Assigned Reference Method Targets for the Comparison of Enzyme Assays in the UK

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INTRODUCTION

EQA organisations provide an essential role in the post market vigilance of the implementation of the IVD Directive. Traceability of results to the SI unit utilising reference target values is the preferred method of comparison of returned results where available, ensuring the transfer of accuracy from definitive methods to routine methods. The current JCTLM approved reference methods for enzymes at 37°C have been published by the IFCC.

REFERENCE METHOD

Uv/Vis spectrophotometry methods for Gamma Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) have been developed based on the IFCC methods[1-4]. The analysis was undertaken by the Weqas Reference Laboratory. Samples were processed as detailed in the method flow diagram (fig. 1). All SRM preparations were made gravimetrically, allowing uncertainty measurements to be estimated according to GUM, with traceability by use of certified reference material (Table 1).

Figure 1
General Method Flow Diagram

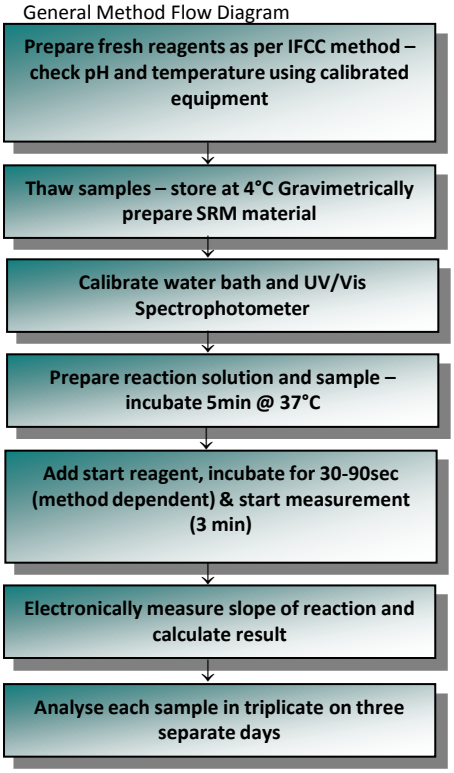


Table 1 *Traceability*

Analyte	Supplier	Control material	Target (IU)
GGT	IRMM,	AD452	114.1 (+/- 2.4)
LDH	DGKL	1212	176.1 (+/-4.2)
	DGKL	1213	379.6 (+/-8.4)
ALT	IRMM	AD454	186 (+/- 4)
AST	JCCLS	CRM003a	171 (+/- 4)

Table 2 *SRM Bias*

Mean value	Target	Bias (%)	Range
SRM (GGT)			
114..02	114.1	-0.07	111.7-116.5
SRM (LDH)			
174.3	176.1	-1.02	171.9-180.3
376.2	379.6	-0.9	371.2-388
SRM (ALT)			
186.25	186	0.13	182-190
SRM (AST)			
105.4	104.6	0.75	101.9-107.3

RESULTS

SRM bias for all measured enzymes was less than +/- 3% (Table 2). The maximum imprecision for each method was 2% based on triplicate analysis of samples on 3 separate days. A good correlation of results was observed for EQA returns for GGT and LDH over an 18 month period (figs 2-3) and AST over a 6 month period (fig 4)

Fig 2

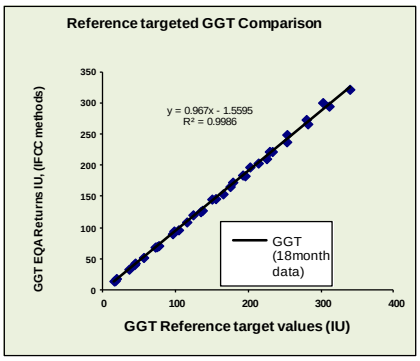


Fig 3

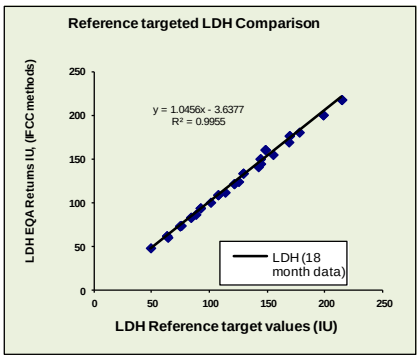
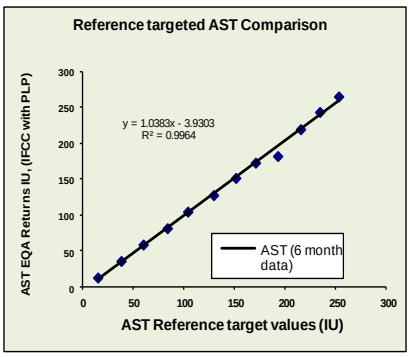


Fig 4



CONCLUSION

Reference target values for all enzymes will be assigned to pools distributed for the Weqas Clinical Chemistry Scheme. The development of reference methods will ensure that Weqas can independently help manufacturers, users and competent authorities in the post–marketing vigilance of the EU Directive 98/79/EC. Weqas is committed to provide traceable reference method target values for the majority of analytes; currently the repertoire includes electrolytes, HbA1c, cholesterol, triglyceride, HDL cholesterol, bile acids, creatinine, uric acid, progesterone, testosterone and cortisol (serum and urine).

REFERENCES

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2. Schumann G IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C Part 4. Reference Procedure for the Measurement of Catalytic Concentration of Alanine Aminotransferase Clin Chem Lab Med 2002; 40/7: 718-724

3. Schumann G IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C Part 5. Reference Procedure for the Measurement of Catalytic Concentration of Aspartate Aminotransferase Clin Chem Lab Med 2002; 40/7: 725-733

4. Schumann G IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C Part 6. Reference Procedure for the Measurement of Catalytic Concentration of g-Glutamyltransferase Clin Chem Lab Med 2002; 40/7: 734-738