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# 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

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



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*Advancing Quality in Healthcare Testing*

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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.

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(Formerly NCCLS)



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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



## 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).