Validating the analysis method: Forensic assay of alcohol in whole blood

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Introduction

By 2015, hospitals must be accredited according to Standardization ISO15189. Without this accreditation they will not be able to carry on their activity. So the hospitals laboratories have to validate all the methods they use..
Consequently it was necessary to validate a forensic assay of alcohol in whole blood with GC/FID because this is the refence method. This validation has been made according to a new approach: Accuracy profile.

Experimental Conditions

During the validation 2 types of samples were used:

- Standards of validation = samples reconstituted in the matrix containing a known concentration (value considered as true by consensus).
- Standards of calibration = samples of known concentration prepared in or outside the matrix. Internal quality controls were used as calibration standards. These allowed us to establish the standard ranges.
  Furthermore three levels of concentrations had been chosen.
  The experiment was repeated three times. Regarding the parameters of the method used:

. Solvent: water
. Internal Standard: Propanol
. Column INNOWAX (polar stationary phase),
. Length: 60 m
. Internal diameter: 0.53mm
. Mode: spitless
. Detector temperature: 250 °C
. Run : 8min

Carrier method:
. Mode: Constant flow
. Gas saver flow: 20 mL/min

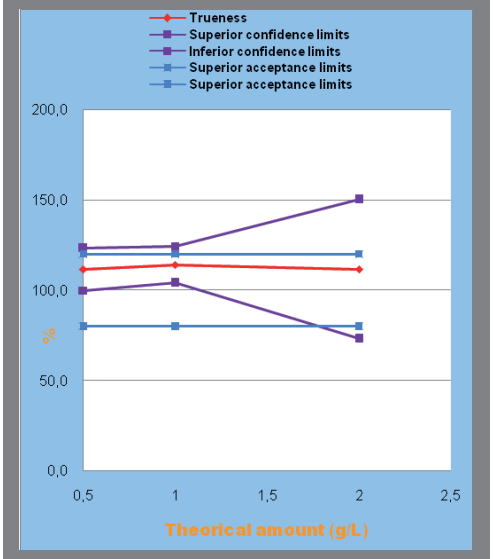
Oven method
. Temperature gradient: 50 °C to 80°C
. Rate (deg/min): 5

Once the samples were prepared, they were treated as patient samples, and analyzed according to the method described previously on the GC/FID.

Results

This new approach of validation allows us to judge the trueness of the method but also its repeatability, since these analyses were conducted over three days. An Accuracy profile (figure 1) presents results of the validation: trueness is represented by the red line.
The blue lines on both sides of trueness represent acceptance limits established by the laboratory's biologist.
These limits depend on the method used and on the matrix. Here, these limits are set at more or less 20%. Finally, purple lines are confidence limits; trueness should not leave these bounds of confidence.

Figure 1 : Accuracy profile



Conclusion

The accuracy profile illustrates the level of measurement uncertainty determined during the validation. It's a visual tool of decision which incorporates in a single graph, all the essential elements to validate the estimated performances of every procedure.

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