Guidelines for CLSI Delegates and Alternate Delegates

Take Advantage of All CLSI Has to Offer With This **Helpful Guide**

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Engage With Colleagues. Access Valuable Resources. Help Raise the Standards of Patient Care.

Dear Delegate,

Welcome to the Clinical and Laboratory Standards Institute (CLSI)! We thank you and your organization for choosing to join CLSI. As a valued member of our team, we hope to make your experience worthwhile, interesting, and enjoyable. As your organization's Delegate to CLSI, you have been selected to be the primary liaison between your organization and CLSI. These guidelines are intended to help you understand your responsibilities, and to ensure that your organization takes full advantage of all CLSI has to offer.

As a Delegate, you are being asked to represent your organization in several aspects of CLSI's work, including voting and commenting on documents, recruiting and nominating committee members, proposing documents your organization needs, and performing other tasks that will be outlined further in these guidelines.

Your commitment to the consensus process supports quality patient testing and the health care community as a whole. Thank you for doing your part to help CLSI set the standard for quality worldwide.

Sincerely,

Glen Fine, MS, MBA, CAE
Chief Executive Officer
CLSI

Your Responsibilities as a Delegate

You have been selected by your organization to manage its membership benefits and be its representative to CLSI.

In this role, you have certain responsibilities that will ensure your organization maximizes its participation in CLSI. Your biggest responsibility is communication, both with CLSI and within your organization regarding CLSI's activities.

In addition to managing your membership benefits, your other responsibilities include:

- **Voting and commenting on draft documents** – Be sure you are representing your organization's voice on documents that pertain to you.
- **Recruiting volunteers to participate in CLSI's consensus process** – Bring your organization's expertise to the table to help create meaningful standards.
- **Proposing standards for development** – Help CLSI brainstorm ideas for new standards applicable to your industry that will make your daily work easier.
- **Nominating candidates for the Board of Directors** – Bring your organization's voice to the highest level within CLSI.
- **Informing your colleagues of the value that CLSI standards bring to your organization** – Make sure you and your team are following the CLSI best practices to ensure high quality.
- **Communicating the value of CLSI to the health care community, whenever possible** – Help bring the good work of CLSI to all the places where it is needed.
- **Administering any membership benefits within your organization** – Make sure your organization is taking full advantage of the resources CLSI provides.

Your organization can also appoint an **Alternate Delegate** who can assist with the responsibilities associated with the position. He or she will be included on communications about your membership, and be able to vote in your place. We recommend that you work closely with the Alternate Delegate to fit CLSI activities and responsibilities into your respective daily routines.

The following pages describe CLSI and our processes to help you better comprehend how we work so you can fully understand your membership and your role on our team.

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Membership in CLSI

Membership is an effective way to take advantage of all CLSI has to offer, including participating in the consensus process. CLSI offers membership options designed to meet every organization's specific needs.

Membership Categories

CLSI offers Organizational Membership for Industry and Large Commercial Laboratories, Health Care Professions, and Government and Public Health Agencies. We also offer Individual Membership for professionals associated with the health care profession and/or clinical and laboratory services as well as full-time students enrolled in academic programs.

A new Health System Membership level, in which one membership will cover all sites with system-wide access to CLSI standards, will be available soon.

Industry and Large Commercial Laboratories

These members Include:

- *In Vitro* Diagnostic Device Manufacturers
- Pharmaceutical Companies
- IT/Laboratory Information Systems
- Start-up Companies
- Consulting Firms
- Large Commercial Laboratories
- Large Independent Laboratories
- Trade Associations

	Membership Level		
Industry and Large Commercial Laboratories Membership Benefits	I	II	III
70% Discounts On CLSI products/services/programs	☑		
60% Discounts On CLSI products/services/programs		☑	
50% Discounts On CLSI products/services/programs			☑
***e*CLIPSE™ Ultimate Access** Online access to all published documents, for everyone at your company	☑		
***e*CLIPSE™ Ultimate Access** Online access to all published documents, for two concurrent users		☑	
Infobase™ CLSI's standards library on CD-ROM	☑	☑	☑
Continuing Education Credits Up to 10 free document competency quizzes per year for a total of 20 continuing education credits per organization	☑	☑	
Educational Webinars One free registration for all CLSI-hosted webinars, approximately 8–10/year	☑	☑	
Companion Products A free copy of any toolkits, DVDs, quick guides, wall charts, etc.	☑		
Free Shipping For orders within the United States	☑	☑	
Recognition as a High-Level Supporter of CLSI at Committee Weeks and Other Meetings Signage at registrations and within the booth	☑	☑	
Membership *e*News	☑	☑	☑
Special Members-Only Deals and Discounts With access to the "Members Only" Web section with a directory and volunteer opportunities	☑	☑	☑
Standards Development Propose new projects; volunteer and nominate candidates to develop consensus standards; vote on consensus documents	☑	☑	☑
Governance Voting member on officer changes and bylaws	☑	☑	☑
Networking With peers, customers, regulators, and accreditation representatives via meetings, online communities, and Members Only Web section access	☑	☑	☑

Health Care Professions

These members Include:

- Hospital, Physician, Veterinary, Academic, and Reference-based Laboratories
- Independent Laboratories
- Small Commercial Laboratories
- Professional Associations and Societies
- Charitable Organizations
- Accreditors
- Colleges and Universities
- Medical Technology Programs
- Pharmacies

Government and Public Health Agencies

These members Include:

- National Agencies/Health Ministries
- State and Provincial Agencies
- Regional and Local Agencies
- Public Health Services
- Veterans Administrations

	Membership Level		
Health Care Professions and Government Membership Benefits	I	II	III
70% Discounts On CLSI products/services/programs	☑		
60% Discounts On CLSI products/services/programs		☑	
50% Discounts On CLSI products/services/programs			☑
***e*CLIPSE™ Ultimate Access** Online access to all published documents, for two concurrent users	☑		
Infobase™ CLSI's standards library on CD-ROM	☑		
All Published Documents An electronic copy of all documents published within the membership year		☑	
Continuing Education Credits Up to 10 free document competency quizzes per year for a total of 20 continuing education credits per organization	☑	☑	
Free Shipping For orders within the United States	☑	☑	
Membership *e*News	☑	☑	☑
Special Members-Only Deals and Discounts With access to the "Members Only" Web section with a directory and volunteer opportunities	☑	☑	☑
Standards Development Propose new projects; volunteer and nominate candidates to develop consensus standards; vote on consensus documents	☑	☑	☑
Governance Voting member on officer changes and bylaws	☑	☑	☑
Networking With peers, customers, regulators, and accreditation representatives via meetings, online communities, and Members Only Web section access	☑	☑	☑

Individuals

Student Member ($25)—Full-time students enrolled in an academic program

Benefits include:

- Participation on document development groups
- Discount on educational products
- A 25% discount on products/services/programs

Associate Member ($75)—Professionals associated with the health care profession and/or clinical and laboratory services

Benefits include:

- Participation on document development groups
- Discount on educational products
- A 15% discount on products/services/programs

Full Member ($250)—Professionals associated with the health care profession and/or clinical and laboratory services

Benefits include:

- Participation on document development groups
- Voting on all documents (concurrent with Delegate voting)
- Participation in governance activities (vote for the Board of Directors, be nominated for the Board, and be eligible to be selected for Board committee service)
- Discount on educational products
- A 25% discount on products/services/programs

Invoices for dues are provided annually for the upcoming year's dues. Delegates receive the invoice electronically with accompanying materials beginning three months in advance, and are responsible for ensuring payment. Please make sure the billing address is current; contact information can be updated in the "My CLSI" section of the website. If there are any difficulties or questions regarding payment, contact CLSI's Customer and Member Services at +1.610.688.0100 or **membership@clsi.org.**

Accessing Your Membership Benefits

As the Delegate for your organization, you have selected a level of membership that fits the needs and budget of your organization. At CLSI, we value your commitment to our organization and would like to make it easy for you to take advantage of the membership level you have selected.

Access to all of the benefits that are included in your membership will help your organization achieve its goals and deliver high-quality results.

Discounts on CLSI Products and Services:

Level I **70%**	Level II **60%**	Level III **50%**

As an organizational member, all employees at your location are eligible to order documents and products at the same discounted rate. In order to shop online with this benefit, they will need to add the member ID to their online profile. You will find the member ID/account number on your membership invoice and in your welcome e-mail. Please distribute this to others within your organization so they can also order at the membership rate. To have their profile added to the account, please e-mail **customerservice@clsi.org.**

Free Shipping: (Level I and Level II Members)

Level I and Level II members receive free shipping on all orders shipped within the United States.

We have extended this membership benefit to subsidiaries for our Level I Industry and Large Commercial Laboratory members. If your organization is a Level I member, all of your locations will receive the same pricing discount, and free shipping within the United States.

Online Access to All Standards: (Level I Members)

*e*CLIPSE Ultimate Access™ is an online portal that allows you and your colleagues to search our full database of 200+ documents. As the Delegate, you have been made the administrator for your account and can add as many users as you like.

- Industry and Large Commercial Laboratory Level I members receive a license for 20 concurrent member licenses.
- Industry and Large Commercial Laboratory Level II members receive a license for two concurrent member licenses.
- Health Care Professions and Government Level I members receive a complimentary license for two concurrent users.
- All other members have the option of purchasing a subscription to *e*CLIPSE with their membership discount.

eCLIPSE Ultimate Access™

Continuing Education Credits and Educational Webinars (Level I and Level II Members)

You and your colleagues can take advantage of CLSI educational programs by registering at the low member rate. Your membership discount extends to CLSI-hosted workshops, webinars, and our *e*Learning programs, including the Laboratory Quality Management System (LQMS) Certificate Program.

Level I Industry and Large Commercial Laboratory members can register one site for CLSI educational webinars for free.

Companion Products: (Level I Industry and Large Commercial Laboratory Members)

Level I Industry and Large Commercial Laboratory members may receive one complimentary copy of each companion product such as wall charts, quick guides, and DVDs upon request. To request a companion product, please e-mail **membership@clsi.org.**

Infobase™:

Level I and Level II Industry and Large Commercial Laboratories, and Level I Health Care Professions/ Government members are automatically sent a copy of Infobase free of charge. All members can order Infobase at their member discount. Infobase is published at the beginning of the year and contains the full library of CLSI documents as of January 1.

Membership *e*Newsletter and Special Offers:

We will send out a members-only *e*Newsletter quarterly featuring new products, special members-only discounts, and a highlight of ways some of our member organizations are taking advantage of CLSI membership and benefits. Please make sure you add **membership@clsi.org** to your e-mail list.

Recognition:

CLSI members are listed in the back of our documents and in the My CLSI section of the website. To be listed, your company must be in good standing at the time the document is distributed to Delegates for voting. All members are listed in the Membership directory in the My CLSI section of the website, and new members are highlighted in the Membership *e*Newsletter.

Level I Industry and Large Commercial Laboratories receive special recognition as high-level supporters of CLSI at the quarterly Committee Weeks, as well as other major meetings.

Networking:

As a Delegate, CLSI connects you with a large and diverse network of more than 2,000 organizations and their representatives, all concerned with quality laboratory testing. As a participant in CLSI's consensus process, you will help to address and mutually resolve important issues.

Volunteering:

CLSI distributes more than 75,000 documents per year, worldwide. Participation allows you to influence the development of these consensus documents by openly presenting your organization's views and perspectives on issues, and having this input considered deliberately and fairly within the process. CLSI consensus standards are increasingly being recognized by regulatory and accrediting organizations. By having an active voice, you can ensure that the documents directly affecting your organization and activities are practical and achievable.

Voting:

All CLSI member organizations are now able to appoint a Delegate who may vote on the Board of Directors and consensus documents. As the Delegate, you will receive an e-mail when an opportunity to vote is available. Voting can be done in the Workspace section on our website: **clsi.okta.com.** Voting on each document is not mandatory and each Delegate may abstain from voting at any time.

Overview of CLSI

For nearly 50 years, CLSI has been bringing together the global laboratory community for a common cause: fostering excellence in laboratory medicine. Our members, volunteers, and customers have made CLSI a respected, transformative leader in developing and implementing clinical laboratory standards.

Together, industry, government, and health care professionals work to create and implement standards that drive quality test results, enhance patient care delivery, and improve the public's health around the world. A not-for-profit organization, CLSI uses a consensus process that respects and includes the voices of laboratory medicine stakeholders.

Our Vision

Quality practices for better health.

Our Mission

Develop clinical and laboratory practices and promote their use worldwide.

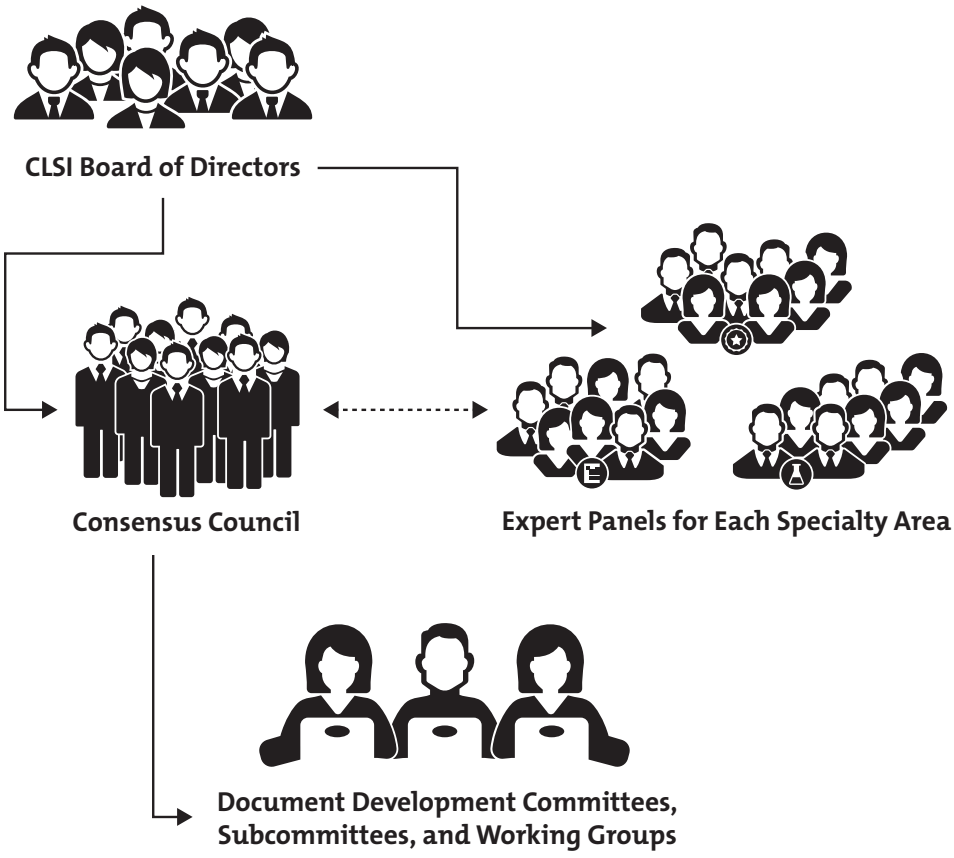
Our Values

- **Inclusiveness** – We include the viewpoints of industry, government, and the health care professions in a consensus-driven process.
- **Excellence** – We continuously improve upon our tradition of technical excellence and superior quality.
- **Responsiveness** – We proactively identify and respond to the needs of our stakeholders in an open and timely manner.
- **Integrity** – We act ethically and with fairness, trust, respect, and openness.
- **Teamwork** – We are committed to effective collaboration among members, volunteers, staff, and other partners.

CLSI's Organizational Structure

CLSI is structured in a cascading series of committees supported by our staff. Each committee includes volunteer representatives from the health care professions, government, and industry.

Each committee has specific assigned responsibilities and accountabilities. The Board of Directors governs CLSI and advances its voluntary consensus processes and its related programs in communication, education, and global harmonization. See the figure below.



CLSI Committee Structure

CLSI Committee Descriptions

Committee	Description
Board of Directors	• Elected officials who establish the policies and procedures that govern CLSI. The Board sets CLSI's vision, mission, values, and strategic direction.
Executive Committee	• Made up of the President, Immediate Past President, President-Elect, Secretary, Treasurer, and Chief Executive Officer; coordinates CLSI's governance and policy-making activities, and oversees implementation and management of programs.
Finance Committee	• Chaired by the Treasurer, this committee oversees the development of CLSI's annual budget.
Nominating Committee	• Chaired by the Immediate Past President, this committee oversees the process of nominating new members for the Board of Directors.
Consensus Council	• The Consensus Council reviews and approves project proposals, prioritizes projects, oversees project status and expenditures, and gives the final consensus approvals for publication. The Consensus Council serves as CLSI's consensus body, and therefore reviews the consensus process, not the technical content of documents.
Expert Panels	• The Consensus Council is supported by Expert Panels, which provide discipline-specific expertise as needed to ensure that the standards CLSI develops are of the highest technical and scientific quality. Approximately 10 CLSI-selected volunteers compose each Expert Panel for our key specialty areas. • Expert Panels also help fill the pipeline for timely document development by proposing new standards to champion through the process.
Document Development Committees	• These committees have primary responsibility for drafting individual consensus documents and for evaluating and addressing comments received during the consensus process. • They are also responsible for considering scientific accuracy, practicality, and comprehensibility, with the goal of creating documents of overall high quality and utility.
Subcommittees	• Primarily responsible for drafting individual consensus documents and for evaluating and addressing comments received during the consensus process. • Usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental updates of the documents and for continuous revision of certain standards. • Typically standing committees.
Working Groups	• Subunits of subcommittees or document development committees. • Assignments are limited in scope and the groups are disbanded upon completion of the assignments.

Distribution of CLSI Information

CLSI considers members to be important partners. As a Delegate, you are an important member of CLSI's team. As the primary liaison between CLSI and your organization, you will be asked to communicate your organization's position on issues—from voting and commenting on draft documents to nominating candidates for the Board of Directors, and determining the direction of CLSI.

Some aspects of your role as Delegate include:

- **Communicating your organization's needs for standardization and program activities. This can be done through direct communication with CLSI, responding to surveys, participating in Delegate focus groups, etc.**
- **Voting and commenting on draft documents in the consensus process**
- **Helping to determine the value of standards and their positive impact on your organization**
- **Encouraging and coordinating participation of experts from your organization in CLSI activities**
- **Communicating whenever possible the value of CLSI to your organization and its importance to laboratory medicine worldwide**

As a Delegate, you are encouraged to circulate CLSI's draft documents within your organization for the purposes of review and comment. For published documents, please respect CLSI's copyright and refrain from posting them on intranet sites or the Internet. Options are available for an organization to have site-wide access to CLSI's published documents. CLSI's full copyright policy can be found at **www.clsi.org/about-clsi/contact-us/copyright-permissions.**

The CLSI Consensus Process

CLSI follows a rigorous process for consensus development that is intended to be open, fair, and inclusive of our three constituencies—industry, health care professions, and government.

Mapping the Evolution of Standards Development

Our new document development process maintains the input of our diverse volunteers in the ideation and conception of new consensus-based standards. At the same time, parallel efficiencies between process and technical oversight empower CLSI to prioritize, drive, and streamline document development and production.

Ideation

New project ideas can be proposed by anyone, including individuals from our vast member base, and from the specialty leaders serving on **Expert Panels.**

Voting

In one consolidated voting period, **CLSI Delegates** and **Development Groups** are encouraged to vote and comment on the document.

Commenting

Expert Panels and the **General Public** are invited to provide meaningful comments and feedback on the document for further development and refinement.

Consensus Council

Selection

The **Consensus Council** evaluates document proposals across specialty areas and focuses resources on those that meet the greatest need.

Development Groups

Expert Panels

Development

The project's **Development Groups,** with oversight from the Consensus Council, work to draft the standard, looking to **Expert Panels** for technical input as needed.

Development Groups

Resolution

Development Groups work to refine the document, resolving all comments and feedback that arose during the voting and commenting period.

Expert Panels

Consensus Council

CLSI Staff

Recruitment

Recruitment is a collaborative effort between the **Expert Panel,** the **Consensus Council,** and **CLSI Staff.**

Consensus Council

Kickoff

Once a **Development Group** is formed, the project is presented to the **Consensus Council** for final review and approval. Development begins.

Consensus Council

Approval

The revised document is presented to the **Consensus Council,** who confirms that the consensus process was followed, and approves it for publication.

Publication

Strategies for Optimizing Organizational Participation		
1	**Uncover interests**	Determine which projects in development, as well as published documents, are of interest to your organization. Identify experts within your organization to participate on active committees. Visit the website frequently to investigate opportunities for committee participation (www.clsi.org/volunteer/call-for-volunteers/).
2	**Submit ideas**	Propose a project if there is not a CLSI document that meets a specific need. A form for preparing a proposal can be found on the CLSI website (www.clsi.org/volunteer/propose-a-project/).
3	**Get involved**	Identify experts in your organization who should be involved in standards development activities. A "Call for Volunteers" is sent to all Delegates by e-mail to solicit for committee participation. As a Delegate, you can act as a facilitator in this process by determining your organization's interest in the topic and identifying and nominating experts. Self-nominations are welcome.
4	**Be heard**	Review and vote on all documents. At the voting stage, Delegates have the opportunity to review, comment on, and vote for approval on all documents. As your organization's Delegate, you should determine whether the document is pertinent to your organization and circulate it to the appropriate experts for review.
4	**Get organized**	If your organization is large, you may want to form a standards working group to be sure that all parts of your organization are aware of CLSI activities and participating where needed.

More detailed information on the CLSI Consensus Process is provided in the CLSI **Standards Development Policies and Process document.**

Promoting CLSI

As a Delegate, you are in a unique position to communicate your involvement with CLSI. You understand the role that CLSI plays in worldwide laboratory medicine, its strategic direction, and the value that CLSI's standards bring to your organization. Feel free to find opportunities to share with others the value that CLSI brings to you!

Committee Composition:

Official committee positions are shown below. Each committee has about 10 members, as many advisors as needed for expertise, and unlimited numbers of contributors or reviewers. The committee members are balanced among CLSI's three constituencies: government, industry, and health care professions.

	DDC	SC	WG
Chairholder	☑	☑	☑
Vice Chairholder	☑	☑	☑
Member	☑	☑	☑
Secretary	☑	☑	☑
Advisor		☑	☑
Contributor	☑		
Reviewer		☑	☑

Abbreviations: DDC, document development committee; SC, subcommittee; WG, working group.

The document development process is dependent on experts' volunteer participation. Ensure that your organization's voice is heard by having your experts take part!

CLSI and ISO

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from 130 countries.

Its mission is to promote the development of standards to facilitate international exchange of goods and services, and develop cooperation in the spheres of intellectual, scientific, technological, and economic activity. ISO's works are published as International Standards.

CLSI has been designated by ANSI as the secretariat for ISO's Technical Committee 212 (ISO/TC 212), Clinical laboratory testing and in vitro diagnostic test systems. As the Secretariat, CLSI manages all of the activities of ISO/TC 212 and acts in an impartial manner to guide the development of ISO/TC 212 standards according to the ISO/IEC Directives. The ISO standards development process is a different and distinct process from that of CLSI. In ISO, each country gets one vote, no matter how many participants they have.

Currently, there are five working groups for ISO/TC 212:

- **Working Group 1, Quality and competence in the medical laboratory**
- **Working Group 2, Reference systems**
- **Working Group 3, In vitro diagnostic products**
- **Working Group 4, Microbiology and molecular diagnostics**
- **Working Group 5, Laboratory biorisk management**

Experts from more than 55 countries participate in the development process for ISO/TC 212 documents via each country's mirror group or Technical Advisory Group (TAG) or through liaison organizations such as BIPM, ILAC, IFCC, and EDMA. The United States has a TAG that US organizations can join through CLSI. US TAG membership is required if an organization wishes to engage in ISO standards development.

- **The member organization must exhibit a direct and material interest in the TAG's work.**
- **The member organization must fulfill relevant obligations including attendance, voting, and correspondence, as well as pay an administrative fee.**

See CLSI's website for more information, or call CLSI Customer Service at +1.610.688.0100.

Sustaining Memberships and Sponsorships

CLSI offers Sustaining Memberships for companies and organizations that wish to support CLSI's mission above and beyond membership dues. In addition, member organizations have the opportunity to sponsor specific CLSI events and programs throughout the year.

Many levels of sponsorships are available, and organizations can choose whether they wish to sponsor meetings, educational sessions, webinars, specific document development activities, or CLSI's Global Health Partnerships program. More information is available on CLSI's website, or by contacting CLSI's Customer and Member Services at **membership@clsi.org.**

Communicating With CLSI

Please do not hesitate to contact us with any questions you may have, or for any information you may need.

You can reach CLSI by telephone between the hours of 8:30 AM and 5:00 PM Eastern (US) Time at +1.610.688.0100. You may also call CLSI Customer and Member Services toll free at 877.447.1888 within the United States.

For e-mail, please send your correspondence to **customerservice@clsi.org,** or for membership inquiries, to **membership@clsi.org.** Technical questions can be directed to **standard@clsi.org.**

Our mailing address is:

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Clinical and Laboratory Standards Institute
(Company Page and Group)

@CLSI_LabNews

About CLSI

The **Clinical and Laboratory Standards Institute** (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: **to foster excellence in laboratory medicine by developing and implementing clinical standards and guidelines** that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

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