

# Development of an ACR assay for the Afinion™ AS100 Analyzer

Kvam C., Dworsky E., Campbell A., Jernberg E., Tøn H., Bernstrom K., Hansen K., Karlson J.R., Holtlund J., Faaren A.L., Nordhei A.K., and Frantzen F., Axis-Shield PoC, Oslo, Norway

## Purpose

The purpose of this publication was to introduce the development of the Afinion™ ACR assay system. The two main objectives of the publication were to demonstrate that the precision and analytical specificity of the Afinion™ AS100 Analyzer's ACR assay were clinically acceptable and to demonstrate the level of correlation between the Afinion™ AS100 Analyzer, DCA 2000, and the Modular®.

## Background

Albumin excretion rate in urine can be used to predict incipient diabetic nephropathy, a serious complication of diabetes mellitus. The Afinion ACR assay is an in vitro diagnostic test for quantitative determination of low urine albumin levels, microalbuminuria, corrected for variable urine volume by simultaneously measuring the creatinine concentration.

## Precision

Precision was evaluated in accordance with the CLSI guideline EP5-A. The total precision study involved performance of 3 urine samples, twice per day for a total of 20 days.

- Results show that the CVs for ACR were in the range 4.6% and 6.0%.

Sample	Albumin (mg/L)		Creatinine (mg/dL)		ACR (mg/g)	
	Mean	CV %	Mean	CV %	Mean	CV %
Urine S1	174.9	5.0	51.4	3.8	340.6	6.0
Urine S2	55.3	4.8	162.3	2.8	34.1	4.6
Urine S3	12.6	5.5	348.1	3.0	3.6	6.0

## Method Comparison

Method comparison analyzed a total of 95 urine samples on 3 analyzers: Afinion, Modular, and DCA 2000. Samples were analyzed for albumin and creatinine. The results were compared separately by Passing/Bablok analysis. The scatter plots comparing Afinion to Modular and DCA 2000 are displayed below.

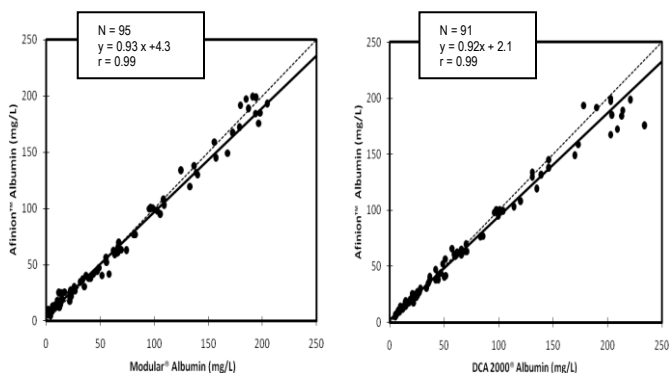


Figure 1: Albumin assay of Afinion™ ACR compared with Modular® and DCA

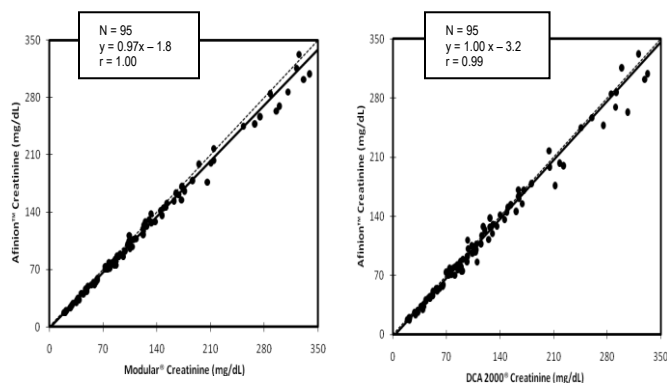


Figure 2: Creatinine assay of Afinion™ ACR compared with Modular® and DCA

## Evaluation of Elevated Albumin Samples

Interference by excess albumin was evaluated by testing urine samples spiked with up to 5000mg/L of albumin to determine if excess albumin would result in a falsely low albumin measurement.

- Based on the data, the Afinion will not report falsely low albumin results in urine samples with excess albumin; thus demonstrating that the Afinion ACR assay displays no hook effect up to 5000 mg/L of albumin.

## Conclusions

The Afinion ACR test provides a reliable, precise, and convenient point of care method for the simultaneous determination of albumin, creatinine and ACR. The Afinion ACR system correlates very well to the Modular laboratory method as well as the DCA 2000 point of care method.