Upgrading of Clinical Chemistry Laboratory Performance

Thesis
Submitted in Partial Fulfillment of
M.D. Degree in Clinical and Chemical Pathology

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Faculty of Medicine
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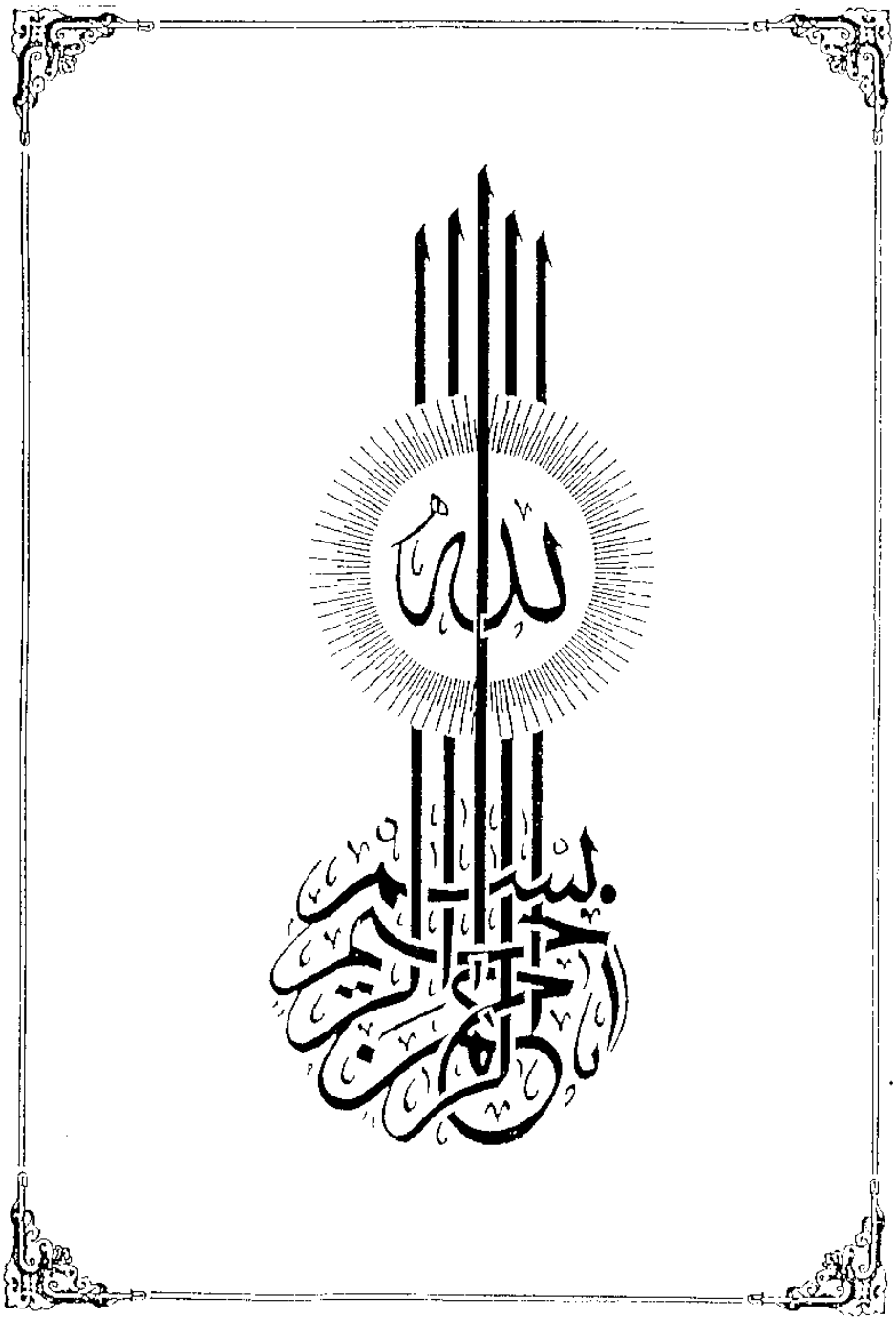

Abstract

The clinical laboratory is a dynamic environment that is continuously changing to meet the needs of the public and the medical profession. The high quality clinical laboratories of the future will have to be expertly managed, perform tests in cost effective, timely and efficient manner and to be responsive to an ever changing environment (Westgard and Klee, 1994).

Quality is defined as conformance to the requirements and expectations of doctors and patients utilizing the laboratory service (Berwick et al., 1990). The traditional framework for managing quality in clinical labs necessitates the establishment of Quality Laboratory Processes "QLP's". QLP include analytical processes as well as the general policies, practices and procedures that define how all aspects of the work get done (Berry, 1991).

Ain Shams University Specialized Hospital is a well known university hospital offering its laboratory services to both inpatients and outpatients. It performs more than 10,000 tests/ month. The Clinical Chemistry Unit alone, performs more than 2,500 tests/ month. From this stand point, it is the duty of this hospital to set up the general policies and procedures for "Quality Assessment" and to identify and eliminate any problems in the lab management; thus ultimately upgrading itself to meet the international standards.

List of Abbreviations

ALT	Alanine Transaminase
CAP	College of American Pathologists
CDC	Centers of Disease Control
CLIA	Clinical Laboratory Improvement Amendments
IFCC	International Federation of Clinical Chemistry
ISO	International Standardization Organization
IUPAC	International Union of Pure and Applied Chemistry
KJA	Key Job Areas
LIS	Laboratory Information System
MSDS	Material Safety Data Sheet
NCCLS	National Committee for Clinical Laboratory Standards
ORDAC	Over Range Detection And Correction
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QLP	Quality Laboratory Practices
QP	Quality Planning
SD	Standard Deviation
TAT	Turnaround Time
TQM	Total Quality Management

List of Tables

	Page
Table (1): The clinical lab information data transaction	**23**
Table (2): NCCLS Specifications For Reagent Grade Water	**27**
Table (3): Causes of systematic and random error	**53**
Table (4) : Some examples of allowable error recommendations for the 1990's	**54**

List of Figures

	Page
Figure (1): A TQM framework for managing quality in a health care laboratory	**6**
Figure (2): A flow diagram that illustrates the process of introducing a new method into routine use	**33**
Figure (3): The total error concept of accuracy	**43**
Figure (4): Conceptual basis of control chart	**49**
Figure (5): Skewness and kurtosis.	**57**

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Table of Contents

	Page
• **Introductin and Aim of the Work**	1
• **Review of Literature**	3
I. Basic Recommendations of the CLIA'88	3
A. Quality Assurance	4
B. Developing Performance Standards For Personnel	8
C. Role of Proficiency Testing in Accreditation	11
II. Pre-Analytical Variables	15
A. Current State of Art in Laboratory Use	15
B. Patient Preparation and Specimen Collection and Transport	17
C. Specimen Identification	19
D. Turnaround Time	23
III. Analytical Variables	26
A. Reagent Grade Water	26
B. General Laboratory Supplies	28
C. Maintenance and Care of Centrigues	30
D. Choice of Analytical Methodology	32
E. Control of Analytical Quality Using QC	47
IV. Establishment and Use of Reference Values	54
V. Laboratory Safety	61
• **Material and Methods**	68
• **Results and Discussion**	107
• **Appendix**	117
• **Refrences**	134
• **Arabic Summary**	

Introduction

and

Aim of the Work

INTRODUCTION

The clinical laboratory is a dynamic environment that is continuously changing to meet the needs of the public and the medical profession. The high quality clinical laboratories of the future will have to be expertly managed, perform tests in cost effective, timely and efficient manner and to be responsive to an ever changing environment (Westgard and Klee, 1994).

Quality is defined as conformance to the requirements and expectations of doctors and patients utilizing the laboratory service (Berwick et al., 1990). The traditional framework for managing quality in clinical labs necessitates the establishment of Quality Laboratory Processes "QLP's". QLP include analytical processes as well as the general policies, practices and procedures that define how all aspects of the work get done (Berry, 1991). The existence of an ISO compliant system is a key to meeting the regulatory requirements mandated by the CLIA'88 for achieving a high laboratory service (Krause, 1996).

Ain Shams University Specialized Hospital is a well-known university hospital offering its laboratory services to both

inpatients and outpatients. It performs more than 100,000 tests per month. The Clinical Chemistry Unit alone, performs more than 25,000 tests per month. From this stand point, it is the duty of this hospital to demonstrate leadership in achieving ISO (International Standardization Organization) registration and later CAP accreditation. This can be achieved by setting up the general policies and procedures for "Quality Assessment" and identifying and eliminating any problems in the lab management.

AIM OF THE WORK:

The aim of this work is to outline a path to successful ISO registration by setting up an inspection sheet for the assessment of quality of the Clinical Chemistry Unit performance and its application to Ain Shams University Specialized Hospital Clinical Chemistry Unit in an attempt to upgrade its performance to provide an outstanding laboratory service to give the most accurate and precise results.

Review of Literature