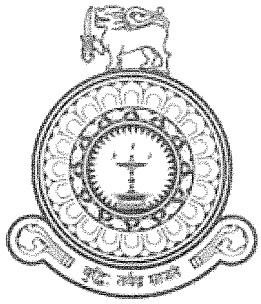

Use of Stored Human Plasma as a Reference Material in Quality Assurance in Private Sector Biomedical Laboratories in Galle District.

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Abstract

The long term goal for any field of measurement is to be able to meaningfully compare quantitative test results for a given quantity (analyte) produced by any laboratory at any time. To achieve this all routine measurement procedures for a given analyte must have a quantifiable relationship to an internationally recognized reference material.

Many methods presently lack certified reference materials. It is often practical to use conventional reference materials and conventional methods to facilitate the comparability of measurements between users of the same measurements procedure within and between laboratories.

Commercially prepared water or saline based reference material has inherent weakness of difference of matrix in which the analyte is present compared to human blood, serum or plasma. Use of pooled human plasma or stored human plasma gives advantage over such material due to the matrix match.

Use of human plasma as a reference material has many limitations including having analyte values within normal range, risk of disease transmission, contamination and deterioration.

In our study it shows that the values of analytes in plasma can be manipulated within required analytical range using pure substances like urea (to change analyte concentration) without affecting integrity and also with minimum facilities, careful laboratory practice can minimize bacterial or fungal contamination and sample deterioration.

According to the results generated for each batch of reference material, differences in values by different laboratories shows still acceptable range according to the Westgard Multi Rules. Those values did not exceed the batch mean plus 2s or mean minus 2s (±2) control limit.

Within laboratory, variation is considerable in values of creatinine compared to urea. This may be due to method dependent effects where kinetic method is applied in creatinine while single point absorbance is used in urea estimation.

Further research is needed to identify various methods of manipulation using chemicals or different solutions to change plasma constituents to prepare reference material similar to disease situations.