Compensated Jaffe Creatinine – a more accurate Method?

- July 2003 – received notification from Roche Diagnostics of removal of non-compensated creatinine values in controls and calibrators.
- Due to lack of IVD traceability these values were no longer supported.

- Analytical sensitivity of assay altered to 18µmol/L.
- Asked to communicate change to EQAS schemes
- For children <3 years of age advised to run enzymatic procedure.

- Compensated Jaffe method offset of minus 18µmol/L .
- Lower detection limit of 36 µmol/L.
- Samples <36µmol/l analysed by enzymatic procedure.

- Cost implications - Jaffe assay cost 3 cents vs. enzymatic cost of 45 cents.
- Increased cost taken into consideration by Roche in 2005/2006 reagent contract

- Compensated Jaffe assay traceability - standardised against Isotope Dilution/Mass Spectrometry.
- Compensated to take into account interference from non-specific chromogens - serum proteins, acetoacetate, acetone, uric acid, ascorbate.

- Ran compensated and non-compensated methods – verified Roche claims that due to slope correction, recovery of creatinine was reduced at lower levels and increased at higher levels.
- Altered reference range from 25 - 70µmol/l to 20 - 55 µmol/l

- Explained change and effect on creatinine values to Consultant Nephrologist.
- Switched to compensated method in August 2004.
- Good correlation between enzymatic and compensated Jaffe methods.

- Developed negative bias in UK NEQAS - Sept 2005 MRBIS -104.
- A number of Roche users still attempting to assign own value to the calibrator for compensated method.

- Recent problem in relation to post renal transplant patients on Tacrolimus Rx.
- If creatinine rises by 20µmol/l – query Tacrolimus toxicity or rejection.
- Noted when creatinine was analysed in labs other than our own.

- Try to avoid having to bring children long distances for further investigation – possibly unnecessarily.
- Requesting external hospitals to send on samples to CUH for analysis in an attempt to obtain consistency in creatinine results.

Conclusions

- Change also affects calculation of creatinine clearance.
- Is this a more specific/accurate method?
- Is your own creatinine assay traceable to a reference method?
- If you alter the manufacturer's calibration value, does this invalidate the CE mark?