

# Lab Guidelines & Standards

## CLSI Issues Unifying Standard for Performing the Erythrocyte Sedimentation Rate Test

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The erythrocyte sedimentation rate (ESR) test has been around for more than 70 years and is one of the most widely performed laboratory tests. It is performed with various types of tubes, using both diluted and undiluted blood, on a variety of automated and manual platforms. In recent years, the laboratory community has witnessed the emergence of a number of technical innovations and semi-automated instruments designed to reduce the risk of exposure to infection in laboratory workers. Each of these innovations requires thorough examination for comparability of results to those of previous methods, as well as the quality assurance of those results. In a particularly timely move, the Clinical and Laboratory Standards Institute (CLSI) has addressed these needs in a new, unifying standard, *Procedure for the Erythrocyte Sedimentation Rate Test: Approved Standard—Fifth Edition (H02-A5)*.<sup>1</sup>

According to Dr. S. Mitchell Lewis, a renowned hematologist and a member of the group of CLSI volunteers who developed the document, H02 outlines a new standard that addresses various methods in use for measuring the ESR, as well as the Westergren method, the benchmark standard against which other methods are evaluated. The document provides guidance on the use of automated instruments and explains how different methods can be compared for accuracy and correlation to one another. H02 also describes the principle, materials, and procedure of the ESR; a procedure to evaluate routine methods; and guidance for developing a quality program for laboratory ESR tests.

Dr. Lewis recognizes that the ESR is sometimes considered a redundant test with little clinical specificity. However, he emphasizes that the test does have a very legitimate value and can be both diagnostic and prognostic when used correctly. He describes its usefulness in following the progress of certain inflammatory processes, and its role as the first indication of a developing illness in certain instances, citing examples in which the ESR may be abnormal while more specific test results may be normal. Its proven value in specific clinical situations makes it essential to perform the ESR in a standardized, carefully controlled manner.

"This particular iteration is a revised format that incorporates new technologies, considers environmental factors, and outlines a new reference method," explains Dr. Lewis. "It discusses current clinical applications and changes to the current reference method, and provides guidance on how to evaluate the reference method for accuracy. It is quite unique in this regard."

The differences pointed out by Dr. Lewis emphasize that this CLSI document is a revision—the fifth edition—and

supersedes the fourth edition that was published in 2006. In addition to the improvements and clarifications mentioned by Dr. Lewis, the new standard contains a comprehensive list of references from the literature, as well as an appendix providing the protocol for the evaluation of routine-working ESR methods against the standardized method, and, finally, a listing of related CLSI documents.

The reference method is based on the original methodology of Pärnström and Westergren and uses a 1:4-diluted blood specimen. Quality assurance includes controlling environmental factors that are frequently overlooked, and addresses the often-confusing method of preparing a fresh blood reference material, given the difficulty of acquiring such material commercially.

"This document is important because universally recognized guidelines help promote awareness and best practices, and keep those who are interested in procedures for ESR up to date," says Dr. Chiara D'Antonio, another expert who contributed to the revision of H02. "The document will contribute to both clinical laboratories and ESR instrument manufacturers, not only because of the ESR test itself, but also owing to the new, updated selection of scientific references."

H02 should find universal appeal, both internationally and among various stakeholders, including clinical laboratories, manufacturers, and regulatory and accrediting agencies. Clinical laboratories will find the document useful for developing policies and procedures, as well as for selecting, evaluating, and comparing devices and methods (both manual and automated). Guidance is also provided for establishing a quality assurance program.

Manufacturers will benefit from the references provided, and, assuming their products meet the specifications of the standard, they will be able to help their customers meet and document requirements of regulatory and accrediting agencies. In turn, these agencies can use this CLSI standard to measure how well clinical laboratories are meeting required performance standards.

Because of the variation that exists in practice, difficulty in obtaining fresh reference material, and the influence of environmental factors (e.g., tubes, angle of tube positioning, surface vibrations), the document is written as a standard, rather than a guideline. A guideline allows more flexibility and customization. A standard, according to Dr. Lewis, is based on more specific, essential requirements for materials, methods, and practice. This contributes to the value and objective utility of this document by all stakeholders.

*H02 is designed to promote one universal standard and one best practice for all those performing the ESR test. It is currently available from CLSI at [www.clsi.org](http://www.clsi.org) or by calling 810-685-9100.*

# Lab Guidelines Labmedicine

**RC Schank**

A red circular graphic with a gradient, appearing as a semi-circle or a partial circle, located to the right of the 'RC Schank' text.

## **Lab Guidelines Labmedicine:**

A Manual of Laboratory and Diagnostic Tests Frances Talaska Fischbach, Marshall Barnett Dunning, 2009 Now in its Eighth Edition this leading comprehensive manual helps nurses deliver safe effective and informed care for patients undergoing diagnostic tests and procedures The book covers a broad range of laboratory and diagnostic tests and studies that are delivered to varied patient populations in varied settings Tests are grouped according to specimen and function test type e g blood urine stool cerebrospinal fluid etc Each test is described in detail with step by step guidance on correct procedure tips for accurate interpretation and instructions for patient preparation and aftercare Clinical Alerts highlight critical safety information      *Immunology & Serology in Laboratory Medicine - E-Book* Mary Louise Turgeon, 2020-12-16 Building on a solid foundation of knowledge and skills this classic text from trusted author Mary Louise Turgeon clearly explains everything from basic immunologic mechanisms and serologic concepts to the theory behind procedures performed in the lab This go to resource prepares you 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 the key to your success in today s modern laboratory environment Procedural protocols help you transition from immunology theory to practical aspects of the clinical lab Case studies allow you to apply your knowledge to real world situations and strengthen your critical thinking skills Updated illustrations photographs and summary tables visually clarify key concepts and information Full color presentation clearly showcases diagrams and micrographs giving you a sense of what you will encounter in the lab Learning objectives and key terms at the beginning of each chapter provide measurable outcomes and a framework for organizing your study efforts Review questions at the end of each chapter provide you with review and self assessment opportunities NEW Highlights of Immunology chapter presents a clear accessible and easy to understand introduction to immunology that will help you grasp the complex concepts you need to understand to practice in the clinical lab NEW Stronger focus on molecular laboratory techniques NEW Ten chapters include COVID 19 related topics including Primer on Vaccines chapter covering newer vaccine production methods focusing on DNA and RNA nucleic acids and viral vectors and covering eight different platforms in use for vaccine research and development against SARS CoV 2 virus NEW All chapters include significant updates based on reviewer feedback NEW Key Concepts interwoven throughout each chapter highlight important facts for more focused learning      **Antibiotics in Laboratory Medicine** Victor Lorian, 2005 Implement the most current science and practice in antimicrobial research Now find the newest approaches for evaluating the activity mechanisms of action and bacterial resistance to antibiotics with this completely updated landmark reference Turn to this comprehensive reference for groundbreaking evidence on the molecular link between chemical disinfectants sterilants and antibiotics On the latest methods for detecting antibacterial resistance genes in the clinical laboratory and antivirogram use to select the most active

antiviral components against your patient's HIV      Clinical Laboratory Medicine Kenneth D. McClatchey, 2002 This thoroughly updated Second Edition of Clinical Laboratory Medicine provides the most complete current and clinically oriented information in the field. The text features over 70 chapters, seven new to this edition, including medical laboratory ethics, point of care testing, bone marrow transplantation, and specimen testing, providing comprehensive coverage of contemporary laboratory medicine. Sections on molecular diagnostics, cytogenetics, and laboratory management, plus the emphasis on interpretation and clinical significance of laboratory tests, why a test or series of tests is being done, and what the results mean for the patient, make this a valuable resource for practicing pathologists, residents, fellows, and laboratorians. Includes over 800 illustrations, 353 in full color and 270 new to this edition. Includes a Self Assessment and Review book.

**Evidence-based Laboratory Medicine** Christopher P. Price, Robert H. Christenson, 2003      **Laboratory Management Information Systems: Current Requirements and Future Perspectives** Moutzoglou, Anastasius, 2014-07-31

Technological advances have revolutionized the way we manage information in our daily workflow. The medical field has especially benefitted from these advancements, improving patient treatment, health data storage, and the management of laboratory samples and results. Laboratory Management Information Systems: Current Requirements and Future Perspectives responds to the issue of administering appropriate regulations in a medical laboratory environment in the era of telemedicine, electronic health records, and other e-health services. Exploring concepts such as the implementation of ISO 15189:2012 policies and the effects of e-health applications, this book is an integral reference source for researchers, academicians, students of health care programs, health professionals, and laboratory personnel.      Tietz Textbook of Laboratory Medicine - E-Book Nader Rifai, 2022-02-03 Use THE definitive reference for laboratory medicine and clinical pathology. Tietz Textbook of Laboratory Medicine, 7th Edition, provides the guidance necessary to select, perform, and evaluate the results of new and established laboratory tests. Comprehensive coverage includes the latest advances in topics such as clinical chemistry, genetic, metabolic disorders, molecular diagnostics, hematology, and coagulation; clinical microbiology, transfusion medicine, and clinical immunology. From a team of expert contributors led by Nader Rifai, this reference includes access to wide-ranging online resources on Expert Consult, featuring the comprehensive product with fully searchable text, regular content updates, animations, podcasts, over 1300 clinical case studies, lecture series, and more. Authoritative current content helps you perform tests in a cost-effective, timely, and efficient manner, provides expertise in managing clinical laboratory needs, and shows how to be responsive to an ever-changing environment. Current guidelines help you select, perform, and evaluate the results of new and established laboratory tests. Expert, internationally recognized chapter authors present guidelines representing different practices and points of view. Analytical criteria focus on the medical usefulness of laboratory procedures. Use of standard and international units of measure makes this text appropriate for any user anywhere in the world. Elsevier eBooks provides the entire text as a fully searchable eBook and includes animations, podcasts, more than 1300 clinical case studies, over 2500

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Henry's Clinical Diagnosis and Management by Laboratory Methods E-Book Richard A. McPherson, Matthew R. Pincus, 2017-04-05 Recognized as the definitive reference in laboratory medicine since 1908 Henry s Clinical Diagnosis continues to offer state of the art guidance on the scientific foundation and clinical application of today s complete range of laboratory tests Employing a multidisciplinary approach it presents the newest information available in the field including new developments in technologies and the automation platforms on which measurements are performed Provides guidance on error detection correction and prevention as well as cost effective test selection Features a full color layout illustrations and visual aids and an organization based on organ system Features the latest knowledge on cutting edge technologies of molecular diagnostics and proteomics Includes a wealth of information on the exciting subject of omics these extraordinarily complex measurements reflect important changes in the body and have the potential to predict the onset of diseases such as diabetes mellitus Coverage of today s hottest topics includes advances

in transfusion medicine and organ transplantation molecular diagnostics in microbiology and infectious diseases point of care testing pharmacogenomics and the microbiome Toxicology and Therapeutic Drug Monitoring chapter discusses the necessity of testing for therapeutic drugs that are more frequently being abused by users

**Henry's Clinical Diagnosis and Management by Laboratory Methods: First South Asia Edition\_E-book** Richard A. McPherson, 2016-08-31 To interpret the laboratory results To distinguish the normal from the abnormal and to understand the merits and demerits of the assays under study The book attempts to train a laboratory medicine student to achieve sound knowledge of analytical methods and quality control practices to interpret the laboratory results to distinguish the normal from the abnormal and to understand the merits and demerits of the assays under study

*Clinical and Laboratory Medicine Textbook* Marcello Ciaccio, 2024-02-21 This textbook describes several diseases and clinical conditions from physiopathological mechanisms to main clinical pictures highlighting the importance of laboratory medicine with the aim to provide the necessary tools for guiding correct laboratory findings interpretation Indeed it is now widely recognized that laboratory medicine has a pivotal role in clinical medicine significantly influencing clinical decisions Thus it is crucial to understand and use laboratory data appropriately This book has the great advantage of describing each topic exhaustively in order to facilitate its understanding Specifically it describes both diseases with a high incidence in the population such as Diabetes Mellitus Cardiovascular Diseases Dyslipidemias and Autoimmune Diseases as well as rare diseases such as Hereditary Metabolic Diseases In addition unusual topics are treated such as Clinical Biochemistry of the Mind as well as hot topics such as Biological Drugs Biobanks Health Technology Assessment and Omics Sciences Finally the book includes a chapter on the new health emergency the SARS CoV 2 pandemic Two appendices are provided at the end of the book a table summarizing the reference range and decisional cut off for the main laboratory parameters and instructions on performing a venous blood sample The book will be an invaluable tool for medical and biomedical students as well as for practitioners

[Lessons from External Quality Control in Laboratory Medicine: Important Implications for Public Health!](#) Klaus-Peter Hunfeld, Hansotto Reiber, Piet Meijer, Peter Lupp, Dirk Schlüter, Michael Spannagl, Douglas Norris, Ingo Schellenberg,

**Molecular Pathology, An Issue of the Clinics in Laboratory Medicine** Lauren Ritterhouse, 2024-06-04 In this issue of Clinics in Laboratory Medicine guest editor Lauren L Ritterhouse brings her considerable expertise to the topic of molecular pathology Experts in the field cover topics such as molecular pathology of lung cancer gliomas prostate cancer and more Contains 14 relevant topics including clinical utilization and designing a test menu molecular alteration in pediatric solid tumors pan cancer molecular biomarkers and more Provides in depth clinical reviews on molecular pathology offering actionable insights for 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

*Mass Spectrometry, An Issue of Clinics in Laboratory Medicine* Nigel Clarke, Andrew N. Hoofnagle, 2011-12-28 This issue of Clinics in Laboratory

Medicine Guest Edited by Nigel Clarke MD and Andrew Hoofnagle MD will focus on Mass Spectrometry with topics including Proteins Peptides Small Molecules Toxicology Small Molecules Diagnostics and Regulatory Considerations Advances in Clinical Cytometry, An Issue of the Clinics in Laboratory Medicine, E-Book Christopher B. Hergott, 2023-07-24 In this issue of Clinics in Laboratory Medicine guest editor Dr Christopher Hergott brings his considerable expertise to the topic of Advances in Clinical Cytometry Flow cytometry is an essential tool in biology pathology and medicine thanks to its combination with the advancements in computer sciences In this issue top experts inform readers on the various aspects of clinical cytometry and its applications in the field as well as new technologies Contains 11 practice oriented topics including immunophenotypic profile of the healthy human bone marrow advances in monitoring and prognostication for lymphoma by flow cytometry clinical flow cytometry for Hodgkin s lymphoma clinical cytometry and translational drug development and more Provides in depth clinical reviews of advances in clinical cytometry 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

*Clinical Laboratory Management* Timothy C. Allen, Vickie S. Baselski, Deirdre L. Church, Donald S. Karcher, Michael R. Lewis, Andrea J. Linscott, Melinda D. Poulter, Gary W. Procop, Alice S. Weissfeld, Donna M. Wolk, 2024-03-25 Clinical Laboratory Management Apply the principles of management in a clinical setting with this vital guide Clinical Laboratory Management Third Edition edited by an esteemed team of professionals under the guidance of editor in chief Lynne S Garcia is a comprehensive and essential reference for managing the complexities of the modern clinical laboratory This newly updated and reorganized edition addresses the fast changing landscape of laboratory management presenting both foundational insights and innovative strategies Topics covered include an introduction to the basics of clinical laboratory management the regulatory landscape and evolving practices in the modern healthcare environment the essence of managerial leadership with insights into employee needs and motivation effective communication and personnel management including the lack of qualified position applicants burnout and more financial management budgeting and strategic planning including outreach up to date resources for laboratory coding reimbursement and compliance reflecting current requirements standards and challenges benchmarking methods to define and measure success the importance of test utilization and clinical relevance future trends in pathology and laboratory science including developments in test systems human resources and workforce development and future directions in laboratory instrumentation and information technology an entirely new section devoted to pandemic planning collaboration and response lessons learned from COVID 19 and a look towards the future of laboratory preparedness This indispensable edition of Clinical Laboratory Management not only meets the needs of today s clinical laboratories but anticipates the future making it a must have resource for laboratory professionals managers and students Get your copy today and equip yourself with the tools strategies and insights to excel in

the complex and ever changing world of the clinical laboratory      Toxicology Testing, An Issue of Clinics in Laboratory Medicine Michael G. Bissell, 2012-09-28 This issue of Clinics in Laboratory Medicine titled Toxicology Testing includes the following topics Progress in Clinical Toxicology Testing The Prescription Drug Abuse Epidemic Substance Abuse Among Healthcare Professionals Pain Management Drug Testing Ethanol Biomarkers Newly emerging Drugs of Abuse Synthetic Cannabinoids Synthetic Cathenones Immunoassay Methodology in Drugs of abuse Testing Toxicology Testing in Alternative Specimen Matrices Principles and Procedures in Postmortem Toxicology and Pharmacogenetics and the Future of Toxicology Testing Advances in toxicology testing are paving the way for major improvements in the way scientists evaluate health risks posed by toxic chemicals Toxicity tests help scientists better understand how the human body carries out normal functions that are key to maintaining health Therefore this topic is important to the field of Laboratory Medicine      **Year Book of Pathology and Laboratory Medicine 2015** Stephen S. Raab, 2016-07-29 The Year Book of Pathology and Laboratory Medicine brings you abstracts of the articles that reported the year s breakthrough developments in pathology and laboratory medicine carefully selected from more than 500 journals worldwide Expert commentaries evaluate the clinical importance of each article and discuss its application to your practice There s no faster or easier way to stay informed Chapters in this annual cover the most current information on all aspects of pathology and laboratory medicine including molecular diagnostics anatomic pathology techniques outcomes analysis cytopathology and clinical immunology and hematology      *Laboratory Medicine in Psychiatry and Behavioral Science, Second Edition* Sandra A. Jacobson, M.D., 2023-03-24 This second edition of Laboratory Medicine in Psychiatry and Behavioral Science is substantially revised from the first edition published in 2012 In the intervening decade an explosion of research and publication related to laboratory science and psychiatry has left virtually no subject area untouched As with the first edition this manual is designed to assist psychiatrists and other behavioral health clinicians in the care of adult psychiatric patients across a wide range of settings Among the thousands of laboratory tests available tests that were selected for inclusion met one or more of the following criteria a core or basic laboratory test for any patient a test that is particularly pertinent to psychiatry or behavioral health or a test that is new to medicine and potentially of interest in the field of behavioral health including geriatrics Diseases and conditions selected for inclusion were those for which laboratory tests are primary or important in diagnosis or differential diagnosis those that are core or common conditions among psychiatric or geriatric patients and those that have important psychiatric cognitive or behavioral consequences The appendixes contain several algorithms tables and figures that may be useful in understanding and interpreting various laboratory tests and their underlying biology      Linne & Ringsrud's Clinical Laboratory Science - E-Book Mary Louise Turgeon, 2015-02-10 Using a discipline by discipline approach Linne perforated pages make it easy for students to remove for use in the lab and for assignment of review questions as homework NEW Instrumentation updates show new technology being used in the lab NEW Additional



key terms in each chapter cover need to know terminology NEW Additional tables and figures in each chapter clarify clinical lab science concepts

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