
How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition



This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.

A guideline for global application developed through the NCCLS consensus process.



Clisi Document C28 A2

**Bernadette F. Rodak, Elaine M.
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Laboratory Test requesting Appropriateness and Patient Safety María Salinas, Maite Lopez-Garrigos, Enrique Rodriguez-Borja, Álvaro Blasco, Arturo Carratalá, 2016-12-05 The global medical process is a chain of different medical multidisciplinary procedures The success in global Patient Safety will depend on the Safety of the consecutive medical processes that intervene in this complex system Laboratory data is an essential part of health care indeed it is used in 70% of clinical decisions Inappropriate laboratory test over requesting is extremely frequent The prevalence of under requesting has been less studied The consequences of under requesting are clear we are missing a diagnosis Inappropriate over requesting can result not only in a problem of cost but also in a problem regarding patient safety Additionally another important consequence of inappropriate tests over requesting is that such amount of unnecessary tests has probably contributed to a significant increase in the volume of those over the last years In all there is general consensus that the inadequacy of test requesting must be corrected through strategies and monitored over time through indicators to assure the optimal laboratory contribution to clinical decision making and patient safety

Modern Clinical Molecular Techniques Peter Hu, Madhuri Hegde, Patrick Alan Lennon, 2012-05-11 This timely book covers the need to know clinical practices for all those involved in molecular laboratory science The field of molecular medicine is evolving at an astounding speed Propelled by the new insights and technologies advances are being made at an unprecedented rate With dual measure given to today's breakthroughs this book is a collection of the most current practices relevant to the clinical molecular laboratorian It begins with an introductory section on techniques and procedure It then presents four separate sections on infectious disease oncology pre post natal and identity testing with specific chapters clearly outlining clinical protocols used in daily practice Modern Clinical Molecular Techniques cuts to the heart of what is essential for the practicing molecular laboratory scientist It is an outstanding resource for those operating within or looking to set up a clinical molecular laboratory

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries Lanju Zhang, 2016-01-13 This book serves as a reference text for regulatory industry and academic statisticians and also a handy manual for entry level Statisticians Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries Specifically the Discovery and Translational sciences the Safety Toxicology sciences and the Chemistry Manufacturing and Controls sciences Drug discovery and development is a long and costly process Most decisions in the drug development process are made with incomplete information The data is rife with uncertainties and hence risky by nature This is therefore the purview of Statistics As such this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas The chapters provide as appropriate a scientific background to the topic relevant regulatory guidance current statistical practice and further research

directions **Tietz Textbook of Clinical Chemistry and Molecular Diagnostics - E-Book** Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2011-12-16 As the definitive reference for clinical chemistry Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 5th Edition offers the most current and authoritative guidance on selecting performing and evaluating results of new and established laboratory tests Up to date encyclopedic coverage details everything you need to know including analytical criteria for the medical usefulness of laboratory procedures new approaches for establishing reference ranges variables that affect tests and results the impact of modern analytical tools on lab management and costs and applications of statistical methods In addition to updated content throughout this two color edition also features a new chapter on hemostasis and the latest advances in molecular diagnostics Section on Molecular Diagnostics and Genetics contains nine expanded chapters that focus on emerging issues and techniques written by experts in field including Y M Dennis Lo Rossa W K Chiu Carl Wittwer Noriko Kusukawa Cindy Vnencak Jones Thomas Williams Victor Weedn Malek Kamoun Howard Baum Angela Caliendo Aaron Bossler Gwendolyn McMillin and Kojo S J Elenitoba Johnson Highly respected author team includes three editors who are well known in the clinical chemistry world Reference values in the appendix give you one location for comparing and evaluating test results NEW Two color design throughout highlights important features illustrations and content for a quick reference NEW Chapter on hemostasis provides you with all the information you need to accurately conduct this type of clinical testing NEW Six associate editors lend even more expertise and insight to the reference NEW Reorganized chapters ensure that only the most current information is included **Immunodiagnosics and Patient Safety** Krystyna Sztefko, 2011 Today most of immunochemistry methods for the determination of proteins peptides drugs and many small molecules are fully automated with good precision excellent sensitivity and short reaction time However inaccuracy due to poor standardization and the presence of interfering substances in biological samples is still a serious and life threatening issue Proper validation of methods and quality assurance have little effect on frequency of occurrence of false positive or false negative results which if unrecognized may lead to patient s misdiagnosis unnecessary treatment or even unnecessary surgery Deep knowledge of basic principles of immunochemical methods antigen antibody reaction standardization matrix effect limit of detection cross reactivity etc sources of analyte independent interferences preanalytical errors the presence of binding proteins the presence of autoantibodies and analyte dependent interferences presence of heterophilic antibodies high dose effect are very important to understand detect reduce and or eliminate the interferences This book helps to reduce false results and at the same time improve patient s care and patient s safety

Hematology - E-Book Bernadette F. Rodak, Elaine M. Keohane, George A. Fritsma, 2013-12-27 Featuring hundreds of full color photomicrographs Hematology Clinical Principles and Applications prepares you for a job in the clinical lab by exploring the essential aspects of hematology It shows how to accurately identify cells simplifies hemostasis and thrombosis concepts and covers normal hematopoiesis through diseases of erythroid myeloid lymphoid and megakaryocytic origins This

book also makes it easy to understand complementary testing areas such as flow cytometry cytogenetics and molecular diagnostics Well known authors Bernadette Rodak George Fritsma and Elaine Keohane cover everything from working in a hematology lab to the parts and functions of the cell to laboratory testing of blood cells and body fluid cells Full color illustrations make it easier to visualize complex concepts and show what you ll encounter in the lab Learning objectives begin each chapter and review questions appear at the end Instructions for lab procedures include sources of possible errors along with comments Case studies provide opportunities to apply hematology concepts to real life scenarios Hematology instruments are described compared and contrasted Coverage of hemostasis and thrombosis includes the development and function of platelets the newest theories of normal coagulation and clear discussions of platelet abnormalities and disorders of coagulation A bulleted summary of important content appears at the end of every chapter A glossary of key terms makes it easy to find and learn definitions Hematology hemostasis reference ranges are listed on the inside front and back covers for quick reference Respected editors Bernadette Rodak George Fritsma and Elaine Keohane are well known in the hematology clinical laboratory science world Student resources on the companion Evolve website include the glossary weblinks and content updates New content is added on basic cell biology and etiology of leukocyte neoplasias Updated Molecular Diagnostics chapter keeps you current on techniques being used in the lab Simplified hemostasis material ensures that you can understand this complex and important subject Coverage of morphologic alteration of monocytes macrophages is condensed into a table as the disorders in this grouping are more of a biochemical nature with minimal hematologic evidence

Clinical Chemistry Wendy L Arneson, Jean M Brickell, 2007-01-25 Meet the learning needs of today s students with a brand new style of textbook designed to excite your students interest in clinical chemistry Organized almost entirely around organ systems to parallel the way physicians order tests this groundbreaking text teaches the concepts and principles of clinical chemistry through realistic situations and scenarios By integrating pathophysiology biochemistry and analytical chemistry for each major system students clearly see the relevance of what they are learning to their future careers This practical approach encourages them how to apply theoretical principles in the laboratory and to develop important critical thinking skills

Quality in Laboratory Hemostasis and Thrombosis Steve Kitchen, John D. Olson, F. Eric Preston, 2013-02-26

Quality in Laboratory Hemostasis and Thrombosis Second Edition Edited by Steve Kitchen Clinical Scientist Sheffield Haemophilia and Thrombosis Centre Royal Hallamshire Hospital and Scientific Director UK National External Quality Assessment Scheme FQAS for Blood Coagulation Scientific Director WHO and WFH International External Quality Assessment Programs for Blood Coagulation Sheffield UK John D Olson Professor and Vice Chair for Clinical Affairs Department of Pathology University of Texas Health Sciences Centre San Antonio Texas USA F Eric Preston Emeritus Professor of Haematology University of Sheffield and Director WHO and WFH International External Quality Assessment Programs for Blood Coagulations Sheffield UK The hemostasis laboratory has a vital role in the diagnosis and management of

patients with familial and acquired hemorrhagic and thrombotic disorders Rapid changes in the number and complexity of tests in this discipline have presented challenges for laboratories as they develop quality programs for the oversight of this testing Quality in Laboratory Hemostasis and Thrombosis has been completely revised and updated to reflect the changing process of managing quality The second edition provides information on all aspects of testing from pre analytic to analytic and result reporting in addition to external quality assurance Chapters throughout the book include the development of global guidelines for methods as well as the preparation of international standard plasmas and reagents Designed to capture the elements of quality at all levels of the practice of laboratory hemostasis and thrombosis this book will guide the reader through the development of a quality program to support all activities in the hemostasis laboratory both simple and complex Titles of related interest Lee Textbook of Hemophilia 2e 2010 ISBN 9781405169141 Federici Von Willebrand Disease Basic and Clinical Aspects 1e 2011 ISBN 9781405195126 Ma Hemophilia and Hemostasis A Case Based Approach to Management 2e 2012 ISBN 9780470659762 **Archives of Pathology & Laboratory Medicine** ,2007 American Journal of Veterinary Research ,2008 Vols for 1956 include selected papers from the proceedings of the American Veterinary Medical Association **CURRENT Diagnosis and Treatment Pediatrics, Nineteenth Edition** William W. Hay, Myron J. Levin, Robin R Deterding, Judith M. Sondheimer, 2008-10-01 Market Pediatricians Pediatrics Residents Pediatric Nurse Practitioners Family Practitioners Medical Students CD ROM with clinical images and references that link to web resources The best selling midsize pediatrics book on the market CURRENT Diagnosis and Treatment Pediatrics, Nineteenth Edition William Hay, Myron Levin, Robin Deterding, Judith Sondheimer, 2008-09-22 The Classic On the Go Guide to Pediatric Practice Now More Current and Essential Than Ever A Doody's Core Title CURRENT Diagnosis and Treatment Pediatrics has long been the go to guide for students residents and practitioners looking for concise reliable and up to date information It continues to provide succinct up to date and clinically relevant coverage of how to assess and treat common disorders in children from eating disorders and cardiovascular diseases to STDs Features Easy to follow LANGE CURRENT outline format Problem Essentials of Diagnosis and Typical Features Clinical Findings Differential Diagnosis Treatment Prognosis Organized by general topics such as care of the newborn and community pediatrics as well as by organ system and specific disease problems Essentials of Diagnosis and Typical Features provide instant guidance on identifying both common and rare problems Accessible overviews of important pediatric health concerns including substance abuse psychiatric disorders child abuse and neglect normal childhood nutrition and its disorders and emergencies and injuries NEW to this edition chapter on Sport Medicine a key area of pediatrics for which students and residents state they need more training ACGME survey completely reorganized section on Infectious Diseases reflecting the most recent clinical perspectives expanded section on lab and reference values **Current Pediatric Diagnosis & Treatment** William W. Hay, 2007 Authoritative timely pediatrics coverage in a find it now format Current Diagnosis Treatment in Pediatrics 18e offers concise clinically oriented

coverage of the ambulatory and hospital care of children from birth through infancy and adolescence Utilizing the popular Current Series format this handy guide answers all the questions that come up in daily practice and provides the details necessary to make a sound diagnosis and treatment plan

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