ACCURACY OF DATA GENERATED THROUGH AN EXTERNAL QUALITY ASSESSMENT PROGRAMME FOR ANALYTICAL PARAMETERS FROM A CHEMISTRY CONTROL MATERIAL

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Introduction

Internal control materials are used routinely for the daily monitoring of analytical performance. They are provided generally in two formats; precision (with approximate target values) to which the laboratories assign their own targets and ranges and then assayed (with assigned target values already defined). The provision of predefined target values reduces the workload for a laboratory and can also minimise bias that could remain undetected by the use of precision material. These benefits are only achieved if the target values are accurate and reliably assigned.

We report here the accuracy of target values, assigned to internal quality control materials, by an external quality assessment scheme with a large population of participating laboratories. This was determined by comparing target values assigned to the same material by reference methods. This is relevant for laboratory internal control as it indicates that the values assigned to the assayed material are close to the true values. Such assayed quality control materials can facilitate reliable bias assessments.

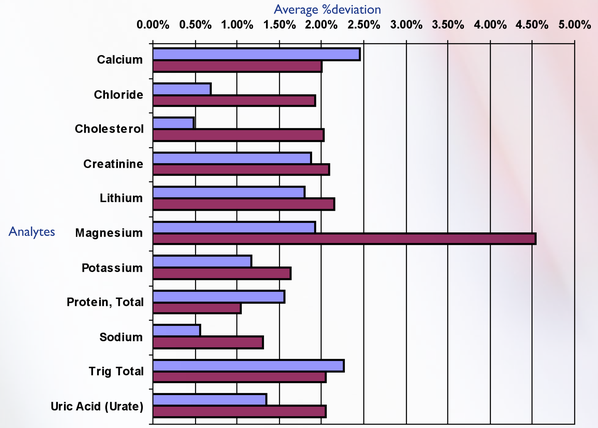
Methodology

Chemistry control materials (HN1530 and HE1532), covering a range of concentrations, were used. Their target values were previously assigned through generation of all method consensus means, by the External Quality Assessment (EQA) programme 'Randox International Quality Assessment Scheme' (ISO/IEC Guide 43-1:1997 accredited). The same controls concurrently had target values, with known uncertainties, assigned by reference laboratories utilizing assigned reference material and methods (isotope dilution mass spectrometry, atomic absorption and flame photometry).

The 5000 participants registered on the clinical chemistry programme provided a large number of results, after removal of outliers, to generate the consensus means. Target values for 11 chemistry parameters (calcium, chloride, cholesterol, creatinine, lithium, magnesium, potassium, sodium, total protein, triglycerides and uric acid) assigned through the EQA and reference methods, were compared and the average % deviation calculated.

Results

Average % deviation for all the parameters assessed



Key:

%Difference between all methods mean from the External Quality Assessment Programme (EQA) and reference methods values

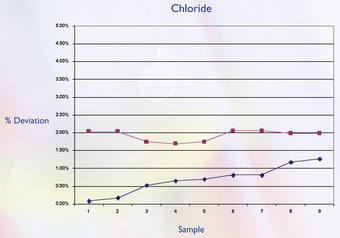
%Difference between the reference method values and their uncertainties

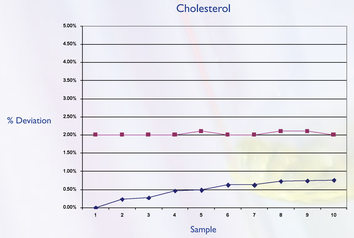
From the 11 parameters assessed:

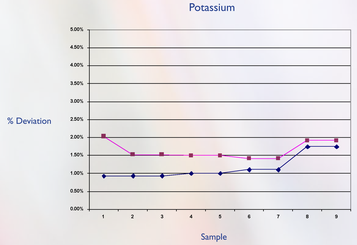
- 3 parameters (chloride, cholesterol and sodium) showed an average %deviation, between the EQA and reference method determinations of less than 0.7%
- 6 parameters (creatinine, lithium, magnesium, potassium, total protein and uric acid) showed % deviations of less than 1.9% and 2 parameters (calcium and triglycerides) of less than 2.5%.

The maximum individual %deviation observed was 6% for calcium, the other parameters tested ranged from 0% to 3.6%.

Examples







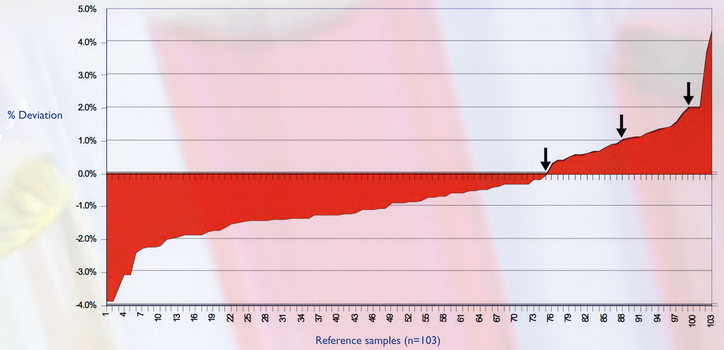
Key:

%Difference between all methods mean from the External Quality Assessment Programme (EQA) and reference methods values

%Difference between the reference method values and their uncertainties

All methods means (AMM) and reference value uncertainty ranges

% deviation between AMM and the reference method value, with expanded uncertainty, for individual reference samples.



73% of the all method means (AMM) generated, fell within the uncertainty ranges quoted for the reference values; 85% fell within the uncertainty range plus 1% while 95% fell within the uncertainty range plus 2%.

Conclusion

These results show that the all methods means of the EQA programme are accurate when compared to the reference methods values.

73% of the all method means (AMM) generated, fell within the uncertainty ranges quoted for the reference values; 85% fell within the uncertainty range plus 1% while 95% fell within the uncertainty range plus 2%.

The data for the 11 chemistry parameters indicates that the internal quality control target values, derived from the reported EQA programme, are traceable to values produced by reference methods. Also the percentage deviation from target falls within the acceptable percentage deviation of the RiliBÄK guidelines.

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