# ANALYTICAL EVALUATION OF DYNATECH SYSTEM 7000: A FULLY AUTOMATED ELISA PROCESSOR

#### THESIS

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Ву

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# بسم الله الرحمن الرحيم

والله أخرجكم من بطون أمماتكم لاتعلمون شيئا وجعل لكم السمع والأبصار والأفئدة لعلكم تشكرون

> صدق الله العظيم النحل الآية ٧٨



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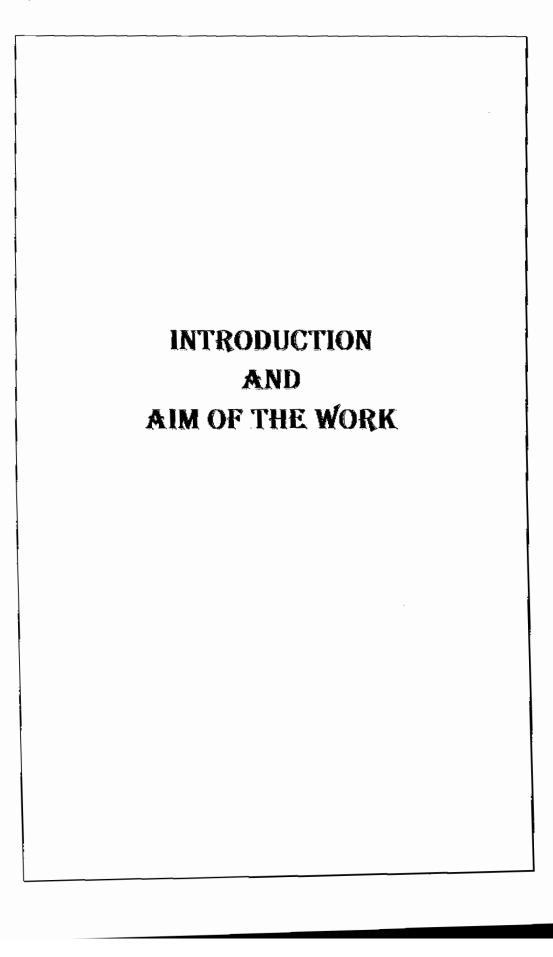
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Analytical automation is no longer a luxury but is considered an essentiality for the clinical laboratory. The increased workload as regards the number of samples and the number of tests requested for each patient was the chief impetus towards laboratory automation. In this respect, automation improves laboratory competence and provides high work output with less errors. Furthermore, it requires less personnel load and space occupiance (Gowenlock, 1988).

One of the major challenges for modern medicine is the incorporation of immunoassays in diagnostic and therapeutic procedures that are useful in practice of clinical medicine. Over the past 3 decades, immunologic laboratory methods have become increasingly more refined and simplified, consequently, immunoassays have now achieved a central role in the modern clinical laboratory (Rodgers, 1994).

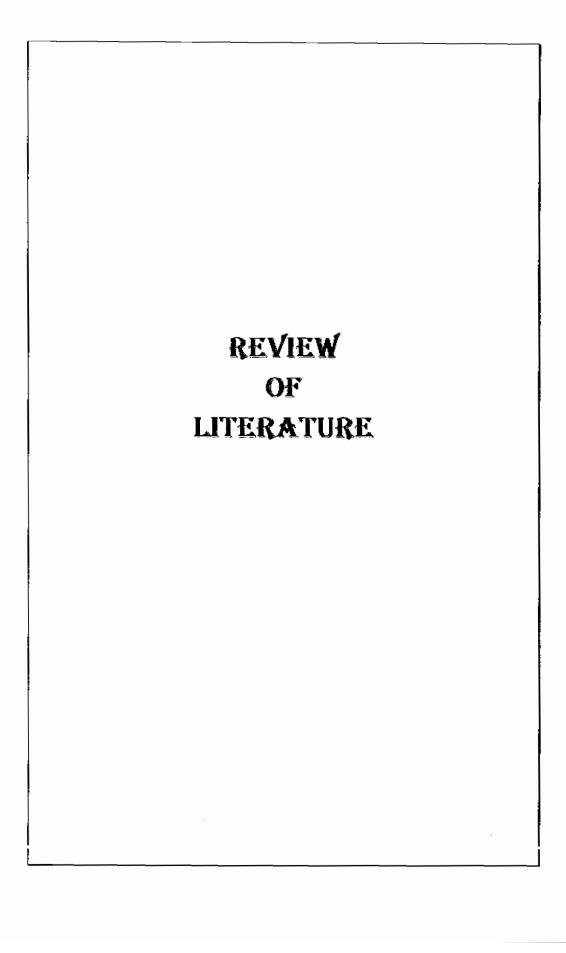
The goals of laboratory medicine are, to improve the availability, accuracy and precision of the medically important laboratory immunoassays, to ensure correct interpretation, to facilitate data transmission and to asses the significance of new tests introduced into clinical medicine. This makes the development of

automated immunoassay systems one of the most exciting areas in the clinical laboratory field. In the last few years, many new systems have been developed and some of them became commercially available (Ng, 1993).

# Aim of the Work:

Evaluation of the analytical performance and the reliability criteria of Dynatech System 7000; a fully automated ELISA processor recently introduced to Ain Shams University Specialized Hospital Laboratory; in comparison with Ciba-Corning Magic Lite Analyzer, using chemiluminescence technique, which is established as a routine analyzer in Ain Shams University Specialized Hospital Laboratory.

TSH is chosen as a candidate analyte to be assayed by the two methods for this evaluation study.



# CHAPTER ONE: IMMUNOASSAY

# 1. Introduction to Immunoassay:

# A. Basic Principle of Immunoassay:

The initial binding of an antibody and an antigen has been demonstrated to be very useful analytically and has been used with labeled antibodies and antigens to develop many sensitive and specific immunochemical assays. Immunoassays are used for detection and quantitation of antigens or antibodies (Anderson et al., 1991).

# B. Methodological Principles of Immunoassays:

#### 1. Non-labeled Versus labeled Immunoassays:

#### a. Non-Labeled Immunoassays:

The non-labeled immunoassays have limitations in their sensitivity, because large antigen-antibody complexes must be formed for their detection. Examples are immunoprecipitin methods, agglutination methods, and light scattering techniques for the detection of antigen-antibody complexes by equilibrium or kinetic approaches. These methods are often used to assay proteins, and the sensitivity is often in the range of micromoles per liter (*Nakamura et al.*, 1991).

# b. Labeled Immunoassays:

Labeled immunoassays use indicator molecules, attached to either the reagent antibody or antigen, to demonstrate that antibody-antigen reaction has taken place. These types of immunoassays are usually quantitative procedures and are sensitive to the microgram and macrogram range (Hurtubise et al., 1989).

# i. Types of Labels:

The indicator molecules used in labeled immunoassays can be radioactive compounds, enzymes or luminescent compounds (fluorescent or chemiluminescent).

Problems of performance and stability are common to all immunoassays, which utilize <sup>125</sup>l, since it is a high energy gamma emitter with shelf life of only 60 days. The limitation of these assay techniques together with the emotive bias against the use of radioisotopes and the labor and cost associated with their disposal have stimulated the search of non-radioactive labels suitable for use in immunoassay (*Metzel and Morris, 1986*).

It is widely accepted that the only potentially viable non-radioisotopic labels are enzymes, lanthidine fuorophores, and chemiluminescent molecules (*Diamandis*, 1991).

A radioactive label, such as <sup>125</sup>l, has low specific activity compared with enzyme labels and chemiluminescent and fluorescent labels. Enzyme labels provide an amplification, where large numbers of enzyme molecules in the complete complex provide a large increase of enzymatic activity coupled with the small amount of antigen being determined. Thus, the sensitivity of the antigen assay is correspondingly greater. Furthermore, the detection limit for an enzyme can be improved by the use of ultrasensitive detection method. Fluorescent labels also have high specific activity, and a single high-quantum-yield fluorophor can produce 100 million photons per second (*Kricka*, 1994).

**Table (1):** Detection Limits for Isotopic and Non-isotopic Immunoassay Labels (Quoted from Kricka, 1994):

Label	Detection Limit in zeptomoles	Method
Alkaline phosphatase	50 000 300 100 10	Photometry Time-resolved fluorescence Fluorescence Enzyme cascade Chemiluminescence
ß-D-galactosidase	5000 1000	Chemiluminescence Fluorescence
Europium chelate	10 000	Time-resolved fluorescence
Glucose-6-phosphate dehydrogenase	1000 1 000 000	Chemiluminescence Scintillation
Horseradish peroxidase ⇒ <sup>125</sup> I	2 000 000 25 000 1000	Photometry Chemiluminescence Scintillation