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June 2006

## H56-A

### Body Fluid Analysis for Cellular Composition; Approved Guideline

This guideline provides users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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## Body Fluid Analysis for Cellular Composition; Approved Guideline

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### Abstract

Clinical and Laboratory Standards Institute document H56-A—*Body Fluid Analysis for Cellular Composition; Approved Guideline* provides recommendations for standardizing the collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid.

Clinical and Laboratory Standards Institute (CLSI). *Body Fluid Analysis for Cellular Composition; Approved Guideline*. CLSI document H56-A (ISBN 1-56238-614-X). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2006.

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## Foreword

Clinical data derived from proper body fluid procedures and accurate test results are essential to make the appropriate diagnosis and administer the proper therapy to patients. Some variables may influence the test results reported. Because these variables are loosely defined, inconsistency from one institution to another may exist. This guideline will provide users with recommendations for the collection and transport of body fluids, procedures for the numeration and identification of cellular components, and guidelines for the qualitative and quantitative assessment of body fluids.

### *A Note on Terminology*

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all challenges to harmonization. Despite these challenges, CLSI recognizes that harmonization of terms facilitates the global application of standards and is an area that needs immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

### **Key Words**

Body fluids, bronchoalveolar lavage, cerebrospinal fluid, pericardial fluid, peritoneal fluid, pleural fluid, serous fluid, synovial fluid

SAMPLE

## Body Fluid Analysis for Cellular Composition; Approved Guideline

### 1 Scope

The intended purpose of this guideline is to explain how to collect, process, examine, store, and report results for body fluid specimens for the characterization of inflammatory, infectious, neoplastic, and immune alterations. It will also discuss preanalytical, analytical, and postanalytical variables related to body fluid cellular analyses. For the purpose of this document, the following body fluids will be discussed: cerebrospinal, serous (pleural, peritoneal, pericardial) and related fluids (i.e., peritoneal dialysate, peritoneal lavage), bronchoalveolar, and synovial fluids.

This guideline describes manual and automated methods to enumerate cellular components and to identify normal and abnormal elements. It also addresses additional studies that may be used for body fluid testing in the routine clinical laboratory.

This document is intended for medical technologists, pathologists, microbiologists, cytologists, nurses, and other healthcare professionals responsible for the collection and transport of body fluid specimens to the clinical laboratory, as well as the processing, testing, and reporting of results. It is also intended for manufacturers of products or instruments used for body fluid testing.

### 2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to “standard precautions.” Standard precautions are guidelines that combine the major features of “universal precautions and body substance isolation” practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol.* 1996;17(1):53-80). For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most current edition of CLSI document M29—*Protection of Laboratory Workers From Occupationally Acquired Infections*.

### 3 Definitions

**accuracy (of measurement)** – closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93).<sup>1</sup>

**analytical sensitivity** – *in quantitative testing*, the change in response of a measuring system or instrument divided by the corresponding change in the stimulus (modified from VIM93)<sup>1</sup>; **NOTE 1:** The sensitivity may depend on the value of the stimulus; **NOTE 2:** The sensitivity depends on the imprecision of the measurements of the sample; **NOTE 3:** *In qualitative testing*, the test method’s ability to obtain positive results in concordance with positive results obtained by the reference method; **NOTE 4:** If the true sensitivity of a device is better than the reference method, its apparent specificity will be less and the level of apparent false-positive results will be greater; **NOTE 5:** For FISH, the percentage of scorable nuclei or metaphase cells with the expected signal pattern (number of signals, size of signals, and color of signals).



**analytical specificity** – ability of a measurement procedure to measure solely the measurand (ISO 17511).<sup>2</sup>

**antibody** – specific immunoglobulin formed by B lymphocytes and plasma cells in response to exposure to an immunogenic substance and able to bind to the antigen.

**anticoagulant (additive)** – an agent that prevents coagulation of blood or blood products.

**arthrocentesis** – aspiration of a joint.

**arthrocentesis fluid** – joint fluid obtained from aspiration of a joint.

**carry-over** – the discrete amount of analyte carried by the measuring system from one specimen reaction into subsequent specimen reactions, thereby erroneously affecting the apparent amounts in subsequent specimens.

**cerebrospinal fluid** – fluid within the ventricles of the brain and the subarachnoid space.

**collection vessel** – any tube or container, preferably plastic, which serves to contain the body fluid specimen.

**empyema fluid** – the presence of pus in a body cavity; usually refers to pus in the pleural cavity.

**epitope** – any site on an antigen molecule at which an antibody can bind; the chemical structure of the site determining the specific combining antibody.

**exudate** – a fluid with a high concentration of protein or cells that accumulates in a body cavity as a result of increased capillary permeability.

**immunocytochemical assay//immunohistochemical assay** – an immunoassay that detects an antigen present in a specimen that is contained within intact or histologically sectioned cells or tissues.

**immunocytology//immunocytochemistry** – localization of immunoreactive substances within cells of a cytological specimen that have been specifically labeled with an antibody.

**immunohistology//immunohistochemistry** – localization of immunoreactive substances within cells or tissues of a histological specimen that have been specifically labeled with an antibody.

**measurand** – particular quantity subject to measurement (VIM93)<sup>1</sup>; **NOTE 1:** For example, vapor pressure of a given sample of water at 20 °C (VIM93)<sup>1</sup>; **NOTE 2:** The specification of a measurand may require statements about quantities such as time, temperature, and pressure (VIM93)<sup>1</sup>; **NOTE 3:** In the example above, the measurand includes not only the entity being measured (water), but the particular quality being measured (vapor pressure), and the specific environmental condition under which it is being measured (20 °C); **NOTE 4:** The term measurand and its definition encompass all quantities, while the commonly used term “analyte” refers to a tangible entity subject to measurement; for example, “substance” concentration is a quantity that may be related to a particular analyte.

**measuring range** – a set of values of measurands for which the error of a measuring instrument is intended to lie within specified limits (VIM93).<sup>1</sup>

**peritoneal dialysate fluid** – a physiologic synthetic fluid introduced into the peritoneal cavity for the purpose of normalizing fluid, electrolyte, and solute balance in the body using the principles of ultrafiltration and diffusion.

## The Quality System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any healthcare service’s path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are:

Documents & Records Organization	Equipment Purchasing & Inventory Process Control	Information Management Occurrence Management Assessment	Process Improvement Service & Satisfaction Facilities & Safety
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H56-A addresses the quality system essentials (QSEs) indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
GP2		GP21			X C49 EP5 EP6 EP9			GP29	GP27		

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

## Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

H56-A addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Patient Assessment	Preexamination				Examination		Postexamination	
	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
		X	X	X GP16	X		X	

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

## Related CLSI/NCCLS Publications\*

- C49-P**      **Analysis of Body Fluids in Clinical Chemistry; Proposed Guideline (2006).** This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays typically have performance claims in the measurement procedure documentation.
- EP5-A2**      **Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (2004).** This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturers' precision performance claims and determining when such comparisons are valid; as well as manufacturers' guidelines for establishing claims.
- EP6-A**      **Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).** This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.
- EP9-A2**      **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (2002).** This document addresses procedures for determining the bias between two clinical methods, and the design of a method comparison experiment using split patient samples and data analysis.
- GP2-A5**      **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.
- GP16-A2**      **Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition (2001).** This guideline describes routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations.
- GP21-A2**      **Training and Competence Assessment; Approved Guideline—Second Edition (2004).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality/regulatory objectives.
- GP27-A**      **Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline (1999).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.
- GP29-A**      **Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline (2002).** This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

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\* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

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