

FEB 12 2008

K072409

510(k) SAFETY AND EFFECTIVENESS SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of CFR.

Ms Jorunn Grevle Lolland
Director Quality Assurance & Regulatory Affairs
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Submission Date: 2007-08-17

Device Name: Afinion™ ACR

Reagents:

Classification Name: 1) Albumin, Antigen, Antiserum, Control
 2) Enzymatic Method, Creatinine

Trade Name: Afinion™ ACR

Common Name: 1) Test for albumin in urine
 2) Test for creatinine in urine

Governing Regulation: 1) 866.5040
 2) 862.1225

Device Classification: Class II

Classification panel: 1) Immunology
 2) Clinical Chemistry

Product Code: 1) DCF
 2) JFY

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Controls:

Classification Name:	Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Trade Name:	Afinion™ ACR Control
Common Name:	Control
Governing Regulation:	862.1660
Device Classification:	Class I
Classification panel:	Clinical Chemistry
Product Code:	JJY

Substantial Equivalence:

Afinion™ ACR is substantial equivalent to the DCA 2000® Microalbumin/Creatinine assay (k963142). These assays yield similar Performance Characteristics.

Intended use

The Afinion™ ACR assay is an *in vitro* diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine using the Afinion™ AS100 Analyzer. The measure of urine albumin aids in the early diagnosis of nephropathy.

The Afinion™ ACR Control kit contains liquid preparations of albumin and creatinine in citrate buffer. The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

Test Description

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 20-200µg/min in at least two of three urine samples within a six month period.

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.

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.

Principle of the device

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

The Afinion™ ACR Test Cartridge contains all the reagents necessary for determining albumin, creatinine and ACR in a human urine sample. The sample material is sampled using the sampling device integrated into 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 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™ AS100 Analyzer.

Comparison of technological characteristics

Afinion™ ACR has different technological characteristics compared to the DCA 2000® Microalbumin/Creatinine assay.

In the Afinion™ ACR assay, albumin is quantified based on an immunometric membrane flow-through principle, where the color intensity of the membrane is measured by reflection. In the DCA 2000® Microalbumin/Creatinine assay, a specific antibody binds with albumin in the presence of polyethylene glycol. The albumin-antibody complexes that are formed cause increased turbidity which is measured as absorbance.

In the Afinion™ ACR assay, creatinine is quantified in an enzymatic colorimetric test where the creatinine concentration is measured by transmission. In the DCA 2000® Microalbumin/Creatinine assay, the creatinine assay is based on the Benedict/Behre chemistry (non enzymatic) and the creatinine concentration is quantified by absorbance.

Standardization

Albumin is calibrated against the ERM®-DA470 reference preparation.
Creatinine is calibrated against SRM 914a.

Summary of Non-Clinical Performance

The Afinion™ ACR assay is substantially equivalent to the DCA 2000® Microalbumin/Creatinine assay as demonstrated by non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance

The Afinion™ ACR assay demonstrated substantially equivalent performance to the DCA 2000® Microalbumin/Creatinine assay as indicated by method comparison and precision tests.

Method Comparison:

At four external study sites 169 urine samples were analyzed with the Afinion™ ACR assay and the DCA 2000® Microalbumin/Creatinine assay. The correlation data (Passing-Bablok analysis) are summarized in Table 1.

Table 1. Method comparison, external study sites. Afinion™ ACR (y) vs. DCA 2000® Microalbumin/Creatinine assay.

Linear regression analysis data, N = number of samples, r = correlation coefficient

Analyte	N	Regression line	Correlation coefficient
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

In an internal method comparison study, 91 - 95 urine samples were analyzed with the Afinion™ ACR assay and the DCA 2000® Microalbumin/Creatinine assay. The correlation data (Passing-Bablok analysis) are summarized in Table 2.

Table 2. Method comparison, internal study. Afinion™ ACR (y) vs. DCA 2000® Microalbumin/Creatinine assay.

Linear regression analysis data, N = number of samples, r = correlation coefficient

Analyte	N	Regression line	Correlation coefficient
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:

An external precision study was performed in accordance with CLSI EP5-A protocol using two levels of urine samples (Sample 1: albumin: < 20 mg/L and creatinine: 110-170 mg/dL, Sample 2: albumin: > 100 mg/L and creatinine > 170 mg/dL). The within-run CV was ≤ 8 % and the total CV was ≤ 9 % for all three analytes with both samples.

Afinion™ ACR Control:

An external precision study for Afinion™ ACR Control C I and C II was performed at 3 study sites. The Afinion™ ACR Controls were run in 6 replicates each day over 5 operating days. The

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within-day CV was $\leq 7\%$, the within-site CV was $\leq 7\%$ and the between-site CV was $\leq 4\%$ for all three analytes with both control levels.

Conclusion

The Afinion™ ACR assay is substantially equivalent to the DCA 2000® Microalbumin/Creatinine assay (k963142) as demonstrated.



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Axis-Shield POC As
c/o Mr. Jorunn Greive Lolland
Director of Quality Assurance
& Regulatory Affair
Marstrandgata 6, PO Box 6863
Rodelokka, Oslo, Norway N-0504

Re: k072409
Trade/Device Name: Afinion™ ACR and Afinion™ ACR Control
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine test system.
Regulatory Class: Class II
Product Code: JFY, JIR, JJY
Dated: February 4, 2008
Received: February 7, 2008

Dear Mr. Lolland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

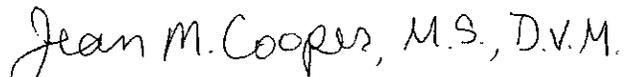
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072409

Device Name: Afinion™ ACR and Afinion™ ACR Control

Indication For 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.

Afinion™ ACR Control is a assayed in vitro diagnostic quality control material used to confirm that the Afinion™ ACR and the Afinion™ AS100 Analyzer System is working properly and provides reliable results

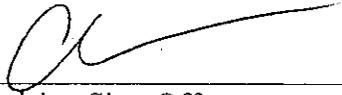
Prescription Use
 (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
 (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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