

VALIDATION OF FOUR ENZYME METHODS ON XXX XXX™ CHEMISTRY ANALYZER

Aim of the study: To evaluate the accuracy and the traceability of four enzymatic methods (ALT, CK, GGT, and LDH) on the XXX system by comparison with IFCC reference measurement procedures. As a result of this operation, generate appropriate values for the K factor or calibration material of the system, if needed.

Materials: IRMM/IFCC reference materials (provided by the company):

GGT IRMM/IFCC 452
LDH IRMM/IFCC 453
ALT IRMM/IFCC 454
CK IRMM/IFCC 455

XXX XXX Enzyme Reagents (provided by the company):

GGT List # XXX
LDH List # XXX
ALT List # XXX
CK List # XXX

Analytical platform (provided by the company)

XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Control Material (to verify XXX XXX system – provided by the company):

Enzyme assay test results obtained from the XXX system will be verified using control material and its associated target values (and range) provided by the manufacturer. Control material will be assayed in singlicate both before and after testing of samples.

Human Samples (provided by the Reference Laboratory):

50 human serum (leftover) samples for each enzyme studied. The observed enzyme activity should be distributed across the reportable range for each enzyme assay (see CLSI EP9-A protocol for sample distribution selection).

Methods: XXX XXX Enzyme Methods:

see 'XXX Application Manual'. The XXX method will initially utilize the existing value of the calibrator or the corresponding K factor for calibration.

IFCC Reference Measurement Procedures:

Enzyme methods on XXX

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see the corresponding SOPs.

Method Comparison Protocol (CLSI EP9-A):

Samples (n=50) and IRMM/IFCC monoenzyme reference materials will be assayed in duplicate using both each XXX XXX method and appropriate IFCC SOP. *XXX results should be stored as they can be subsequently recalculated using the obtained regression equation from the correlation of data.*

Evaluation:

From the correlation, obtain appropriate K value and/or appropriate activity concentration for the calibration material. Using this new value, perform a recalculation of stored enzyme results for each of the assayed samples.

Replot these results against the results obtained for the IFCC reference procedure and obtain a new method comparison plots. The recalculated results should presumably demonstrate excellent correlation ($r \cong 1.0$, slope $\cong 1.0$, intercept $\cong 0$) with the IFCC reference procedure results.