Certification of an automated method for citric acid in human urine

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Introduction

By 2016, medical biology laboratories will have to be accredited according to ISO 15 189 standardization. This accreditation certifies that the laboratories are able to carry on their activities.
Biomnis laboratory automated a method to quantify citric acid in human urine. Citric acid is a metabolite of the Krebs cycle. In urine, it inhibits the formation of kidney stones.
Different parameters must be evaluated according to the technical guide of accreditation in medical biology before operating this method routinely.

Experimental conditions

TCitric acid is quantified by UV spectrometry with the PENTRA 400 automat. The quantification is made with a 340 nm wavelength and at a temperature of 37°C required for enzymatic reaction.
Before any analysis, calibration with three levels of known concentrations has to be made. Internal quality controls are used as calibration standards because of lack of certified calibrators.
Two other internal quality controls from a different brand are used to test the parameters for the certification: a low and a high control with citrate concentrations respectively of 230 and 1025 mg/L. They surround reference values of citric acid in human urine.

Statistic approach

Several parameters were successfully tested: linearity, limit of quantification, repeatability, reproducibility, inter contamination samples…

Results and Discussion

	Average	Standards derivation	Coefficient of variation
LEVEL 1	250	10	5
LEVEL 2	1130	60	5

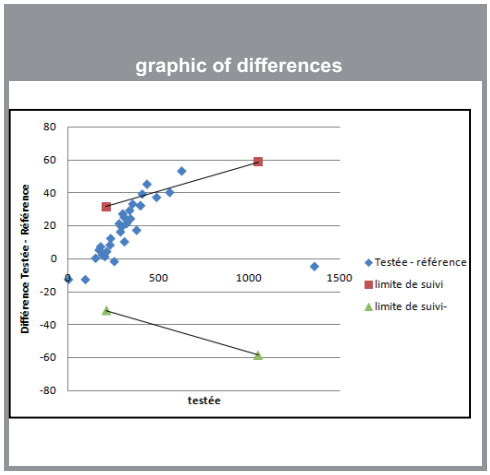
Table 1: *Low and high intern quality reproducibility controls*

	Average	Standard derivation	Coefficient of variation
LEVEL 1	240	2	1
LEVEL 2	1170	4	0,4

Table 2: *Low and high intern quality repeatability controls*

Repeatability and reproducibility assess the reliability of this method.
Reproducibility is an important parameter because it attests that the method is stable in time. These parameters are validated according to biologist requirements and the bibliography. However variation coefficients are well under the 10 % defined by biologists.

This method is able to discriminate until 0,03g/L and line up to 1,025 g/L. The limit of quantification and the linearity verify the reliability of the method on a large concentration range. This range is fully representative of the population.



The automat overcomes the errors from the manual method currently used. This graph attests that the manual method under estimated the quantification of citric acid in urine. Lots of parameters like the homogeneity of sample, the temperature of the reaction, the accuracy of the swab are controlled with the automat. Moreover this automated method doesn't require preparation of samples and a kit for citric acid in urine is used.

Conclusion

All the analytical parameters are performed with the automated method for which Biomnis laboratory will soon be audited by COFRAC.

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