

# Afinion™ ACR

REF 1115022

Albumin/Creatinine Ratio	GB	5...13
Albumin/Kreatinin ratio	NO	14...22
Albumin/Kreatininkvot	SE	23...31
Albumin/Kreatinine-ratio	DK	32...40
Albumiini/Kreatiniini suhde	FI	41...49










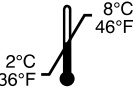

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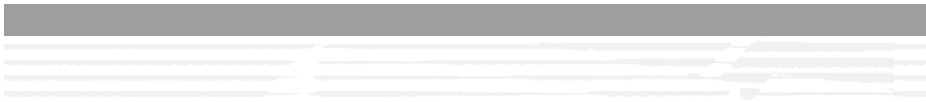
**afinion**<sup>TM</sup>  
POINT OF CARE CENTER





**SYMBOLS/ SYMBOLER/ SYMBOLIT**

	<p>Conformity to the European directive 98/79/EC on <i>in vitro</i> diagnostic medical devices          Overensstemmelse med EU-direktiv 98/79/EC for <i>in vitro</i> diagnostisk medisinsk utstyr          Överensstämmer med EU-direktiv 98/79/EC för <i>in vitro</i> diagnostisk medicinsk utrustning          Overensstemmelse med EU-direktivet 98/79/EC om <i>in vitro</i> diagnostisk utstyr til medicinsk brug          Yhdenmukainen Euroopan direktiivin 98/79/EC kanssa koskien <i>in vitro</i> diagnostisia lääkinällisiä laitteita</p>
	<p><i>In Vitro</i> Diagnostic Medical Device          Medisinsk utstyr til <i>in vitro</i> diagnostikk  <i>In vitro</i> diagnostisk medicinsk utrustning  <i>In vitro</i> diagnostisk medicinsk utstyr  <i>In vitro</i> diagnostinen lääkinällinen laite</p>
	<p>Catalogue number          Katalognummer          Artikelnummer          Katalognummer          Luettelonumero</p>
	<p>Lot number          Lotnummer          Lotnummer          Lot-nummer (produktionsserienummer)          Eränumero</p>
	<p>Test Cartridge          Testkassett          Testkassett          Testkassette          Testikasetti</p>
	<p>Contents sufficient for "Σ" number of tests          Innholdet rekker til "Σ" antall tester          Innehåller tillräckligt för "Σ" antal analyser          Indholdet er tilstrækkeligt til "Σ" antal test          Sisältö riittää "Σ" testimäärälle</p>
	<p>Consult the Afinion™ user instructions          Les Afinion™ bruksanvisningene          Läs bruksanvisningarna för Afinion™          Læs Afinion™ -brugervejledningerne          Katso tarkemmin Afinion™ käyttöohjeita</p>
	<p>Caution, consult instructions for use          Forsiktig, se bruksanvisningen          Varning, läs bruksanvisningen          Forsiktig, læs instruktionerne før brug          Varoitus, katso käyttöohje</p>
	<p>Expiry date (year-month)          Utløpsdato (år-måned)          Utgångsdatum (år-månad)          Udløbsdato (år-måned)          Viimeinen käyttöpäivämäärä (vuosi-kuukausi)</p>
	<p>Storage temperature 2-8°C (36-46°F)          Lagringstemperatur 2-8°C (36-46°F)          Förvaringstemperatur 2-8°C (36-46°F)          Opbevaringstemperatur 2-8°C (36-46°F)          Säilytyslämpötila 2-8°C (36-46°F)</p>
	<p>Manufacturer          Produsent          Tillverkare          Producent          Valmistaja</p>



For use with the 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 measure of urine albumin aids in the early diagnosis of nephropathy<sup>1,2</sup>.

### 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 also defined as a urinary excretion rate (AER) between 20-200 µg/min in at least two of three urine samples within a six month period<sup>3</sup>.

Creatinine is a degradation product of the muscle tissue protein creatine. All creatinine crosses the glomerular basement membrane and is excreted with 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 albumin/creatinine ratio will give a more accurate result of the albumin excretion rate<sup>2,4</sup>.

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<sup>5,6,7</sup>.

### Principle of the assay

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

The Afinion™ ACR Test Cartridge contains all reagents necessary for determination of albumin, creatinine and albumin/creatinine ratio 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 stained membrane. Excess gold-antibody conjugate is removed in a washing step. The Afinion™ AS100 Analyzer measures the colour 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 coloured 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™ AS100 Analyzer.

### Standardization

Albumin is calibrated against the ERM®-DA470<sup>9</sup> reference preparation. Creatinine is calibrated against SRM 914a<sup>10</sup>.

### Kit contents (per 15 tests unit)

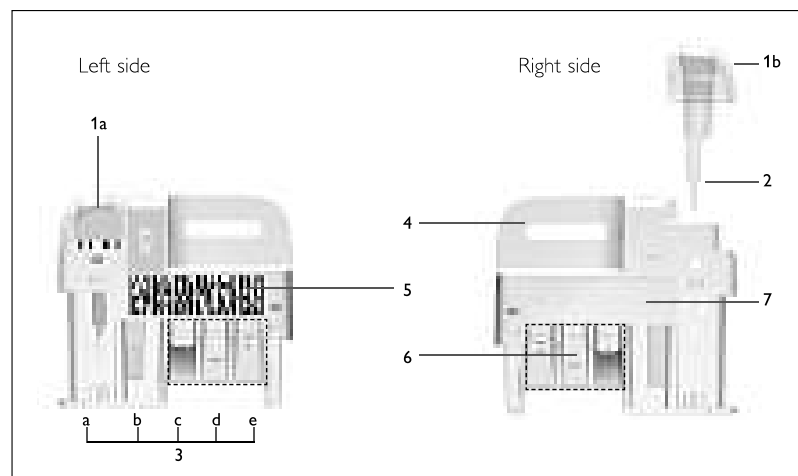
- 15 Test Cartridges packaged separately in foil pouches with a desiccant bag
- 1 Package Insert

### Materials required but not provided with the kit

- Afinion™ AS100 Analyzer
- Afinion™ ACR Control
- Standard urine collection equipment

### Description of the Test Cartridge

The main components of the Test Cartridge are the sampling device and the reagent container. The Test Cartridge has a handle, a barcode label with lot-specific information and an area for sample ID. See figure and table below.



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 wells a. Capillary wiper b. Membrane tube c. Conjugate solution d. Enzyme solution 2 e. Enzyme solution 1	Contains reagents necessary for one test: Plastic laminated paper; Tube with a nitrocellulose membrane coated with anti-albumin antibodies. Anti-albumin antibodies conjugated with ultra-small gold particles. Enzymes buffered in HEPES, detergents and preservative. Enzymes buffered in HEPES, detergents and preservative.

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 labelled sample identification.

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use Test Cartridges after the expiry 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 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.
- The Afinion™ ACR Test Cartridge contains sodium azide as a preservative. The concentration is < 0,1%, which is below that which is considered hazardous in normal use<sup>8</sup>. In case of leakage, avoid contact with eyes and skin. Wash with plenty of water.
- Do not re-use any part of the Test Cartridge.
- The used Test Cartridges, sampling equipment, patient samples and controls are potentially infectious. The Test Cartridges should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with local or national regulations. Use gloves.

## STORAGE

### Refrigerated storage (2-8°C)

- The Afinion™ ACR Test Cartridges are stable until the expiry date only when stored refrigerated in sealed foil pouches. The expiry date is the last day of the month stated on the foil pouch and kit container.
- Do not freeze.
- Do not store at room temperature. However, the Test Cartridges are stable for maximum 8 hours up to 30°C. 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 must be used within 10 minutes after opening the foil pouch.
- Avoid exposure to direct sunlight.
- Avoid relative humidity above 90%.

## SAMPLE MATERIAL


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

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

### Sample storage

- Human urine samples can be stored refrigerated (2-8 °C) for 5 days. Stored samples should be mixed well before analysis.
- Do not use urine samples which have been frozen.
- Consult the Afinion™ ACR Control Package Insert for storage of control materials.

## PREPARING FOR ANALYSIS

 Consult the Afinion™ AS100 Analyzer User Manual for detailed instructions on how to analyse a patient or control sample. The Afinion™ ACR Quick Guide also provides an illustrated step-by-step procedure.

- The Afinion™ ACR Test Cartridge must reach an operating temperature of 20-30°C before use. Upon removal from refrigerated storage, leave the Test Cartridge in unopened foil pouch for at least 15 minutes.
- Open the foil pouch just before use.
- Do not touch the Test Cartridge optical reading area.
- Label the Test Cartridge with patient or control ID. Use the dedicated ID area.

## COLLECTING A SAMPLE

### Urine sample

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

### Afinion™ ACR Control

- 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.

### Filling the capillary

- 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 with sample, the analysis of the Test Cartridge must start within 1 minute.
  - Do not use a Test Cartridge that has been accidentally dropped on the floor or lab bench after sample collection.

## ANALYSING A SAMPLE

- Analyse the Test Cartridge following the procedure described in the Afinion™ AS100 Analyzer User Manual.
- The analysis time is 5 minutes and 35 seconds.

## INTERPRETATION OF RESULTS

Interpret the Afinion™ ACR test results 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, re-test the sample or confirm the result using another method. Analyse control materials frequently to verify the performance of the Afinion™ AS100 Analyzer System.

### Measuring range

	Albumin (mg/L)	Creatinine (mmol/L)	ACR (mg/mmol)
<b>Measuring range</b>	5.0-200.0	1.5-30.0	0.1-140.0
<b>Interval</b>	0.1	0.1	0.1

If the albumin or creatinine value is outside the measuring range, no ACR value will be calculated. See the table below.

Symbol	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: < 1.5 mmol/L	The creatinine concentration is below 1.5 mmol/L
Creatinine: > 30.0 mmol/L	The creatinine concentration is above 30.0 mmol/L
ACR: — — —	The ACR value cannot be calculated as the albumin or creatinine value is outside range.

If the albumin or creatinine value is above the measuring range, the patient sample can be diluted with saline (0.9% NaCl) up to 4 times (1:4) and re-tested.

### 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.

## 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
Paracetamol	0.2 mg/mL	1.5 mmol/L
Paracetamol-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.

## Limitations of the test


- Only samples with > 2% v/v whole blood, or > 5% v/v hemolyzed blood, will return information code #108. Urine samples containing whole blood, up to 2% v/v, or hemolysed blood, up to 5% v/v, will give falsely elevated ACR results due to falsely elevated albumin results. Hence, urine samples containing blood should not be used in the Afinion™ ACR assay. If unexpectedly high albumin results are observed, good laboratory practice is to test the sample for blood with commercially available urine sticks.
- Ingestion of acetylsalicylic acid in dosages higher than 1200 mg/day may result in too low creatinine result and thus too high ACR result.

## Reference range<sup>1,2</sup>


Category	24-h	Timed	Spot	
	collection	collection	collection	
	Albumin	Albumin	ACR	
	mg/24h	µg/min	µg/mg	mg/mmol
Normal	<30	<20	<30	<2.5
Microalbuminuria	30-300	20-200	30-300	2.5-25
Clinical albuminuria	>300	>200	>300	26-300

## QUALITY CONTROL

Quality control testing should be done to confirm that your Afinion™ AS100 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.

 It is recommended to keep a permanent record of all quality control results. The Afinion™ AS100 Analyzer automatically stores the control results in a separate log. Consult the Afinion™ AS100 Analyzer User Manual.

### Choosing control material

 Afinion™ ACR Control from Axis-Shield is recommended for routine quality control testing. Consult the Afinion™ ACR Control Package Insert.


If controls from another supplier are used, the precision must be determined and acceptable ranges for the Afinion™ AS100 Analyzer System must be established.

### Frequency of control testing

Controls should be analysed:

- anytime an unexpected test result is obtained.
- with each shipment of Afinion™ ACR test kits.
- with each new lot of Afinion™ ACR test kits.
- when training new operators in correct use of Afinion™ ACR and the Afinion™ AS100 Analyzer.
- in compliance with national or local 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 control is outside the acceptable limits, make sure that:

- patient samples are not analysed until control results are within acceptable limits.
- the control vial has not passed its expiry 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 re-test the control material.

If no procedural errors are detected:

- Re-test 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 local supplier for advice before analysing patient samples.

## TROUBLESHOOTING

To ensure that correct albumin, creatinine and ACR results are reported, the Afinion™ AS100 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 Afinion™ ACR specific information codes. Consult the Afinion™ AS100 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*

\* Only samples with > 2% v/v whole blood, or > 5% v/v hemolysed blood, will return information code #108. Urine samples containing whole blood, up to 2% v/v, or hemolysed blood, up to 5% v/v, will give falsely elevated ACR results due to falsely elevated albumin results. Hence, urine samples containing blood should not be used in the Afinion™ ACR assay. If unexpectedly high albumin results are observed, good laboratory practice is to test the sample for blood with commercially available urine sticks.

## PERFORMANCE CHARACTERISTICS

### Method comparison

Method comparison studies, comprising 95 urine samples (ACR values distributed over the measuring range) were analysed with Afinion™ ACR, one automated laboratory method and another point-of-care method. The correlation data (Passing-Bablok analysis) are summarized in Table 1.

Table 1: Method comparison. Afinion™ ACR (y) vs. one automated laboratory method (1) and another point-of care method (2).

Method	Analyte	Number of samples	Regression line	Correlation coefficient (r)
1	Albumin	95	$y = 0.93x + 4.3$	0.99
	Creatinine	95	$y = 0.97x - 0.2$	1.00
	ACR	95	$y = 1.01x + 0.3$	1.00
2	Albumin	91	$y = 0.92x + 2.1$	0.99
	Creatinine	95	$y = 1.00x - 0.2$	0.99
	ACR	91	$y = 1.00x + 0.1$	0.99

### Precision

Within-run, between-day and total precision were determined according to the NCCLSI Guidelines EP5-A. Three urine samples were assayed for 20 days. The samples were analysed in duplicate twice a day. Precision data are summarized in Table 2, 3 and 4.

Table 2: 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 3: Creatinine. Within-run, between-day and total precision.  
N=number of days, CV=Coefficient of Variation.

Sample	N	Mean			
		Creatinine (mmol/L)	Within-run CV (%)	Between-day CV (%)	Total CV (%)
1	20	4.5	3.6	0.0	3.8
2	20	14.4	2.0	0.0	2.7
3	20	30.8	2.6	0.6	3.0

Table 4: ACR. Within-run, between-day and total precision.  
N=number of days, CV=Coefficient of Variation.

Sample	N	Mean			
		ACR (mg/mmol)	Within-run CV (%)	Between-day CV (%)	Total CV (%)
1	20	38.5	5.3	2.8	6.0
2	20	3.9	3.8	0.6	4.6
3	20	0.4	4.8	0.0	4.8