

Quality Assurance and Quality Control in Clinical Laboratories

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Abstract

Health care delivery is no longer a simple process of examining the patient and giving him a prescription. Over the years there has been rapid expansion in the various branches of health care services. As part of this expansion process and explosion of scientific medical knowledge, laboratory diagnosis has gained tremendous importance in today's practice. Especially in our country since the beginning of 80's we have been witnessing significant growth in laboratory services. Through quality management process the laboratory can ensure that the result being issued by the laboratory is reliable to allow decisions to be taken with confidence. Quality control and quality assurance are parts of quality management. Quality control is focused on fulfilling quality requirements, whereas quality assurance is focused on providing confidence that quality requirements are fulfilled. By utilizing quality control practices, a laboratory is able to find and correct flaws in the analytical processes of a lab before potentially incorrect patient results are released.

Key words

Quality assurance, quality control, quality management

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives."

The issue of Laboratory quality has evolved over more than 4 decades since the 1st recommendation for quality control was published in 1965.¹ Now Quality Control is seen as only one part of a total laboratory program. Government of Bangladesh has recently approved a draft on National Health Policy with an aim to reach the minimum Health care facility (MDG) by 2015.²

The purpose of the health care system in a country is to correctly diagnose the disease,

identify the factors responsible for the disease and take appropriate preventive and curative measures to control the disease. The pathologists and laboratory people are very much involved in the correct diagnosis, effective treatment and follow up of the patients. For correct diagnosis quality assurance and quality control are very important. Laboratory quality control is designed to detect, reduce and correct deficiencies in laboratories analytical process to release patient results and improve the quality of test result.³

Quality assurance (QA) is aimed at ensuring quality test results. The purpose of quality assurance is to give relevant, reliable, timely test

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Quality Control Manual In Medical Laboratories

Mary Louise Turgeon



Quality Control Manual In Medical Laboratories:

The Laboratory Quality Assurance System Thomas A. Ratliff, 2005-02-25 Both the 17025 1999 standard and especially ANSI ISO ASQ 9001 2000 standard require that a laboratory document its procedures for obtaining reliable results The Laboratory Quality Assurance Manual details to the user how to prepare a new laboratory quality assurance manual which will be appropriate to use as a procedures manual for a particular laboratory a sales tool to attract potential customers a document that can be to answer regulatory questions and ultimately a tool to become a registered ISO 9001 2000 Lab and gain related certifications based on the standard The Laboratory Quality Assurance Manual Incorporates changes to ANSI ISO ASQ 9001 2000 pertaining to laboratories Provides blank forms used in preparing a quality manual Provides information on the interrelationship of ANSI ISO 17025 1999 and ANSI ISO ASQ 9001 2000 The Laboratory Quality Assurance System

Thomas A. Ratliff, 1993 **Basic Laboratory Procedures in Clinical Bacteriology** Vandepitte J., World Health Organization, 2003-12-31 The 2nd edition of this publication updates the various guidelines produced by the World Health Organization on the sampling of specimens for laboratory investigation identification of bacteria and the testing of antibiotic resistance focusing on quality control and assessment procedures to be followed rather than on basic techniques of microscopy and staining The publication is split into two parts part one deals with bacteriological investigations regarding blood cerebrospinal fluid urine stools upper and lower respiratory tract infections sexually transmitted diseases purulent exudates wounds and abscesses anaerobic bacteriology antimicrobial susceptibility testing and serological tests and part two considers key pathogens media and diagnostic reagents *Laboratory Techniques in Thrombosis — a Manual* J. Jespersen, R.M. Bertina, F. Haverkate, 2013-12-01 The first edition of this manual appeared in 1992 and was entitled ECAT Assay Procedures It was the result of a unique cooperation between experts brought together by the European Concerted Action on Thrombosis and Disabilities ECAT The Concerted Action was at that time under the auspices of the Commission of the European Union The second edition like the first edition deals with diagnostic tests within the field of thrombosis However the second edition has a broader scope because it is no longer limited by the frontiers of ECAT Experts all over the world in and outside ECAT have contributed to this edition The editors are very grateful for their contributions The need for a new edition is obvious Since 1992 new assays have been introduced for research diagnosis and therapy of thrombosis for other assays improvements have been suggested while a few others became redundant The editors waived the radioimmunoassays of thromboglobulin and platelet factor 4 due to the fact that the kits required for these assays are rarely or no longer available Also the PAI 1 activity assay was waived as it is liable to many inconsistencies and to large variations A list of names and addresses of manufacturers marketing the kits and reagents has been compiled together with a list of the recommended nomenclature of quantities in thrombosis and haemostasis in order to facilitate the use of the updated version These lists have been carefully compiled by Johannes J Sidelmann PhD Department of Clinical Biochemistry in Esbjerg

Denmark Quality-assurance/quality-control Manual for Collection and Analysis of Water-quality Data in the Ohio District, U.S. Geological Survey, 1998 **Manual of Food Quality Control** Food and Agriculture Organization of the United Nations, 1993-01-01 **Advances in Clinical Toxicology Testing, An Issue of the Clinics in Laboratory Medicine** Joe M El-Khoury, 2025-05-21 In this issue of Clinics in Laboratory Medicine guest editor Dr Joe El Khoury brings his considerable expertise to the topic of Advances in Clinical Toxicology Testing Top experts discuss significant technological advances for the purposes of toxicological analysis and how readers can incorporate this new knowledge and innovative tools into their clinical practice Contains 16 relevant practice oriented topics including practical considerations for implementing immunoassays for urine drug testing in clinical laboratories point of care drug testing toxicology results interpretation improves values and diagnostic utilities of large drug testing panels clinical utility of specimen validity testing emerging threats special considerations and more Provides in depth clinical reviews on advances in clinical toxicology testing offering actionable insights for clinical practice Presents the latest information on this timely focused topic under the leadership of experienced editors in the field Authors synthesize and distill the latest research and practice guidelines to create clinically significant topic based reviews **Handbook of Quality Assurance in Laboratory Medicine** Shubhangi Tambweker, 2009 **Immunology & Serology in Laboratory Medicine** Mary Louise Turgeon, 2013-02-15 The 5th edition of this classic text sets the standard for comprehensive coverage of immunology Building from a solid foundation of knowledge and skills trusted author Mary Louise Turgeon takes you from basic immunologic mechanisms and serologic concepts to the theory behind the procedures you ll perform in the lab Immunology Serology in Laboratory Medicine Fifth Edition is the go to resource for everything from mastering automated techniques to understanding immunoassay instrumentation and disorders of infectious and immunologic origin Packed with learning objectives review questions step by step procedures and case studies this text is your key to succeeding in today s modern laboratory environment Full color six page insert of photomicrographs provide a better picture of what you ll see in the laboratory Learning objectives at the beginning of each chapter offer a measurable outcome you can achieve by completing the material Chapter highlights at the end of each chapter provide a summary of the most important information covered in each chapter Review questions at the end of each chapter are tied to learning objectives further enhance your understanding Case studies challenge you to apply your knowledge and help strengthen your critical thinking skills Glossary at the end of the book provides quick access to key terms and definitions NEW Expanded chapter on Vaccines as the importance of vaccines continues to become more evident NEW Updated chapter on Molecular Techniques incorporates the newest technology specific to immunology NEW Key terms at the beginning of each chapter help you learn the important vocabulary in immunology NEW Case studies with added multiple choice questions in addition to critical thinking questions will help you apply your knowledge and develop critical thinking skills Immunology & Serology in Laboratory Medicine - E-BOOK Mary Louise Turgeon, 2024-12-30 Selected for

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