Abbott

AFINION™ HbA1c

Hemoglobin A1c test
For use with AFINION™ 2 and Alere Afinion™ AS100 Analyzer

Please consult the Afinion™ Analyzer User Manual for operation of the analyzer and general handling of the test cartridge.

Technical Support
The manufacturer provides a toll free line for technical support.
Call 1-866-216-9505 (available for use only in the United States of America)

REF 1116974

℞ Only IVD CE

1117104 Rev. A 2020/10

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For use with Afinion™ 2 and Alere Afinion™ AS100 Analyzer

CLIA statement

Afinion™ HbA1c is waived under the Clinical Laboratory Improvement Amendment of 1988 (CLIA`88). A CLIA Certificate of Waiver is needed to perform testing in a waived setting.

If the laboratory does not have a Certificate of Waiver, the Application for Certification (Form CMS-116) can be obtained from the U.S Department of Health & Human Services, Centers for Medicare & Medicaid Services. The form should be sent to the local State Agency of the State in which the laboratory resides.

If the laboratory modifies the Afinion HbA1c Test or Afinion Analyzer System instructions, the test no longer meets the requirements for waived categorization. A modified test is considered *high complexity* and is subject to all applicable CLIA requirements.

PRODUCT DESCRIPTION

Intended use

Afinion HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human capillary and venous whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus[1].

Summary and explanation of the test

The human erythrocyte is freely permeable to glucose. Within each erythrocyte a slow, continuous, non-enzymatic process between hemoglobin A and various sugars takes place. The product formed is known as glycated hemoglobin, or glycohemoglobin[2].

The chronic elevated blood sugar level of persons with diabetes mellitus will over time cause damage to the small vessels of the body. This damage develops slowly over years and is known to cause late complications[3].

Good metabolic control, i.e. lowering the % HbA1c, has proven to delay the onset and slowing the progression of diabetes late complications[3,4,5].

Principle of the assay

Afinion HbA1c is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human whole blood.

The Afinion HbA1c Test Cartridge contains all the reagents necessary for the determination of % HbA1c. The sample material is collected with the integrated sampling device before the test cartridge is placed in the cartridge chamber of the Afinion Analyzer. The blood sample is then automatically diluted and mixed with a solution that releases hemoglobin from the erythrocytes. The hemoglobin precipitates. This sample mixture is transferred to a blue boronic acid conjugate, which binds to the cis-diols of glycated hemoglobin. This reaction mixture is soaked through a filter membrane and all precipitated hemoglobin, conjugate-bound and unbound (i.e. glycated and non-glycated

hemoglobin) remains on the membrane. Any excess of conjugate is removed with a washing reagent.

The analyzer evaluates the precipitate on the membrane.
By measuring the reflectance, the blue (glycated hemoglobin) and the red (total hemoglobin) color intensities are evaluated, the ratio between them being proportional to the percentage of HbA1c in the sample. The % HbA1c is displayed on the Afinion Analyzer.

Standardization

Afinion HbA1c is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c[6,7,8]. HbA1c values are reported according to the NGSP recommendations at DCCT (Diabetes Control and Complications Trial) level[7].

Afinion HbA1c is certified by NGSP.

Materials provided (contents per 15 tests unit)

15 Test cartridges packed separately in foil pouches with a desiccant bag
1 Package insert

Materials required, but not provided with the kit

- Alere Afinion AS100 Analyzer (REF 1115175/1115390) or Afinion 2 Analyzer (REF 1116554/1116663/1116970/1116971/1116985/1116986)
- Afinion HbA1c Control (REF 1116975)
- Standard blood collection equipment
- Afinion User Manual (provided with the analyzer)
- Afinion HbA1c Quick Guide (provided with the analyzer)

Electronic copies of Afinion User Manuals and Quick Guides are available at www.globalpointofcare.abbott

Description of the test cartridge

The main components of the test cartridge are the sampling device (1) and the reaction container (3). The test cartridge has a handle (4), a barcode label with lot specific information (5) and an ID area for sample ID (7). See figure and table below.

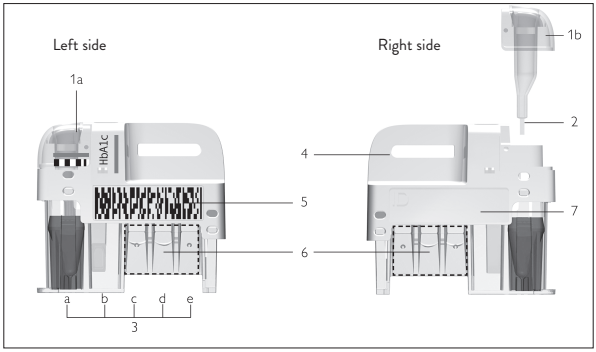


Figure 1 Afinion HbA1c Test Cartridge.

Component	Function/composition
1 Sampling device a. Closed position b. Lifted position	For collection of patient sample or control.
2 Capillary	1.5 µL capillary to be filled with sample material.
3 Reaction container a. Conjugate b. Membrane tube c. Washing solution d. Reconstitution reagent e. Empty	Contains reagents necessary for one test: Blue boronic acid conjugate. Tube with a polyethersulfone membrane. Morpholine buffered sodium chloride solution with detergents and preservative. HEPES buffered sodium chloride with lysis and precipitation agents. N/A
4 Handle	For correct finger grip.
5 Barcode label	Contains assay- and lot-specific information for the analyzer.
6 Optical reading area	Area for transmission measurement.
7 ID area	Space for written or labeled sample identification.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use test cartridges after the expiration date.
- Do not use test cartridges that have not been stored in accordance with recommendations.
- Do not use the test cartridge if the foil pouch is damaged.
- Do not use if the test cartridge itself has been damaged.
- Each foil pouch contains a desiccant bag with 1 g silica gel. This material shall not be used in the assay. Discard the desiccant bag in a suitable container. Do not swallow.
- Do not use the test cartridge if the desiccant bag is damaged and desiccant particles are found on the test cartridge. Do not wipe off.
- Do not touch the test cartridge optical reading area (figure 1).
- Do not reuse any part of the test cartridge.
- The test cartridge contains sodium azide (< 0.1 %) as a preservative. In case of leakage from the test cartridge, avoid contact with eyes and skin.
- The used test cartridges, sampling equipment, patient samples and controls are potentially infectious. Dispose immediately after use. Proper handling and disposal methods should be followed in accordance with local, state and federal regulations. Please also refer to the Safety Data Sheet available at https://www.globalpointofcare.abbott.
- Use personal protective equipment.

STORAGE AND STABILITY

Refrigerated storage 2-8°C (36-46°F)

- The Afinion HbA1c Test Cartridges are stable until the expiration date only when stored refrigerated. The expiration date is stated on each foil pouch and on the kit box.
- The Afinion HbA1c Test Cartridge must reach a temperature of 18-30°C (64-86°F) before use. Upon removal from the refrigerator, leave the test cartridge in the unopened foil pouch for at least 15 minutes. No test result will be obtained if the test cartridge is too cold when used. An information code will be displayed.
- Do not freeze.

Room temperature storage 15-25°C (59-77°F)

- The Afinion HbA1c Test Cartridges can be stored in unopened foil pouches at room temperature for 90 days.
  Note the date placed at room temperature and the new expiration date on the kit box.
- Avoid exposure to direct sunlight.

Opened foil pouch

- The test cartridge should be used within 10 minutes after opening.
- Avoid exposure to direct sunlight.

SAMPLE MATERIALS AND STORAGE

The following sample materials can be used with the Afinion HbA1c test:

- Capillary blood sample (from finger prick).
- Venous whole blood with anticoagulants (ethylene diamine tetra-acetic acid (EDTA), heparin or citrate).

Sample storage

- Capillary blood samples cannot be stored.
- Venous whole blood with anticoagulants (EDTA, heparin or citrate) can be stored
  - refrigerated for 10 days
  - at room temperature (18-30°C, 64-86°F) for 8 hours.
- Do not freeze.
- Consult the Afinion HbA1c Control Package Insert for storage of control materials.

Notes!

- Diluted samples cannot be used with Afinion HbA1c.
- Coagulated or hemolyzed samples cannot be used with Afinion HbA1c. An information code will be displayed and no result obtained if hemolyzed or coagulated samples are analyzed.

TEST PROCEDURE

Consult the Afinion HbA1c Quick Guide for detailed instructions on how to collect and analyze a patient sample or control.

Test procedure overview

- Switch on the Afinion Analyzer.
- Allow the Afinion HbA1c Test Cartridge to reach operating temperature 18-30°C (64-86°F). Open the foil pouch just before use.
- Be sure to properly label the test cartridge with sample ID. The test cartridge has a dedicated ID area.
- Collect a sample following the sample collection procedure described below. Once the capillary is filled, analysis of the test cartridge must start within 1 minute.
- Insert the test cartridge in the analyzer. The analysis time is approximately 3.5 minutes.
- Record the test results according to the laboratory guidelines. The results will be stored in the analyzer electronic result records.
- Remove the test cartridge from the analyzer.

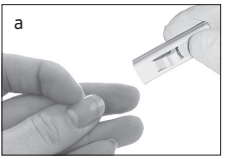
Important!

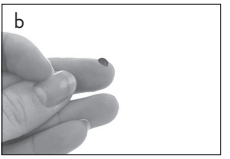
- Do not use test cartridges that have been accidentally dropped on the floor or lab bench after sample collection.
- Do not use cold test cartridges.
- Use the test cartridge within 10 minutes after opening the foil pouch.
- Analysis of the test cartridge must start within 1 minute after the capillary is filled with sample material.

Sample collection

Blood sampling from finger

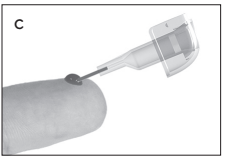
- Always use gloves.
- Clean the finger using alcohol. Allow the area to air dry.
- Use a lancet and firmly prick the finger (a). Properly dispose the lancet.
- Allow a good drop of blood to form before sampling (b).
- Apply direct pressure to the wound site with a clean gauze pad.





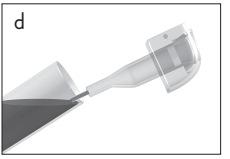
Sampling from a tube

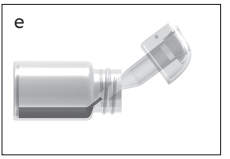
- Patient samples can be used directly from the refrigerator.
- Mix the sample material well. Invert the tube 8-10 times before collecting a sample.



Sampling from the AFINION™ HbA1c Control vial

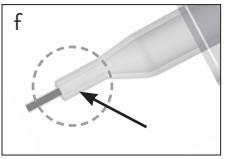
- Allow the control material to reach ambient operating temperature (18-30°C, 64-86°F) before use. This takes approximately 45 minutes.
- Mix the control material thoroughly by shaking the vial for 30 seconds. A Vortex mixer may be used.
- Extract a sample from the vial or the cap.





Important!

- Bring the tip of the capillary just beneath the surface of the blood drop/ sample material as shown in figures (c), (d) and (e).
- Be sure that the capillary is completely filled as shown in figure (f). It is not possible to overfill the capillary. Avoid air bubbles.
- Do not wipe off the capillary.



TEST RESULT REPORTING

Afinion HbA1c measures the total glycated hemoglobin and the total hemoglobin concentration. The ratio between them is proportional to the % HbA1c of the sample. The analyzer calculates the ratio, and the test result is displayed as % HbA1c.

Reportable range

The Afinion HbA1c measuring range is 4.0-15.0% HbA1c.
The HbA1c results are displayed in 0.1% intervals.
The hemoglobin measuring range is 6.0-20.0 g/dL.

Values outside the HbA1c measuring range

Valid for SW ≤ 7.03 (Afinion AS100) and SW ≤ 21.09 (Afinion 2):
If the patient's HbA1c value is outside the measuring range, no test result will be reported and an information code will be displayed (see "Troubleshooting").

Valid for SW ≥ 7.04 (Afinion AS100) and SW ≥ 21.10 (Afinion 2):

- HbA1c < 4.0 % is displayed if the HbA1c value is below the measuring range.
- HbA1c > 15.0 % is displayed if the HbA1c value is above the measuring range.

Expected values

Recommendations from American Diabetes Association (ADA):
A reasonable goal for many nonpregnant adults with diabetes is HbA1c < 7.0% (53 mmol/mol). More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations[9].

Interpretation of results

Despite a reliable internal process control of the analysis, each individual test result should be interpreted with careful consideration to the patient's medical history, clinical examinations and other laboratory results. If the test result is questionable or if clinical signs and symptoms appear inconsistent with the test result, analyze the Afinion HbA1c Controls and retest the sample using a new Afinion HbA1c Test Cartridge.

Analytical specificity

The following hemoglobin (Hb) variants have been analyzed and found not to affect the Afinion HbA1c test result: HbAC, HbAD, HbAE, HbF, HbAJ and HbAS[6]. Carbamylated hemoglobin does not affect the Afinion HbA1c test result[6]. Pre-glycated hemoglobin does not affect the Afinion HbA1c result.

Limitations of the test

- Any cause of shortened erythrocyte life span will reduce exposure of erythrocytes to glucose, resulting in a decrease in HbA1c values, regardless of the method used. Caution should be used when interpreting the HbA1c results from patients with conditions such as hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, blood loss, polycythemia, iron deficiency etc.

- Diluted samples cannot be used with Afinion HbA1c.
- Coagulated or hemolyzed samples cannot be used with Afinion HbA1c. Samples with >14% (2000 mg/dL) hemolysis may return an information code.
- If the sample has a hemoglobin value below 6.0 g/dL or above 20.0 g/dL, no test result will be reported and an information code will be displayed.

Interference

No significant interference (<5%) was observed up to the following concentrations:

- Bilirubin 342 µmol/L (20 mg/dL)
- Triglycerides 15.7 mmol/L (1389 mg/dL)
- Cholesterol 9.1 mmol/L(351 mg/dL)
- Glucose 27.8 mmol/L (500 mg/dL)
- Fructosamine 680 µmol/L
- Hemolysis 5.0%
- Anticoagulants (EDTA, heparin and citrate) at concentrations normally used in blood collection tubes.

Over-the-counter and prescription drugs:

- Acetaminophen 1.7 mmol/L (256 µg/mL)
- Ibuprofen 1.8 mmol/L (372 µg/mL)
- Acetylsalicylic acid 3.3 mmol/L (599 µg/mL)
- Salicylic acid 4.3 mmol/L (593 µg/mL)
- Glyburide 3.9 µmol/L
- Metformin 310 µmol/L

No significant interference (<5%) was observed at expected serum levels for the above-mentioned drugs.

Important!
It is possible that other substances and/or factors not listed above may interfere with the test and cause false results.

QUALITY CONTROL

Quality control testing should be done to confirm that your Afinion Analyzer System is working properly and providing reliable results. Only when controls are used routinely and the values are within acceptable ranges can accurate results be assured for patient samples.

Each laboratory site can benefit from establishing a quality control plan. The laboratory director should determine whether additional testing is appropriate for their laboratory.

It is recommended to keep a permanent record of all quality control results. The Afinion Analyzer automatically stores the control results in a separate record. Consult the Afinion Analyzer User Manual.

Control material

Afinion HbA1c Control is recommended for routine quality control testing. Consult the Afinion HbA1c Control Package Insert.

Frequency of control testing

Controls should be analyzed:

- with each new shipment of Afinion HbA1c Test Kits.
- with each new lot of Afinion HbA1c Test Kits.
- at least every 30 days.
- when training new operators.
- anytime an unexpected test result is obtained.

Make sure to test controls in compliance with any local, state and/or federal regulations. CLIA waived laboratories should follow the manufacturer's quality control guidelines.

Verifying the control results

The measured value should be within the acceptable limits for the control. Consult the Afinion HbA1c Control Package Insert.

If the measured value is outside the acceptable limits, make sure that:

- patient samples are not analyzed.
- the control vial is not expired.
- the control vial has not been in use for more than 60 days.
- the control vial has been stored according to recommendations.
- Afinion HbA1c Test Cartridges have been stored according to recommendations.
- there is no visual sign of contamination of the control vial.

Correct any procedural error. Retest the control material.

If *no* procedural errors are detected:

- investigate the frequency of control failures.
- examine the laboratory's quality control records.
- ensure that there is no trend in out-of-range quality control results.
- retest the control material using a new control vial.
- patient results must be declared invalid. Contact customer service for advice. Do not analyze patient samples.

TROUBLESHOOTING

To ensure that correct HbA1c results are reported, the Afinion Analyzer performs optical, electronic and mechanical controls. The capillary, the test cartridge and all individual processing steps are checked during the course of each analysis. When problems are detected, the analyzer terminates the test and displays an information code.

The table below contains the assay specific information codes. Consult the Afinion Analyzer User Manual for information codes not listed in this table.

Code #	Cause
103	The hemoglobin concentration is below 6.0 g/dL
104	The hemoglobin is above 20.0 g/dL
105	The HbA1c value is below 4.0%
106	The HbA1c value is above 15.0%

Follow the actions listed in the user manual to correct the error.

Important!
The manufacturer must be notified of any test system that is perceived or validated to be outside of the performance specifications outlined in the instructions.

Technical support
The manufacturer provides a toll free line for technical support.
Call 1-866-216-9505. The toll free number is available for use only in the United States of America.
E-mail: Afinion.Support@abbott.com

PERFORMANCE CHARACTERISTICS

The performance data presented in this section are representative data from internal and external studies. Results obtained in individual laboratories may vary.

Linearity

The linearity of the Afinion HbA1c Assay was verified using two fresh EDTA blood samples. Varying amounts of sample 1 (17.9% HbA1c) and sample 9 (5.3% HbA1c) were mixed in different proportions to obtain a total of 9 samples. Sample 2-8 were analyzed in triplicate, while sample 1 and sample 9 (native samples) were analyzed in six replicates with the Alere Afinion AS100 Analyzer. A linear regression was calculated based on the theoretical vs. measured % HbA1c values. The results are shown in Table 1.

Table 1: Linear regression of Afinion HbA1c: measured (y) vs. theoretical (x) % HbA1c values. N=number of samples, r=correlation coefficient.

N	Regression line	r
9	y=1.01x + 0.07	1.00

The mean recovery of the measured % HbA1c values compared to the theoretical values (Table 2), were calculated for each sample, using the following equation:

$$\text{Mean recovery, (\%)} = \frac{\text{Measured mean value (\% HbA1c)}}{\text{Theoretical value (\% HbA1c)}} \times 100\%$$

Table 2: Linearity of Afinion HbA1c. Theoretical and measured mean value (% HbA1c), Coefficient of Variation (CV) and recovery mean value.

Sample	Theoretical % HbA1c	Measured % HbA1c	CV (%)	Recovery (%)
1*	N/A	17.9	3.8	N/A
2	14.1	14.2	2.0	101
3	12.9	13.3	0.4	103
4	11.6	11.8	2.5	102
5	10.3	10.4	1.5	101
6	9.1	9.2	2.3	101
7	7.8	8.0	1.3	102
8	6.6	6.6	2.6	101
9*	N/A	5.3	2.1	N/A

*Native sample

N/A Not applicable

Method comparison

A method comparison study, comprising a total of 75 samples (4.9-14.1% HbA1c) was performed at three physician office laboratories. A capillary finger prick sample and a venous EDTA sample were collected from each donor. The capillary blood samples were analyzed with the Alere Afinion AS100 Analyzer. The EDTA venous blood samples were analyzed with the Alere Afinion AS100 Analyzer and another Point of Care Testing (POCT) system at the study sites (Table 3, 4). A total of 11 operators participated in the study. Three Alere Afinion AS100 Analyzers were used.

Table 3: Method comparison; Afinion HbA1c (y) vs. another POCT system (x). Linear regression analysis data. N=number of samples, r=correlation coefficient.

No. sites	N	Regression line	r
3	75	y=0.92x + 0.21	0.98

Table 4: Capillary vs. EDTA whole blood with Afinion HbA1c. Linear regression analysis data. N=number of samples, r=correlation coefficient.

No. sites	N	Regression line	r
3	74	y=0.99x + 0.07	1.00

In a second method comparison study 39 blood samples (4.9-11.7% HbA1c) were analyzed with an affinity HPLC (High Pressure Liquid Chromatography) system by the European Reference Laboratory for Glycohemoglobin (ERL). The samples were analyzed by the manufacturer, using the Alere Afinion AS100 Analyzer (Table 5).

Table 5: Method comparison. Afinion HbA1c (y) vs. an affinity HPLC system (x). Linear regression analysis data. N=number of samples, r=correlation coefficient.

No. sites	Regression line	r
39	y=0.96x + 0.33	0.99

Precision

Precision studies were performed by the staff at three separate physician office sites (external study), and by the manufacturer (internal study). The CLSI (Clinical and Laboratory Standards Institute) Guideline EP5-A2 was followed.

Internal study

Within-run, between-day and total precision were determined for Afinion HbA1c Control C I, Control C II and one EDTA sample assayed for 20 days and one EDTA sample assayed for 17 days. The samples were analyzed in duplicate twice a day using the Alere Afinion AS100 Analyzer.

Table 6: Within-run, between-day and total precision. N=number of days, CV=Coefficient of Variation.

Sample	N	Average % HbA1c	Within-run CV (%)	Between-day CV (%)	Total CV (%)
Control C I	20	6.5	0.9	0.6	1.4
Control C II	20	9.1	0.6	0.5	1.1
Sample 1	17*	5.6	0.9	0.2	1.1
Sample 2	20	10.0	0.7	0.0	1.1

* Based on 17 days of analysis due to hemolysis of the sample.

External study
A precision study was performed at three physician office laboratories (site 1-3) with three levels of HbA1c EDTA blood (sample A-C). The study was performed over 10 consecutive days. Afinion HbA1c Lot 1 was used the first five days and Lot 2 the next five days. Each day six replicates of the samples were measured. Eleven operators participated in the study. Three Alere Afinion AS100 Analyzers were used, one at each study site.

Table 7: Results from analysis of three blood samples at three physician offices. Within-day, within-site and total precision. N=number of parallels, CV=Coefficient of Variation.

Sample	Lot	Site	Average % HbA1c (N=6)	Within-day CV (%)	Within-site CV (%)	Total CV (%)
A	1	1	5.0	1.7	1.9	2.5
		2	5.0	2.9	2.9	
		3	4.9	1.5	2.0	
	2	1	5.1	1.1	1.2	2.2
		2	5.0	1.8	2.0	
		3	4.9	1.6	1.8	
B	1	1	6.2	2.4	2.4	2.3
		2	6.1	2.0	2.0	
		3	6.0	1.2	1.4	
	2	1	6.3	1.3	1.8	1.7
		2	6.2	1.2	1.2	
		3	6.2	0.8	0.9	
C	1	1	9.1	1.3	1.4	2.6
		2	8.8	1.4	1.6	
		3	8.7	2.0	1.9	
	2	1	9.1	0.9	1.0	2.0
		2	8.8	1.1	1.0	
		3	8.8	1.1	1.0	

Based on the experience obtained from internal and external documentation of Afinion HbA1c, a precision of <3%, expressed by the coefficient of variation (CV), is expected in a controlled laboratory setting.

Between instruments precision

The between instrument precision of the Afinion HbA1c Assay was evaluated by five operators analyzing two fresh EDTA samples on 10 randomly selected Alere Afinion AS100 Analyzers. Sample 1 and sample 2 were analyzed in six replicates on each analyzer. The mean % HbA1c and coefficient of variation (CV) were calculated for each sample on each analyzer and for all 10 analyzers. The results are shown in Table 8.

Table 8: Alere Afinion AS100 between instrument precision. Mean % HbA1c and coefficient of variation (CV) of six replicates.

Analyzer	Sample 1		Sample 2	
	% HbA1c	CV (%)	% HbA1c	CV (%)
1	5.2	1.6	10.2	1.3
2	5.1	1.2	10.4	2.6
3	5.1	0.8	10.3	2.8
4	5.3	1.0	10.4	1.4
5	5.2	1.0	10.7	3.4
6	5.1	1.0	10.4	1.6
7	5.2	1.7	10.2	1.6
8	5.3	1.2	10.7	1.7
9	5.2	1.7	10.8	1.3
10	5.2	1.0	10.4	0.8
All	**5.2**	**2.0**	**10.4**	**2.7**

Lot-to-lot variation

The consistency between different manufacturing lots of Afinion HbA1c was evaluated by measuring 16 fresh EDTA samples in duplicate using three different lots of Afinion HbA1c. The study was performed using one Alere Afinion AS100 Analyzer.

A Bland-Altman analysis comparing two lots at the time was performed. The bias and the limits of agreement with 95% confidence were calculated. The results are shown in Table 9.

Table 9: Bias and 95% limits of agreement calculated for three lots of Afinion HbA1c using the Bland-Altman analysis.

	Lot 1 - Lot 2	Lot 3 - Lot 2	Lot 3 - Lot 1
Bias	0.0%	1.7%	1.7%
95% Limits of agreement	-2.6 to 2.5%	-1.9 to 5.2%	-2.5 to 5.8%

Precision AFINION™ HbA1c Control

The precision of the Afinion HbA1c Control C I and Control C II were evaluated externally at three study sites. Each study site measured each control in six replicates on five subsequent days using the Alere Afinion AS100 Analyzer. The within day, within-site and between-site precisions were calculated. The results are shown in Table 10.

Table 10: External validation of Afinion HbA1c Control at three study sites. Within day, within-site and between-site precision. CV=Coefficient of variation. N=Number of analysis.

	Site	Mean % HbA1c (N=30)	Within-day CV (%)	Within-site CV (%)	Mean % HbA1c (N=90)	Between-site CV (%)
Control C I	1	6.0	1.4	1.4	6.0	1.3
	2	6.0	1.2	1.3		
	3	6.0	1.0	1.2		
Control C II	1	9.0	1.2	1.1	9.0	1.5
	2	8.9	0.9	1.1		
	3	9.1	1.6	1.6		

Expected CLIA Waiver performance

CLIA-waived studies were performed at three non-laboratory sites. The 68 participants were a demographically diverse population, had no previous laboratory experience and received no training for the study. Three blood samples (sample A-C) were analyzed by each operator using the Alere Afinion AS100 Analyzer. The Allowable Limits of Error (A.L.E., Tonks Limit) were calculated and the observed results compared to these limits. The results are shown in Table 11.

Tonks Limit

$$\text{A.L.E. (\%)} = \pm \frac{\text{1/4 normal range}}{\text{Mean of normal range}} \times 100\% = 10\%$$

where normal range is 4-6% HbA1c.

Table 11: Allowable Limits of Error (A.L.E.). N=Number of measurements. SD=Standard Deviation. CV=Coefficient of Variation.

	Sample A	Sample B	Sample C
N	67*	68	68
Mean (% HbA1c)	6.0	7.6	5.2
SD	0.09	0.13	0.08
CV	1.6%	1.7%	1.6%
Range (% HbA1c)	5.8-6.2	7.3-7.9	5.0-5.4
A.L.E. (% HbA1c)	5.4-6.6	6.8-8.4	4.7-5.7
No. values within A.L.E.	100% (67/67)	100% (68/68)	100% (68/68)

*Test result for sample A was missing from one operator.

For each sample tested, there was no statistically significant difference in the mean % HbA1c values among sites (F-test).

Performance testing with the AFINION™ 2 Analyzer

The performance of Afinion HbA1c and Afinion HbA1c Control obtained with the Afinion 2 Analyzer have been demonstrated to be equivalent to the performance obtained with the Alere Afinion AS100 Analyzer.

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SYMBOLS

The following symbols are used in the packaging material for Afinion HbA1c.

CE	Conformity to the European directive 98/79/EC on *in vitro* diagnostic medical devices
IVD	*In vitro* diagnostic medical device
REF	Catalog number
LOT	Lot number
TEST CARTRIDGE	Test cartridge
Σ 1	Contents are sufficient for one test
Σ 15	Contents sufficient for 15 tests
	Do not reuse
	Consult instructions for use
	Caution, consult instructions for use
	Expiration date (year-month-day)
2°C 36°F 8°C 46°F	Storage temperature (store at 2-8°C, 36-46°F)
	Manufacturer
	Date of manufacture (year-month-day)
Rx Only	Federal law restricts this device to sale by or on the order of a licensed healthcare professional

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