Abbott

AFINION™ ACR

Albumin/Creatinine Ratio 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 1116972

℞ Only IVD CE

1116906 Rev. A 2019/01

AFINION™ ACR

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

PRODUCT DESCRIPTION

Intended use

Afinion™ ACR is an *in vitro* diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine. The measurement of urine albumin, creatinine and albumin/creatinine ratio aids in the early diagnosis of nephropathy[1,2].

Summary and explanation of the test

Albumin is a small protein present in high concentrations in plasma. Normally only small amounts of albumin are excreted in urine. Sustained elevations of urinary albumin concentrations are known as microalbuminuria. Microalbuminuria is defined as an ACR between 30 -300 mg/g in at least two of three urine samples within a three to six month period[1,3].

Creatinine is a degradation product of the muscle tissue protein creatine. All creatinine crosses the glomerular basement membrane and is excreted in the urine. As muscle degradation is a continuous process, creatinine is filtered at a constant rate. Measurements of creatinine in urine will thus correct for varying diuresis and calculating the ACR will give a more accurate result of the albumin excretion rate[2,3].

Microalbuminuria is connected to several late complications of diabetes such as retinopathy and neuropathy, as well as essential hypertension, preeclampsia, cardiovascular diseases, inflammatory conditions and mortality. Today ACR is a predictive marker of great importance in the early detection of kidney disease and identification of patients at risk for complications of diabetes or hypertension[4,5,6].

Recommendations from American Diabetes Association: At least once a year, assess urinary albumin (e.g., spot urinary albumin–to–creatinine ratio) and estimated glomerular filtration rate in patients with type 1 diabetes with duration of ≥ 5 years, in all patients with type 2 diabetes, and in all patients with comorbid hypertension[2].

Principle of the assay

Afinion ACR is a fully automated assay for determination of albumin, creatinine and ACR in human urine.

The Afinion ACR Test Cartridge contains all reagents necessary for determination of albumin, creatinine and ACR in a human urine sample. The sample material is collected using the sampling device integrated in the test cartridge.

Albumin is quantified using a solid phase immunochemical assay. In the Afinion ACR Test Cartridge the sample is automatically diluted and aspirated through a membrane coated with anti-albumin antibodies, which concentrates and immobilizes the albumin from the sample. A gold-antibody conjugate then binds to the immobilized albumin resulting in a red-brown colored membrane. Excess gold-antibody conjugate is removed in a washing step. The Afinion Analyzer measures the color intensity of the membrane, which is proportional to the amount of albumin in the sample.

Creatinine is quantified using an enzymatic colorimetric test that involves four enzymatic steps. The test requires incubation with two distinct enzyme solutions. A colored end product is measured in one of the cartridge wells.

The concentration of albumin, the concentration of creatinine and the calculated albumin/creatinine ratio are displayed on the Afinion Analyzer.

Standardization

Albumin is calibrated against the ERM®-DA470[7] reference preparation. Creatinine is calibrated against SRM 914[8].

Materials provided (contents per 15 test unit)

15 Afinion ACR Test Cartridges packaged 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)
- Afinion User Manual (provided with the analyzer)
- Afinion ACR Quick Guide (provided with the analyzer)
- Afinion ACR Control (REF 1115239/1116973)
- Standard urine collection equipment

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 area for sample ID (7). See figure and table below.

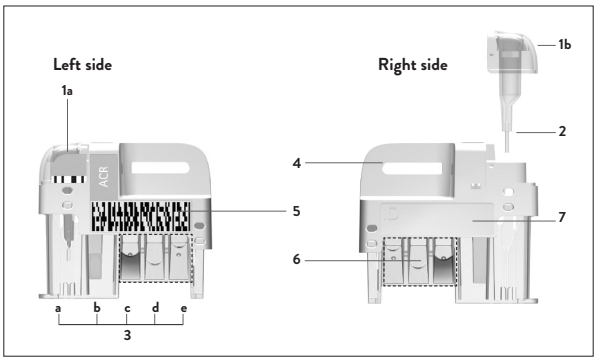


Figure 1 Afinion ACR Test Cartridge.

Component	Function/composition
1 Sampling device a. Closed position b. Lifted position	For collection of patient sample or control.
2 Capillary	3.5 µL glass capillary to be filled with sample material.
3 Reaction container	Contains reagents necessary for one test:
a. Capillary wiper	Plastic laminated paper.
b. Membrane tube	Tube with a nitrocellulose membrane coated with monoclonal anti-albumin antibodies.
c. Conjugate solution	Anti-albumin antibodies conjugated with ultra-small gold particles.
d. Enzyme solution 2	Enzymes buffered in HEPES, detergents and preservative.
e. Enzyme solution 1	Enzymes buffered in HEPES, detergents and preservative.
4 Handle	The correct place to hold the test cartridge.
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 or if the test cartridges have not been stored in accordance with recommendations.
- Do not use the test cartridge if the foil pouch or 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).
- In case of leakage from the test cartridge, avoid contact with eyes and skin. Wash with plenty of water.
- Do not reuse any part of the test cartridge.
- The used test cartridges, sampling equipment, patient samples and controls are potentially infectious and should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with local state and federal regulations. Use personal protective equipment.

STORAGE AND STABILITY

Refrigerated storage 2–8°C (36–46°F)

- The Afinion ACR Test Cartridges are stable until the expiration date only when stored refrigerated in sealed foil pouches. The expiration date is stated on the foil pouch and the outer container.
- The Afinion ACR Test Cartridge must reach an operating temperature of 20–30°C (68–86°F) before use. Upon removal from refrigerated storage, leave the test cartridge in the unopened foil pouch for at least 15 minutes. Information code 210 will be displayed and no result obtained if the test cartridge is too cold when used.
- Do not freeze.

Short term storage at room temperature

- The Afinion ACR Test Cartridges are stable for maximum 8 hours up to 30°C (86°F). It is thus recommended to store the kit in the refrigerator and remove a limited number of test cartridges at a time.

Opened foil pouch

- The test cartridge should be used within 10 minutes after opening the foil pouch.
- Avoid exposure to direct sunlight.
- Avoid relative humidity above 80%.

SPECIMEN MATERIALS AND STORAGE

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

- Human urine (preferably first-morning, midstream).
- Afinion ACR Control.

Specimen storage

- Human urine samples can be stored refrigerated for 5 days. Stored samples should be mixed well by inverting the cup 8–10 times before collecting the sample.
- Do not use urine samples which have been previously frozen.
- Consult the Afinion ACR Control Package Insert for storage of the control material.

TEST PROCEDURE

Consult the Afinion ACR 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 ACR Test Cartridge to reach operating temperature of 20–30°C (68–86 °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 for labeling.

- Collect specimen following the specimen collection procedure described below. Once the capillary is filled, the analysis of the test cartridge must start within 1 minute.
- Insert the test cartridge in the analyzer. The analysis time is 5 minutes and 35 seconds.
- Record the test result in the proper place according to the laboratory guidelines. The result will be stored in the analyzer electronic result records.
- Remove the test cartridge from the analyzer and discard in appropriate container.

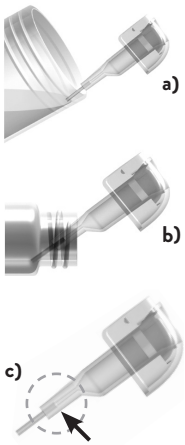
Important!
Do not use test cartridges that have been accidentally dropped on the floor or lab bench after the specimen has been collected.

Specimen collection

Sampling from a urine cup
- Always use gloves.
- Patient samples stored refrigerated can be used without equilibration to room temperature.
- Mix the sample material well by inverting the urine cup 8-10 times before collecting the sample.
- The sample can be extracted from the urine cup or the cap.

Sampling from the AFINION™ ACR Control vial
- The control material can be used without equilibration to room temperature.
- Mix the control material well by inverting the vial 8-10 times before collecting a sample.
- The sample can be extracted from the vial.

Filling the capillary (Important!)
- Remove the sampling device from the test cartridge.
- Fill the capillary; bring the tip of the capillary just beneath the surface of the patient sample (a) or control material (b). Be sure that the capillary is completely filled, see arrow (c). It is not possible to overfill.
- Avoid air bubbles and excess sample on the outside of the capillary.
- Do not wipe off the capillary.
- Immediately replace the sampling device into the test cartridge.
- Once the capillary is filled, the analysis of the test cartridge must start within 1 minute.



TEST RESULT REPORTING

Afinion ACR measures albumin and creatinine in the urine sample, and the analyzer calculates the albumin/creatinine ratio (ACR). Albumin, creatinine and ACR results are displayed.

AFINION™ ACR reportable range

	Albumin (mg/L)	Creatinine (mg/dL)	ACR (mg/g)
Reportable range	5.0-200.0	16.4-339.9	1.0-1225.0
Interval	0.1	0.1	0.1

If the patient's albumin and/or creatinine value is outside the reportable range, one or two of the messages in the list below will be displayed. In this case an ACR test result will not be reported, and the last message listed below (ACR: ---) will be displayed.

Message	Cause/Explanation
Albumin: < 5.0 mg/L	The albumin concentration is below 5.0 mg/L
Albumin: > 200.0 mg/L	The albumin concentration is above 200.0 mg/L
Creatinine: < 16.4 mg/dL	The creatinine concentration is below 16.4 mg/dL
Creatinine: > 339.9 mg/dL	The creatinine concentration is above 339.9 mg/dL
ACR: — — —	The ACR value cannot be calculated as the albumin or creatinine value is outside range.

Expected values

The expected values are according to recommendation given by the American Diabetes Association[1, 2].

Category	24-h collection Albumin	Timed collection Albumin	Spot collection ACR
	mg/24h	µg/min	mg/g
Normal	<30	<20	<30
Microalbuminuria	30-300	20-200	30-300
Clinical albuminuria	>300	>200	>300

The concentration of creatinine in urine is normally within the range of 34–147 mg/dL[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 medical history, clinical examination 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 ACR Controls and retest the sample using a new Afinion ACR Test Cartridge.

Analytical specificity

Monoclonal antibodies specific to human albumin are used in Afinion ACR. No cross-reaction was found when tested on human hemoglobin, IgG, IgA, beta-2 microglobulin, myoglobin and bovine serum albumin.

Limitations of the test

- If the ACR result is > 30 mg/g and the albumin result is > 20 mg/L the urine sample should be tested for blood with a commercially available urine stick. If the urine sticks result is ≥ 25 erythrocytes/µL the ACR and albumin results may be falsely elevated due to the interference of blood in the urine sample.
- Information code # 108 will only occur for urine samples with > 200 erythrocytes/µL (see troubleshooting).
- Ingestion of acetylsalicylic acid in dosages higher than 1200 mg/day may result in too low creatinine result and thus too high ACR result.
- Do not use cold test cartridges.
- Use the test cartridge within 10 minutes after opening the foil pouch.
- Place the test cartridge in the analyzer within one minute after the capillary is filled with the sample material.

Important!
Do not use a test cartridge that has been accidentally dropped on the floor or lab bench after the specimen has been collected.

Interference

No significant interference was observed up to the following concentrations in urine:

• Acetoacetate	0.84 mg/mL	7.8 mmol/L
• Acetone	800 mg/L	13.8 mmol/L
• Ascorbic acid	3000 mg/L	16.7 mmol/L
• Bilirubin	3.5 mg/dL	0.06 mmol/L
• Creatine	0.52 mg/mL	4.0 mmol/L
• Glucose	45 mg/mL	250 mmol/L
• beta-hydroxybutyric acid	5.9 mg/mL	46.8 mmol/L
• IgG	20 mg/L	
• Beta-2 microglobulin	20 mg/L	
• Myoglobin	20 mg/L	
• Urea	30 mg/mL	500 mmol/L

Over-the-counter and prescription drugs:

• Acetaminophen	0.2 mg/mL	1.5 mmol/L
• Acetaminophen-glucuronide	10.5 mg/mL	30.0 mmol/L
• Glyburide	14.8 µg/mL	30 µmol/L
• Ibuprofen	2.0 mg/mL	10 mmol/L
• Metformin	4.0 mg/mL	24 mmol/L

No “Hook effect” was observed at albumin concentrations up to 5000 mg/L.

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 offers the possibility to store control results electronically in a separate record. Consult the Afinion User Manual.

Control material

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

Frequency of control testing

Controls should be analyzed:

- with each new shipment of Afinion ACR Test Kits.
- with each new lot of Afinion ACR Test Kits.
- at least every 30 days.
- when training new operators in correct use of Afinion ACR and the Afinion Analyzer.
- anytime an unexpected test result is obtained.

If local state and/or federal regulations require more frequent testing of control material, then quality control should be performed in compliance with these regulations.

Verifying the control results

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

If the result obtained for the Afinion ACR Control is outside the acceptable limits, make sure that:

- patient samples are not analyzed until control results are within acceptable limits.
- the control vial has not passed its expiration date.
- the control vial has not been used for more than 8 weeks.
- the control vial and Afinion ACR Test Cartridges have been stored according to recommendations.
- there is no evidence of bacterial or fungal contamination of the control vial.

Correct any procedural error and retest the control material.

If *no* procedural errors are detected:

- retest the control material using a new control vial.
- examine the laboratory's quality control record to investigate the frequency of control failures.
- ensure that there is no trend in out-of-range quality control results.
- patient results must be declared invalid when controls do not perform as expected. Contact your customer service representative for advice *before* analyzing patient samples.

TROUBLESHOOTING

To ensure that correct albumin, creatinine and ACR results are reported, the Afinion Analyzer performs optical, electronic and mechanical controls of the capillary, the test cartridge and all individual processing steps during the course of each analysis. When problems are detected by the built-in failsafe mechanisms, 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
107	Creatine too high
108	Blood in the urine detected by the analyzer*

* Information code # 108 will only occur for urine samples with > 200 erythrocytes/µL. If the ACR result is > 30 mg/g and the albumin result is > 20 mg/L the urine sample should be tested for blood with a commercially available urine stick. If the urine stick result is ≥ 25 erythrocytes/µL the ACR and albumin results may be falsely elevated due to the interference of blood in the urine sample.

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

Important!
The manufacturer must be notified of any 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@alere.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 ACR Assay in the reportable range was verified using three native urine samples; one with high albumin (202.8 mg/L), one with high creatinine (350.4 mg/dL) and one with low albumin (3.5 mg/L) and creatinine (9.9 mg/dL). Two dilution series, one for albumin and one for creatinine, were made by intermixing the three samples. The samples were analyzed in 4-6 replicates. A linear regression was calculated based on the theoretical vs. measured albumin and creatinine values. The results are shown in Table 1.

Table 1: Linear regression of Afinion ACR (albumin and creatinine): Measured mean (y) vs. theoretical (x). N=number of samples, r=correlation coefficient.

Analyte	N	Regression line	r^2
Albumin	10	y = 0.98x + 4.2	1.00
Creatinine	10	y = 1.01x - 0.3	1.00

The mean recovery of the measured values compared to the theoretical values (Table 2 and 3), were calculated for each sample, using the following equation:

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

Table 2: Linearity of Afinion ACR. Measured mean and theoretical albumin values.

Sample	Theoretical albumin (mg/L)	Measured mean albumin (mg/L)	CV (%)	Recovery (%)
1	201.8	201.8	5.3	N/A
2	162.2	159.0	3.9	98
3	142.5	148.4	3.0	104
4	122.7	124.3	4.0	101
5	102.9	106.8	4.7	104
6	83.1	89.7	4.6	108
7	63.3	67.3	4.6	106
8	43.6	48.3	2.7	111
9	23.8	27.5	4.4	116
10	4.0	4.0	4.3	N/A

Table 3: Linearity of Afinion ACR. Measured mean and theoretical creatinine values.

Sample	Theoretical creatinine (mg/dL)	Measured mean creatinine (mg/dL)	CV (%)	Recovery (%)
1	343.7	343.7	2.2	N/A
2	277.2	275.3	2.0	99
3	244.0	250.8	2.0	103
4	210.7	217.4	3.8	103
5	177.5	174.2	4.4	98
6	144.3	145.8	1.5	101
7	111.0	109.5	3.5	99
8	77.8	77.4	1.8	99
9	44.5	44.4	4.1	100
10	11.3	11.3	8.2	N/A

The Limits of Quantitation (LoQ) was determined according to CLSI protocol EP17-A. The LoQ is 2.5 mg/L for albumin and 5.0 mg/dL for creatinine.

Reportable range for albumin is: 5.0 - 200.0 mg/L
Reportable range for creatinine is: 16.4 – 339.9 mg/dL

Method comparison

Method comparison studies were performed by the staff of four separate physician office sites (external study), and by the manufacturer (internal study).

External study

A method comparison study comprising 169 urine samples was performed at four physicians' office laboratories. Urine samples were collected from the donors and analyzed with Alere Afinion AS100 Analyzer and another Point of Care Testing (POCT) system at the four study sites. The correlation data (Passing-Bablok analysis) are summarized in Table 4.

Table 4: Method comparison. Afinion ACR (y) vs. another POCT system (x) at four sites. Linear regression analysis data, N= number of samples, r=correlation coefficient

Analyte	N	Regression line	r
Albumin (mg/L)	169	y = 1.10x + 1.4	0.99
Creatinine (mg/dL)	169	y = 0.93x + 2.3	0.99
ACR (mg/g)	169	y = 1.16x + 1.0	0.99

Internal study performed at Abbott Diagnostics Technologies AS

A method comparison study comprising 91-95 urine samples was peformed with the Alere Afinion AS100 Analyzer and another Point of Care Testing (POCT) system. The correlation data (Passing-Bablok analysis) are summarized in Table 5.

Table 5: Method comparison. Afinion ACR (y) vs. another POCT system (x). Linear regression analysis data, N=number of samples, r=correlation coefficient.

Analyte	N	Regression line	r
Albumin (mg/L)	91	y = 0.92x + 2.1	0.99
Creatinine (mg/dL)	95	y = 1.00x – 3.2	0.99
ACR (mg/g)	91	y = 1.01x + 0.7	0.99

Precision

Precision studies were performed by the staff of three separate physician office sites (external study), and by the manufacturer (internal study). The CLSI Guideline EP5-A was followed.

Internal study performed at Abbott Diagnostics Technologies AS

Within-day, between-day and total precision were determined for three urine samples assayed for 20 days. The samples were assayed in duplicate twice a day using the Alere Afinion AS100 Analyzer. The results are shown in tables 6, 7 and 8.

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

Sample	N	Mean Albumin (mg/L)	Within-run CV (%)	Between-day CV (%)	Total CV (%)
1	20	174.9	4.3	2.0	5.0
2	20	55.3	3.3	0.0	4.8
3	20	12.6	4.4	1.2	5.5

Table 7: Creatinine. Within-run, between-day and total precision. N=number of days, CV=Coefficient of Variation.

Sample	N	Mean Creatinine (mg/dL)	Within-run CV (%)	Between-day CV (%)	Total CV (%)
1	20	51.4	3.4	0.0	3.8
2	20	162.3	2.1	0.0	2.8
3	20	348.1	2.7	0.6	3.0

Table 8: ACR. Within-run, between-day and total precision. N=number of days, CV=Coefficient of Variation.

Sample	N	Mean ACR (mg/g)	Within-run CV (%)	Between-day CV (%)	Total CV (%)
1	20	340.6	5.3	2.8	6.0
2	20	34.1	3.7	0.7	4.6
3	20	3.6	5.0	0.0	6.0

External study

A precision study was performed at three physician office laboratories (site 1-3) with two levels of native urine samples, sample 1 and sample 2. The study was performed during ten operating days. Afinion ACR Lot 1 was used for the first five days and Lot 2 was used for the next five days. Each day four replicates of the samples were measured. The within-run CV calculated according to Guideline EP5-A is reported as within-day CV. The results are shown in table 9.

Table 9: Results from analysis of two native urine samples at three physicians' offices. Within-day, between-day and total precision. CV=Coefficient of variation.

Sample	Lot	Site	Mean Albumin (mg/L)	Within-day CV (%)	Between-day CV (%)	Total CV (%)
S1	1	1	13.9	5	2	6
		2	13.6	5	2	7
		3	14.1	2	1	3
	2	1	12.9	6	2	7
		2	12.9	3	5	6
		3	13.0	5	1	5
S2	1	1	142.1	4	3	6
		2	141.8	5	2	8
		3	142.2	4	2	5
	2	1	126.8	5	3	7
		2	117.3	4	2	5
		3	121.9	3	2	4
Sample	**Lot**	**Site**	**Mean Creatinine (mg/L)**	**Within-day CV (%)**	**Between-day CV (%)**	**Total CV (%)**
S1	1	1	159.0	5	3	6
		2	158.0	3	1	3
		3	155.1	3	1	3
	2	1	152.4	3	3	4
		2	148.8	2	1	3
		3	148.6	3	0	4
S2	1	1	219.9	4	0	4
		2	227.0	7	0	8
		3	218.2	2	0	3
	2	1	217.8	4	0	5
		2	208.8	3	1	3
		3	208.0	4	3	5
Sample	**Lot**	**Site**	**Mean ACR (mg/L)**	**Within-day CV (%)**	**Between-day CV (%)**	**Total CV (%)**
S1	1	1	8.8	5	0	6
		2	8.6	5	0	7
		3	9.2	4	0	5
	2	1	8.4	7	0	7
		2	8.7	3	2	4
		3	8.8	4	1	4
S2	1	1	64.6	3	3	4
		2	62.6	4	1	7
		3	65.3	3	0	4
	2	1	58.4	4	0	8
		2	57.3	8	3	9
		3	58.6	6	4	7

Between instruments precision
The between instrument precision of the Afinion ACR Assay was evaluated by five operators analyzing three native urine samples on 5 randomly selected Alere Afinion AS100 Analyzers. Sample 1, 2, and 3 were analyzed in 10 replicates on each analyzer. The mean albumin, creatinine, ACR, and coefficient of variation (CV) were calculated for each sample on each analyzer and for all five analyzers. The results are shown in table 10.

Table 10: Between instrument precision. Mean albumin, creatinine and ACR, and Coefficient of Variation (CV) of ten replicates.

Sample	Albumin (mg/L)		Creatinine (mg/dL)		ACR (mg/g)	
	Mean	% CV	Mean	% CV	Mean	% CV
1	12.5	2.0	280.6	2.1	4.4	3.3
2	101.9	3.5	54.8	1.4	186.3	2.4
3	30.4	3.2	157.8	3.6	19.3	3.1

Lot-to-lot variation
The consistency between different manufacturing lots of the Afinion ACR were evaluated by measuring 17–18 urine samples in duplicate using three different lots of the Afinion ACR. The study was performed using one Alere Afinion AS100 Analyzer.

A Bland-Altman analysis comparing two lots at a time was performed. The bias and the limits of agreement with 95% confidence interval were calculated. The results are shown in tables 11, 12 and 13.

Table 11: Bland-Altman analysis for albumin; bias (mg/L) and 95% limit of agreement for lots 1, 2, and 3.

Albumin	Lot 2 - Lot 1	Lot 3 - Lot 1	Lot 3 - Lot 2
Bias (mg/L)	-0.6	5.2	5.7
95% Limits of agreement	-5.1 to 3.9	-7.8 to 18.3	-7.3 to 18.7

Table 12: Bland-Altman analysis for creatinine; bias (mg/dL) and 95% limit of agreement for lots 1, 2 and 3.

Creatinine	Lot 2 - Lot 1	Lot 3 - Lot 1	Lot 3 - Lot 2
Bias (mg/dL)	4.9	5.9	0.8
95% Limits of agreement	-6.0 to 15.8	-3.4 to 15.1	-8.3 to 9.8

Table 13: Bland-Altman analysis for ACR; bias (mg/g) and 95% limit of agreement for lots 1, 2 and 3.

ACR	Lot 2 - Lot 1	Lot 3 - Lot 1	Lot 3 - Lot 2
Bias (mg/g)	-0.8	5.3	5.9
95% Limits of agreement	-12.8 to 11.2	-20.8 to 31.4	-11.0 to 22.8

Precision AFINION™ ACR Controls
The precision of the Afinion ACR Control C I and Control C II were evaluated externally at three different sites. Each study site measured each control in six replicates on five operating days using the Alere Afinion AS100 Analyzer. The within-day, within-site and between-site precision were calculated. The results are shown in Table 14.

Table 14: External validation of Afinion ACR Control at three study sites. Within-day, within-site and between-site precision.

	Within-day CV (%)		Within-site CV (%)		Between-site CV (%)	
Control	C I	C II	C I	C II	C I	C II
Albumin	≤ 6	≤ 5	≤ 6	≤ 6	2	2
Creatinine	≤ 7	≤ 5	≤ 7	≤ 5	5	4
ACR	≤ 6	≤ 6	≤ 6	≤ 6	5	4

Performance testing with the AFINION™ 2 Analyzer
The performance of Afinion ACR and Afinion ACR 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 ACR.

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 sufficient for 1 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 2-8°C, 36-46°F
	Manufacturer
	Date of manufacture
℞ Only	Federal law restricts this device to sale by or on the order of a licensed healthcare professional

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