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Evaluation of a Fully Mechanised Immunoassay — Enzymun-Test System ES 300 — and Comparison with In-House Methods for 8 Analytes

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Summary: The following analytes were determined with the automated enzyme immunoassay unit, Enzymun-Test System ES 300, and by routine in-house tests, and the results were compared: thyrotropin, free thyroxine, cortisol, immunoglobulin E, digoxin, digitoxin, insulin and carcinoembryonic antigen. The methods used for comparison included two radioimmunoassays, one with enzyme labelling, two with fluorescence enhanced enzyme reactions and 3 luminescence immunoassays. In most cases, the precision of the ES 300 lay between 2 and 5% in all assays in the concentration ranges of clinical interest. The inter-assay variation was almost identical to the intra-assay precision, which reflects the constancy of reagent quality and machine performance.

The correlation between in-house and Enzymun-Test was excellent, even though the slope of the regression line was sometimes far from unity, due to the calibration materials used.

ES 300 can be used as a stand alone unit and connected to a host computer. As a “walk-away” machine, it is suitable for laboratories with medium length series. It is a multi-batch analyser capable of taking 12 analytes and a maximal series length of 136 tubes excluding standards and controls.

Introduction

Enzymun-Test System ES 300 is a fully automated enzyme immunoassay analysis system consisting of a pipettor, incubator, photometer and electronic data processing (EDP)-unit. Interfacing to a central or host computer is possible as is a manual input via a conventional PC-keyboard. Enzymun-Test System ES 300 is a bench-top analyser, related to Enzymun-Test System ES 600 from the same manufacturer (1), and it is a stand-alone unit. Enzymun-Test System ES 300 is a patient orientated multibatch analyser designed as a workhorse for middle sized laboratories and it can incorporate from 1 to 12 analytes and up to 150 samples in one run.

Materials and Methods

Table 1 shows the list of analytes tested, together with the methods used for comparison.

Tab. 1. List of analytes tested together with methods used for comparison

Analyte	Method of comparison*)	Producer of Kit
CEA	IEMA	Abbott — EIA Monoclonal
Cortisol	RIA	Diagnostic Products-Coat-a-Count
Thyrotropin	ILMA	Behringwerke — BeriLux
Free T ₄	LIA	Ciba-Corning — Magic Lite
Digoxin	FEIA	Baxter — Stratus
Digitoxin	FEIA	Baxter — Stratus
IgE	ILMA	In-house assay
Insulin	RIA	Medgenix

*) Key: RIA — Radioimmunoassay
LIA — Luminescence Immunoassay
IEMA — Immunoenzymometric Assay
ILMA — Immunoluminometric Assay
FEIA — Fluorescence Enhanced Enzyme Immunoassay