c Reagent Kit

Intended Use

The Eclipse A1c™ Hemoglobin A1c Reagent Kit is designed to work with the Eclipse A1c™ Analyzer for the quantitative measurement of the percent of glycohemoglobin (%HbA1c) in capillary (fingerstick) or venous whole blood. It is intended for in vitro diagnostic and professional use at clinical settings to monitor glycemic control in people with diabetes.

Before You Begin

- Carefully read this entire insert.
- If you have any question and/or need assistance, please contact our authorized dealer in your country.

Summary

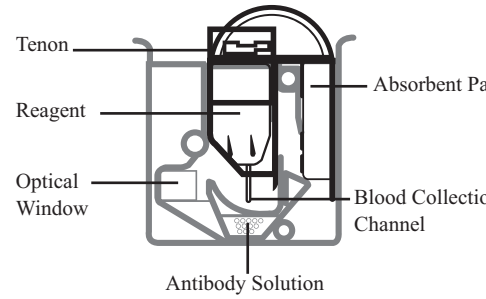
The DCCT study, a prospective RCT of intensive versus standard glycemic control in patients with relatively recently diagnosed type 1 diabetes, showed definitively that improved glycemic control is associated with significantly decreased rates of microvascular (retinopathy and nephropathy) and neuropathic complications.(1)
The Diabetes Association (ADA) recommends HbA1c testing should be performed routinely in all patients with diabetes.

- Perform the HbA1c test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).
- Perform the HbA1c test quarterly in patients whose therapy has changed or who are not meeting glycemic goals.(2)

HbA1c is a widely used marker of chronic glycemia, reflecting average blood glucose levels over a 2- to 3-month period of time.(3)
Studies have shown that the clinical values obtained through regular measurement of HbA1c leads to changes in diabetes treatment and improvement of metabolic control as indicated by a lowering of HbA1c values.

Principles of procedure

The Eclipse A1c™ Analyzer is based on a latex agglutination immunoassay for the determination of the percentage of HbA1c (%HbA1c) in human whole blood. HbA1c in test samples is absorbed onto the surface of latex particles, which react with anti-HbA1c (antigen-antibody reaction). The turbidity cause by latex agglutination is measured at 630 nm, and HbA1c concentration whole blood is calculated from reaction cartridges.
The Eclipse A1c™ Hemoglobin A1c Reagent Kit is composed of a reaction cartridge containing the anti-HbA1c antibody reactions necessary for the determination of hemoglobin A1c, and a reagent container for blood sample collection and latex reaction. The concentration of hemoglobin A1c specifically are measured, and the ratio reported as percent hemoglobin A1c. All of the reactions for performing reaction are contained in the reaction cartridge (Figure 1).



The detection method is based on immune-turbidity analysis, firstly, the HbA1c antigen is binding to affinity-latex surface, further, Antibody-complex (Anti-HbA1c antibody and Anti-mouse IgG antibody constitute) recognizes HbA1c antigen and cause latex agglutination. This agglutination reaction causes increased scattering of light which is measured as an increase in absorbance at 630 nm. The HbA1c concentration is then quantified using a calibration curve of absorbance versus HbA1c concentration.

% HbA1c = [HbA1c-latex turbidity - HbA1c-latex react Antibody-complex turbidity]/ HbA1c-latex turbidity *100%

All measurements and calculations are performed automatically by Eclipse A1c™ Analyzer, and the screen displays percent HbA1c at the end of the assay.

Reagent Kit Composition

Ingredients	Concentration
Antibody (for HbA1c)	60 µl
Latex	60%
Lysis reagent	22.3% w/v
Antibody stabilizer	0.1% w/v

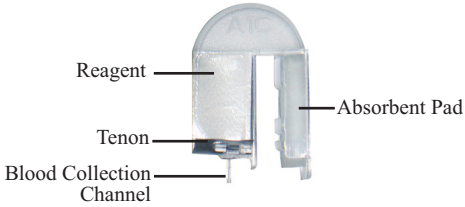
Use Life

Reagent Kit can be kept for up to one month at room temperature (20~30°C or 68~86°F) anytime before the expiration date.

Please check the expiration date on the aluminum foil pouch for refrigerated storage. Record the expiration date and unsealed time on the reaction cartridge and reagent container.
Recommended procedures for handling reaction cartridges:

- Tear the foil pouch on the side with the serrated edge.

- Discard the whole reagent kit including reaction cartridge and reagent container if the cartridge is damaged, the desiccant is missing, the indicators inside the desiccant turns green, or if loose desiccant particles are found inside the foil pouch.
- Discard the whole reagent kit including reaction cartridge and reagent container if any of the following are missing from the reagent container: Blood Collection Channel, Absorbent Pad, Reagent.



⚠ Warnings and Precautions

- For professional use only.
- For *in vitro* diagnostic use only IVD.
- Do not use damp, bended, expired ⌛ or used reagent kit ⊘.
- Do not use scissors to open the foil pouch. Scissors can damage reaction cartridge or cartridge.
- Always wear gloves when taking blood samples and performing the test.
- Do not touch the optical window of the cartridge.
- Dispose all waste in accordance with applicable national and/or local regulations.

Stability and Storage

- Store reaction cartridge refrigerated at 2~8°C (36~46°F). Do not freeze.
- Upon removal from refrigerated storage, allow the reagent kit to warm up at room temperature for 15 minutes.
- Avoid exposure to direct sunlight.
- The reagent kit should be used within 1 hour after opening.

Temperature Indicator

Upon receipt of this kit, check the temperature indicator on the carton. If the indicator has turned black, do not use the reagent cartridges.

Sample Collection and Preparation

The Eclipse A1c™ Hemoglobin A1c Reagent Kit is designed specifically for use with fresh capillary whole blood taken from a fingertip and venous blood drawn from the arm. Neonatal, plasma, or serum samples are not validated and should not be used with the Eclipse A1c™ Hemoglobin A1c Reagent Kit. Use the reagent container to collect 0.5µL capillary whole blood from fingertip or venous blood from the arm. Testing must be performed immediately after the sample is obtained. Samples may be collected with EDTA tubes. DO NOT use tubes with heparin preservative. Samples collected by the EDTA tubes may be preserved for one weeks when stored at 4°C (39.2°F). DO NOT freeze the collected samples.

Specimen Materials and Storage

The following specimens can be used with the Eclipse A1c™ HbA1c test:

- Capillary whole blood (from finger prick).
- Venous whole blood with anticoagulants (EDTA).

Specimen storage

- Capillary whole blood samples cannot be stored.
- Venous whole blood with anticoagulants (EDTA) may be stored at 4°C (39.2°F) for 7 days. Do not freeze.

Test Procedure

Consult the User's Manual of the Eclipse A1c™ Analyzer for detailed instructions on how to collect and analyzer a patient sample or control.

Test procedure overview

- Switch on the Eclipse A1c™ Analyzer.
- Allow the reagent kit to reach room temperature for 15 minutes. Open the foil pouch just before use.
- Collect a specimen following the procedure described below. Once the blood collection channel is filled, analysis of the reaction cartridge must start immediately.
- Insert the reaction cartridge in the analyzer. The

analysis Time is 5~6 minutes.
- Record the test results in the proper place according to the laboratory guidelines. The results will be stored in the analyzer electronic result records.
- Remove the reaction cartridge from the Analyzer.

⚠ Important

Do not use reagent kit that has been accidentally dropped on the floor or lab bench after specimen collection.

Expected Values

According to publication of the American Diabetes Association (ADA), a reasonable A1C goal for many non-pregnant adults is < 7%. [2]

The relationships between NGSP HbA1c (%) and IFCC HbA1c (mmol/mol) as well as with eAG (mg/dL or mmol/L) are shown as below.[4]

IFCC HbA1c (mmol/mol)	NGSP HbA1c (%)	eAG (mg/dL)	(mmol/L)
20	4	68	3.8
31	5	97	5.4
42	6	126	7.0
53	7	154	8.5
64	8	183	10.2
75	9	212	11.8
86	10	240	13.3
97	11	269	14.9
108	12	298	16.5
119	13	326	18.1
130	14	355	19.7

Convert between NGSP, IFCC and eAG

Convert between NGSP (%), IFCC (mmol/mol) and eAG (mg/dL) using the following equations:

IFCC HbA1c (mmol/mol) = (10.93 × NGSP HbA1c%) - 23.52

eAG (mg/dL) = (28.7 × NGSP HbA1c%) - 46.7[5]

Quality Control

Please contact your local distributor for purchasing information. Follow the manufacturer's instruction for how the control solution should be used.

Problem Solving

- Make sure the reaction cartridge is within the expiration date.
- Check the analyzer by performing the Control Solutions Test.
- Refer to 8. Troubleshooting in the User's Manual of Eclipse A1c™ Analyzer for additional information.

Limitations

- Eclipse A1c™ Hemoglobin A1c Reagent Kit is designed for use with fresh capillary whole blood from fingertips or venous blood taken from the arm. DO NOT use plasma or serum samples.
- For testing samples with total hemoglobin out of the range 7~23 g/dL, the analyzer will give inaccurate results.
- Heparin will interfere with the reading of reagent kit.

Performance Evaluation Data

Accuracy

Test whole blood on the Eclipse A1c™ Analyzer with one reaction cartridge lot. Both the fingertip capillary and forearm venous blood was tested. Compare test results to a standard laboratory method. Constitute linear regression results as the following:

Clinical Site Studies with Capillary Blood Sample	
Number of Samples:	90
Range:	4.6 % ~ 12.1 %
Slope:	1.0033
Intercept:	-0.1062
Correlation Coefficient:	0.983

Clinical Site Studies with Venous-EDTA Blood	
Number of Samples :	90
Range:	4.7% ~ 12.3 %
Slope:	1.0046
Intercept:	-0.0749
Correlation Coefficient:	0.985

Precision

One lot of reagent kit was used for within-run repeatability study. Venous blood in EDTA tubes was spiked to 3 concentrations. Readings of HbA1c were recorded for 60 data points for each concentration; as shown in the following table:

Repeatability Study			
Range	Level 1 (5.2%)	Level 2 (8.4%)	Level 3 (11.8%)
Mean	5.2	8.3	11.8
S.D.	0.150	0.217	0.263
C.V.	2.90	2.60	2.23

Patent

US8617490 ; TMI414771

References

1. *The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. N Engl J Med. 1993 Sep 30;329(14):977-86.*
2. *Standards of medical care in diabetes--2012. Diabetes Care. 2012 Jan;35 Suppl 1:S11-63.*
3. *Diagnosis and classification of diabetes mellitus. Diabetes Care. 2012 Jan;35 Suppl 1:S64-71.*
4. *International Federation of Clinical Chemistry (IFCC) Standardization of HbA1c. http://www.ngsp.org/ifccngsp.asp*
5. *Translating the A1C assay into estimated average glucose values. Diabetes Care. 2008 Aug;31(8):1473-8. Epub 2008 Jun 7.*

Symbols

- Use-by date
- IVD *In vitro* diagnostic medical device
- LOT Batch code
- Consult instructions for use
- Temperature limit
- REF Catalogue number
- Do not reuse
- Manufacturer
- Keep away from sunlight
- Caution
- EC REP Authorized Representative in the European Community

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