Quality Control in Hematological Laboratories and Transfusion Medicine

Essay

Submitted for Partial Fulfillment of Master Degree in Clinical Pathology

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List of Abbreviations

A : Adenine.

AABB : American Association of Blood Banks.

Ab. : Antibody.

ACD : Acid Citrate Dextrose.

ANSI : American National Standards Institute.

APCR : Activated Protein C Resistance.

APPT : Activated Partial Thromboplastin Time.

APTT : Activated Partial Thromboplastin Time.

ASQ : American Society For Quality

AT : Antithrombin.

BCSH : British Society of Clinical Hypnosis.

BT : Bleeding Time.

BTG : Beta Thrombo Globulin.

BTS : Blood Transfusion Service.

C : Cytosine.

CAP : College of American Pathologists.

CBC : Complete Blood Count.

cDNA : complementary Deoxyribonucleic Acid.

CGH : Comparative Genomic Hybridization.

cGMP : current Good Manufacturing Practices.

CLIA : Clinical Laboratory Improvement Amendment.

CLSI : Clinical and Laboratory Standards Institute.

CO : Cut-Off.

CPA : Cone and Platelet Analyser.

CQI : Continuous Quality Improvement.

CSA : Clot Signature Analysis.

CUSUM : Cumulative Sum.

CV : Coefficient of Variation.

ddATP : Dideoxyadenosine 5'-Triphosphate

ddNTPs : Dideoxynucleotide Triphosphate.

DNA : Deoxyribonucleic Acid.

dNTPs : Deoxynucleotide Triphosphates.

EDTA : Ethylenediaminetetraacetic acid.

EQA : External Quality Assessment.

ESR : Erythrocyte Sedimentation Rate.

FDA : Food and Drug Administration.

FFP : Fresh Frozen Plasma.

FISH : Fluorescence In Situ Hybridization.

FVL : Factor V Leiden.

G : Guanine.

G6PD : Glucose-6-Phosphate Dehydrogenase.

Hb : Hemoglobin.

HBsAg : Hepatitis B surface Antigen.

HBV : Hepatitis B Virus.

Hct : Hemtocrit.

HCV : Hepatitis C Virus.

hESC : Human Embryonic Stem Cell.

HIV : Human Immunodeficiency Virus.

HPLC : High-performance liquid chromatography.

HTLV : Human T-lymphotropic virus.

ICSH : International Council for Standardization In Haematology.

Ig : Immunoglobulin.

IQC : Internal quality control.

ISBT : International Society Blood Transfusion.

ISLH : International Society for Laboratory Hematology.

ISO : International Organization for Standardization.

JCAHO : Joint Commission on Accreditation of Healthcare Organizations .

MCHC : Mean Corpuscular Hemoglobin Concentration.

MCV : Mean Corpuscular Volume.

mRNA : Messenger Ribonucleic Acid.

NADP : Nicotinamide Adenine Dinucleotide Phosphate.

NADPH : Nicotinamide Adenine Dinucleotide Phosphate Hydrogenase.

NAT : Nuclear Acid Testing.

NBS : National Bureau of Standards.

NCCLS : National Committee for Clinical Laboratory Standards.

NIST : National Institute of Standards and Technology.

NRBC : Nucleated Red Blood Cells.

OFT : Osmotic Fragility Test.

PA : Platelet Aggregometer.

PC : Protein C.

PCR : Polymerase Chain Reaction.

PCV : Packed Cell Volume.

PF : Platelet Factor.

PFA : Platelet Function Analyser.

PLT : Platelet.

PMT : Photomultiplier Tube.

PRBCs : Packed Red Blood Cells.

PS : Protein S.

PT : Proficiency Testing.

PT : Prothrombin Time.

QA : Quality Assessment.

QAP : Quality Assurance Program.

QC : Quality Control.

QLP : Quality Laboratory Process.

RBCs : Red Blood Cells.

RFIQ : Radio Frequency Identification Devices.

RNA : Ribonucleic Acid.

RPFA : Rapid Platelet Function Analyser.

RPM : Revolution Per Minute.

S/CO : Sample/ Cut-Off.

SD : Standard Deviation.

SDI : Standard Deviation Index.

T : Thymine.

TAT : Turn Around Time.

TEG : Thromboelastography.

TQM : Total Quality Management.

TRITC : Tetra Methyl Rhodamine Iso Thio Cyanate.

TSA : Thrombotic Status Analyser.

TT : Thromboplastin Time.

UV : Ultra Violet.

vWF : Von Willebrand factor.

WBC : White Blood Cells.

WHO : World Health Organization.

Content

List of Tables

L ist of F igures

Introduction

In the medical world a large number of different national and international organizations in the field of medical laboratories have picked up the signs of the need for quality management systems ***(NCCLS, 2003).***

Quality control in laboratory medicines in general and in hematology in particular encompasses a set of procedures which ensure the reliable and timely test results are received by the users of laboratory service. Reliability implies both precision and accuracy. There are four components of quality assurance program: Internal quality control (IQC), External quality control or external quality assessment (EQA), Standardization and Proficiency surveillance ***(Bilwani, 2001).***

Internal Quality Control is done by: Testing Control Sample, Control Chart (Levy-Jennings or L-J chart), Cusum Analysis, Duplicate Tests and Inbuilt Quality Control (***Bilwani, 2001)***. In principle, the External Quality Control requires all providers of laboratory services to have access to a range of EQA schemes ***(BCSH Guidelines, 1995).***

As regard Standardization, modern diagnostic systems depend on a calibration procedure for accurate performance. The WHO (World Health Organization) provides a wide range of biologically