

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 infectious 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)*.¹

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 methodologies, 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 2000. 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 Pálfi 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 Derioni, 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 (eg, 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 our best practice for all those performing the ESR test. It is currently available from CLSI at www.clsi.org or by calling 610-685-9120.

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