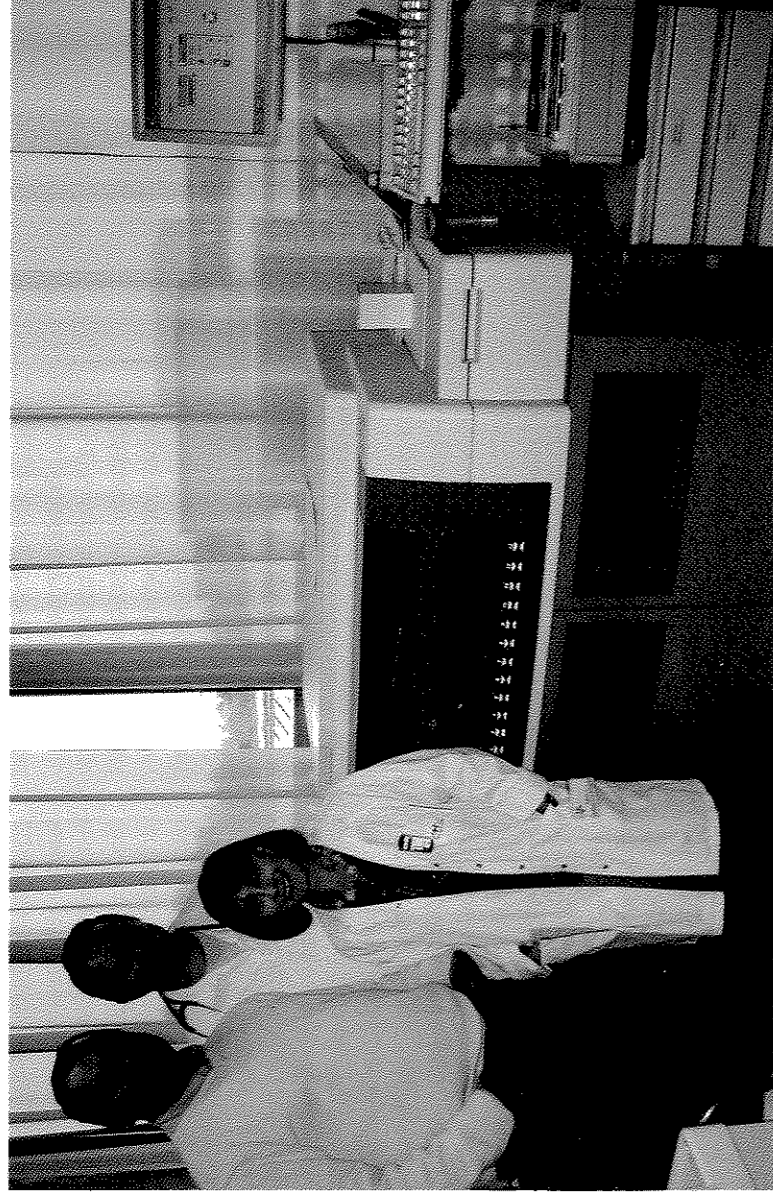


Evaluation meets Precision



From left to right: Dr. Cavalier, Dr. Delanaye, Mrs Agnès Carlisi standing in front of an ARCHITECT system.

Experts with big interest.

Dr. Cavalier, Clinical Biologist, Head of the Laboratory of Endocrinology of the Clinical Chemistry Department and Dr. Delanaye, Nephrologist, from the Nephrology, Dialysis and Transplantation Department of the University Hospital of Liège are sharing their experiences with Urine NGAL assays.

What has been your major findings during the analytical evaluation of the ARCHITECT urine NGAL assay compared to other NGAL assays?

Dr. Cavalier: We performed an analytical validation of the test according to our quality policy requirements. Our results showed that Abbott ARCHITECT urine

NGAL is a very robust method, with excellent repeatability and good precision. The recovery and linearity were also very nice.

Measurement uncertainty was quite low and the accuracy profile showed that the method was completely validated in the dosing range.

From your point of view, which role plays the matrix of an NGAL assay?

Dr. Cavalier: From the Biologist's point of view, it is sometimes more difficult to deal with urine (ratio to creatinine? Complete diuresis? 24 hours or spot?...), but for me, the main point is the analytical performance of the test. I am very satisfied with the performance of the NGAL on ARCHITECT, particularly when compared to our experience with plasma NGAL.

is not needed directly. Moreover, the quality of the results is higher when the samples are given to the technicians in the laboratory.

Dr. Cavalier: An immediate answer is not needed; however one should expect the results within a few hours rather than days.

Point-of-care tests can be quite difficult because the personnel needs to be trained, the department needs to be informed and you do not know how the test was performed. The point-of-care tests will never have the same quality as the instruments that are located in the laboratory.

In particular, the imprecision of point-of-care tests is much higher compared to laboratory instruments.

When should NGAL be measured?

Dr. Cavalier: NGAL should be measured in patients at risk of developing acute kidney injury. From my point of view, it is more important to test NGAL in a longitudinal mood vs. a one-shot test. Studies have shown the interest on NGAL in the follow-up of patients who have had cardiac surgery. We are still lacking some evidence to propose a daily follow-up of all the patients hospitalized in the ICU or in the emergencies (as about 20% of them will develop AKI), but now that we have a robust well analytically validated method, I believe that many studies will show that. Meanwhile we "intend" (most beneficial) to screen patients in the ICU.

Which changes in patient's medication or treatment plan will be done after an elevated NGAL test will be reported?

Dr. Delanaye: In general, point-of-care tests are important, such as for glucose. However, in practice, for NGAL in particular (as for creatinine), I can wait one or two hours for the results. The answer

Dr. Delanaye: In general, we have to be more attentive to dehydration when we are going to give early therapy. Also, we do not use contrast agents nor nephrotoxic antibiotics. Therefore, most of the measures are preventative as opposed to reactive. Once a traditional marker, like creatinine, is present the damage is already done and from that point it is not really the question what medication we use but rather what we should not do.

Which benefits do you see for NGAL in terms of health economics and improved patient care?

Dr. Cavalier: The interesting aspect is that the test could perhaps shorten the stay and the length of time the patient needs to receive intensive care. Therefore, in the end, the national health would benefit with the upfront costs of an NGAL assay.

If you could summarise the key advantages of ARCHITECT urine NGAL into three points, what would they be?

Dr Cavalier:

1. Urine NGAL is an early marker of acute kidney injury (1-2 days earlier than creatinine).
2. Urine NGAL is specific of tubular damage in the kidney.
3. The ARCHITECT urine NGAL is very precise, CV values below 6% in the concentration range 22 to 1315 µg/L were found during our evaluations.

ACTIVE

A Team to fight Kidney Disease

Around the world, Abbott is helping to fight kidney disease on multiple fronts. As a healthcare company focused on advancing patient care, we recognize this global public health problem and are partnering to create innovative solutions to help fight kidney disease. Abbott is putting its "Promise for Life" at work and helping improve the lives of these patients. We are collaborating with distinguished investigators on research in the areas of nutrition, secondary hyperparathyroidism, diabetes and its complications, and diagnostics to develop new therapies and detection methods for patients with kidney disease; Improving patient care through high-quality products used to diagnose, monitor, and help manage kidney disease. We are also partnering with patients, healthcare professionals, and professional societies around the world to help increase awareness of kidney disease. Join the fight against kidney disease and learn more about Abbott's commitment at Abbott.com.