

rchitect urine NGAL.

Introduction. The urine Neutrophil Gelatinase-Associated Lipocalin (NGAL) is a promising early new marker of acute kidney injury. Different studies have shown that it was one of the earliest protein to rise after kidney insult. However, most of these studies have been obtained with cumbersome techniques, particularly difficult to implement in an emergency laboratory. Very recently, Abbot Laboratories launched the urine NGAL on the Architect platform. The aim of this study was to perform a complete and strong analytical validation of this new test. We verified the reference range of the parameter in a healthy population. Finally, we studied the stability of urine NGAL at room temperature, +4°C, -20°C and -80°C.

Material and methods: We evaluated the precision with a modified protocol based on CLSI EP-5A2: five urine pools were assayed in triplicate once per day on five different days. Linearity was evaluated based on CLSI EP-6A. Recovery was determined according to CLSI EP-6P. Finally, we evaluated the measurement uncertainty, accuracy and β -expectation limits by assaying 5 urine pools in triplicate during five different days. We settled the β -expectation tolerance limits with $\beta=0.95$ and considered the method as valid if each future measurements of the same level had a probability of 95% to fall in the $\pm 20\%$ accepted limits of accuracy. For stability studies, 9 samples were assayed in duplicate at T0 and after 5 and 24 hours of storage at 23°C, and after 24 and 48 hours at +4°C. Stability after storage at -20°C and -80°C was studied by assaying in duplicate the 9 same pools at T0 and after 1,2,8,15,30 and 60 days. Forty-five healthy laboratory volunteers' urine samples were used to verify the 95th percentile proposed by the manufacturer.

Results: Repeatability did not exceed 3% and the intermediate precision 6% in the concentration range 81 to 1315 $\mu\text{g/L}$. The mean recovery was $101.8 \pm 6.7\%$. The method was found to be linear until the 1/10 dilution. Measurement uncertainty was comprised between 3.4 and 12.5%. The accuracy profile built with the predictive tolerance interval method shows that, on average, 95% of the future results that will be generated by this method will be included in the computed tolerance intervals of $\pm 20\%$ in the 81-1315 $\mu\text{g/L}$ studied range. NGAL was shown to be stable after 24 hours of storage at +23°C, 48 hours at +4°C and up to 60 days at either -20°C or -80°C. In the healthy population, the 95th percentile was found at 148.5 $\mu\text{g/L}$, (median: 23 $\mu\text{g/L}$), very close to the cut-off proposed by the manufacturer (131.7 $\mu\text{g/L}$).

Conclusions: Abbott Architect urine NGAL is a very robust method. The accuracy profile shows that the method is completely validated between 81 and 1315 $\mu\text{g/L}$: in this range, we are sure that the values obtained are not at risk of being over $\pm 20\%$ of the true values. We confirmed the expected range proposed by the manufacturer. Samples can be stored up to 1 day at room temperature, 2 days in the fridge and up to two months at -20°C or -80°C.