



COLLEGE of AMERICAN  
PATHOLOGISTS

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2024

# Laboratory-Developed Tests Advocacy Toolkit

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## INTRODUCTION

Members of the College of American Pathologists (CAP) must engage with their elected representatives to build, or enhance, relationships with legislators and their staff to address pressing issues affecting the pathology profession, such as the oversight of laboratory-developed tests (LDTs). This guide provides clear steps for reaching out to congressional offices, setting up in-district meetings, and coordinating site visits.

Inside this kit, you'll find guidance on how to initiate contact with your legislators, along with sample scripts to help you request meetings and site visits. We recommend focusing first on the legislators representing your home—your US House Representative and two Senators. You may also consider engaging with those whose districts include your workplace, but the primary focus should be on those from your home district.

We encourage you to start your outreach immediately, especially during congressional recess periods when members of Congress are most likely to be in their local districts. These periods are ideal for connecting with your lawmakers in a convenient, local setting, allowing for productive discussions on the issues that matter most to our profession.

### Call to Action

The CAP encourages you to advocate to Congress regarding laboratory-developed tests (LDTs) and the Food and Drug Administration (FDA) final rule. In May 2025, the first phase of the FDA oversight regulations on LDTs takes effect and thousands of laboratories with LDTs must comply. The CAP does not support the FDA moving forward with its regulatory oversight plan. Congress needs to enact a balanced, risk-based approach to the federal oversight of LDTs that promotes continued innovation, meets patient needs, and ensures that each test is valid, safe, and reliable. The CAP has advocated for three main principles for LDT oversight:

- Protect patients,
- Ensure continued access to safe and innovative diagnostic tests, and
- Develop a framework that is the least burdensome for pathologists and their laboratories.

## HOW TO GET INVOLVED

1. **Action alert.** [Contact legislators](#) to urge Congress to intervene with a legislative solution and stop the FDA's final rule to protect patient access to diagnostic care.
- **Virtual and/or in-district meetings with members of Congress' offices.** Conducting virtual meetings with your members of Congress provides CAP members with a convenient and flexible way to engage directly with lawmakers, discuss critical issues like the regulation of LDTs, and advocate for policies that impact the practice of pathology. Virtual meetings allow for focused discussions without the logistical challenges of in-person meetings, ensuring your voice is heard. Additionally, in-district meetings offer a powerful opportunity to connect face-to-face with legislators in their local offices, fostering stronger relationships and providing a more personal platform to discuss the needs of the pathology profession. By taking advantage of both virtual and in-district meetings, CAP members can effectively shape legislative priorities and advocate for policies that enhance patient care and support the profession of pathology.
  - **Community Events.** Members of Congress frequently participate in various community events within their district or state, which is an opportunity to connect and advocate on key issues. To stay informed, regularly check your legislators' websites, social media channels, and local town calendars. Signing up for their email updates is also helpful, as these often include details about their upcoming district schedules.
  - **Op-ed to local newspapers.** It's an election year and members of Congress are listening intently to what is happening in their district or state. Write an op-ed and submit it to your local newspaper about the importance of pathology in your community and how the FDA rule will impact your laboratory's ability to provide innovative diagnostics to patients. CAP staff can also help with drafting and submitting these op-eds.
  - **Social media communications.** Get the word out! Post about the importance of Congress stepping in with a legislative solution that provides a balanced regulatory framework that protects patient safety while maintaining access to innovative and accurate testing, and delaying the final rule while work continues. You can share the link to the [sign up form](#) on various social media platforms to encourage your fellow CAP members to participate.
  - **In-district laboratory tours with members of Congress.** Laboratory tours provide a unique, hands-on opportunity to familiarize members of Congress with the important role pathologists play in health care. When members of Congress are making legislative decisions that impact pathologists, it is crucial that they understand what pathologists do and how changes to the system will impact their ability to deliver quality care and accurately diagnose their patients. You can show the real-world impact of the FDA rule during the lab tour by even demonstrating an LDT if possible. Check out the laboratory tour toolkit [here](#). You can also send a laboratory tour request to your Congressional offices [here](#).
  - **Political fundraisers.** Attending a political fundraising event for your member of Congress offers CAP members a vital opportunity to discuss the critical issue of LDTs directly with lawmakers. This is your chance to ensure that the concerns and perspectives of pathologists are heard as Congress considers policies that could impact the future of LDTs. By connecting with your legislator in this setting, you can advocate for balanced oversight that protects patient care while fostering innovation, helping to shape the legislative approach to this essential aspect of pathology. To become more involved in PathPAC, you can email [pathpac@cap.org](mailto:pathpac@cap.org).



## ADVOCACY ACTIVITY DETAILS

### Virtual/In-district Meetings

**How to request a meeting with congressional offices.** After finding the contact information on the Congressional member's official website, you can either call or submit your request via email, webform, or simply visit the [CAP's Action Center](#) to submit your request.

#### ***For calling the office***

Hello, my name is [YOUR NAME], and I'm a pathologist residing in your district/state. I'm reaching out to arrange a meeting with [SENATOR/REPRESENTATIVE] [LAST NAME], either in person at the [CITY OF MEMBER'S OFFICE] office or virtually, to discuss important concerns regarding the regulation of laboratory-developed tests. Could you please guide me on the best way to submit a formal meeting request, and if it should be directed to [SCHEDULER'S NAME]?

#### ***For submitting your meeting request in writing:***

Dear [SENATOR/REPRESENTATIVE] [LAST NAME],

As a pathologist in your community, I am writing to request a meeting to discuss the pressing need for a balanced regulatory approach to laboratory-developed tests.

I am available to meet either in person at your [CITY OF MEMBER'S OFFICE] office or virtually on [DATES & TIMES AVAILABLE] and would greatly appreciate the opportunity to discuss how these regulatory issues affect patient care and the future of diagnostic testing. Please feel free to contact me via email or at the phone numbers listed below to arrange a convenient meeting time.

Thank you for your time and consideration.

Best regards,

[NAME & TITLE]

[PREFERRED ADDRESS]

M: [MOBILE PHONE]

O: [OFFICE PHONE]

H: [HOME PHONE]

### A Road Map for Your Legislative Meeting

- Review the LDT educational materials below:
  - [LDT issue brief](#)
  - [Testimony of Dr. Donald Karcher, MD, FCAP](#)
- Look up the staffer on LinkedIn to see their previous work and education history. It could help with structuring the conversation.
- If you'd like a legislative prep meeting with CAP Advocacy staff before your Congressional meeting, contact [pathnet@cap.org](mailto:pathnet@cap.org).
- Decide the order of who will be speaking if other colleagues will be on the call.

### During the Meeting

- Make sure you dial in to the call 5-10 minutes before the start time.
- Thank the staffer (and legislator if they are also on the call) for taking the time to meet with you.

- Discuss what practicing pathology currently looks like in your community. Remember, your legislators want to hear from you! Members of Congress are accountable to their constituents. Not only do you vote in their district/state, but you also are an integral part of the health care system.
- Tie the stories to the legislative ask. Illustrate how the legislative ask will impact the practice of pathology and its patients. You may want to pause a few times to see if the staffer has any questions. The staffer will most likely have questions in order to learn more.
- Don't worry about knowing the intricacies of the legislative process. Staffers realize you are a health care expert and will ask questions pertaining to your expertise. The staffer may ask questions directed toward CAP staff about aspects of an issue.
- Feel free to ask your questions to the staffer. Listen to and write down their answers. If possible, extend an invitation for the legislator to tour your laboratory in the future.
- Repeat the ask for Congress to enact legislation for the oversight of LDTs and intervene and stop the FDA rule.

### **After the Meeting**

- Follow up with an email thanking the staffer for their time, along with your contact information and any further materials.
- CAP staff is available for any questions that arose that you may be unfamiliar with.
- Fill out this [form](#) with feedback from the meeting.
- Keep up to date on the issue.
  - Follow [CAP Advocacy](#) on X.
  - Read CAP's [Advocacy Update newsletter](#).
- Follow your member of Congress on social media.

### **LDT Talking Points**

- FDA's final rule on laboratory-developed tests (LDTs) is overly restrictive and could have harmful consequences for patient care.
- Historically, LDTs were considered "lower risk" and not regulated by the FDA. However, advancements in technology have made LDTs more complex and widely used, necessitating balanced oversight.
- The new FDA rule could reduce the availability of highly accurate LDTs, delay patient care, and hinder innovation in diagnostic testing.
- The College of American Pathologists (CAP) advocates for proper but balanced oversight of LDTs to ensure both patient safety and continued access to innovative testing.
- Urge Congress to pass legislation that proposes a reasonable regulatory framework that focuses oversight on high-risk tests and minimizes the burden on laboratories while promoting innovation and intervene to stop the implementation of the FDA's final rule.



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# LABORATORY TOUR TOOLKIT



## HOSTING A LABORATORY TOUR

A laboratory tour is the single best way to advocate for pathology and one of the most effective means to help you develop a relationship with your members of Congress.

These tours are useful to put a face on the profession and demonstrate pathology's crucial role in the delivery of quality health care. Many of the CAP's strongest allies on Capitol Hill first became acquainted with their local pathologists and the issues affecting their practice during a lab tour.





## TOUR PREPARATION

- Use the template provided ([page 3](#)) to send an invitation on your facility's letterhead to the legislator's scheduler.
  - Email the invitation to the scheduler and copy Jake Caccavaro at [jcaccav@cap.org](mailto:jcaccav@cap.org) or [PathNET@cap.org](mailto:PathNET@cap.org) so CAP staff can help you follow up with the offices.
  - If you extended the invitation to the Congressional staffer you met with during Hill Day, please send the invitation to them and cc CAP staff.
  - Contact Jake Caccavaro at [jcaccav@cap.org](mailto:jcaccav@cap.org) or [PathNET@cap.org](mailto:PathNET@cap.org) for the scheduler's contact information.
- If appropriate, invite your facility's top staff to participate in the tour but avoid having too large of a group.
- Map out a route. Plan ahead to select particular areas that illustrate the points you want to make. See [page 4](#) for a sample itinerary.
- Demonstrate the process involved in various tests. Create a schedule that allows time for breaks, discussion, and delays.
  - If desired, CAP staff will work with the legislator's and your facility's press offices to arrange for local media coverage during the tour.
  - Rehearse the day before and have your colleagues ask possible questions.
  - CAP Advocacy staff can set up a prep call before the tour to discuss legislative issues, send you issue briefs or other policy materials, and provide other assistance. Contact [PathNET@cap.org](mailto:PathNET@cap.org) to set up the call.
  - Make sure the legislator's office has the laboratory's address and any necessary instructions regarding parking, which entrance to use, etc.
  - Provide the legislator's office with a contact name and phone number in case of last-minute schedule changes.
  - Designate one of the laboratory staff if possible to take photos during the tour.
  - Designate one of the laboratory staff to take photos during the tour. Send the photos to [PathNET@cap.org](mailto:PathNET@cap.org).



## CONDUCTING THE TOUR

- Be at the entrance to greet the legislator and staff when they arrive and escort them to the laboratory.
- Give a brief overview of the planned tour and a general description of your laboratory.
- During the tour, discuss the facility with your legislator, using simple terms and descriptions as they will not be subject matter experts.
- Introduce employees by name as they are encountered along the tour. As constituents and/or employees working in the legislator's district or state, the legislator will most likely be interested in meeting them as well.
- If possible, tie in legislative issues and asks during tour, such as how Medicare cuts would impact patient access to diagnostic care or the laboratory workforce shortages.
- Stay on schedule. Be aware of the time the legislator has available.

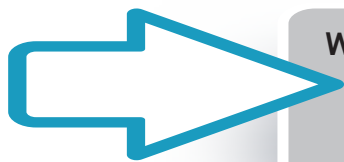


## AFTER THE TOUR

- Send a thank you letter to your legislator using the template provided below ([page 5](#)). Include the names of any key aides who accompanied the legislator on the tour. Reemphasize points made during the visit and answer any questions left unanswered during the tour. You may want to include relevant CAP legislative issue briefs.
  - Fill out the post-event survey by [clicking here](#).
- Send your photos to Jake Caccavaro at [jcaccav@cap.org](mailto:jcaccav@cap.org) or [PathNET@cap.org](mailto:PathNET@cap.org) so that your successful tour may be featured in the CAP's Advocacy Update and/or on the CAP's social media.
- Follow up with the legislator's office and continue to maintain contact. Position yourself to become a resource on pathology for the legislator and staff.
- Social media communications. Get the word out! Post a Twitter message to your colleagues or members of Congress. Find your member of Congress's Twitter handle and send them a social media message. Click these links to find your [Representatives'](#) and [Senators'](#) handles.
- Sample tweet:

***Thank you [@Twitter handle of your member of Congress] for visiting [name of your lab] and its [number of employees] to discuss issues important to pathology!***

- Op-ed to local newspapers.



**Write an op-ed and submit it to your local newspaper about the importance of pathology in your community. CAP staff can also help with drafting and submitting these op-eds**

- Sign up for PathNET, the CAP's grassroots advocacy network. Use [this link](#) to learn more and join. Laboratory tours are eligible to receive 3 PathNET points.

## SAMPLE LAB TOUR INVITE LETTER FOR MEMBERS OF CONGRESS\*

[Date]

The Honorable [Member's Name]  
[U.S. House of Representatives] OR [United States Senate]  
Washington, DC 20515 (House Zip) OR 20510 (Senate Zip)  
Attn: [Scheduler's Name]

Dear [Representative/Senator Name]:

On behalf of [Name of Lab], its pathologists, and its laboratory professionals, I cordially invite you to tour our laboratory in [city location]. This laboratory tour will provide me and many of my colleagues who live and work in your district the opportunity to acquaint you with the role of [type of pathology] pathology in the delivery of health care.

[Text that is pertinent to your lab and what you do]

[Name of Lab] plays a vital role in our community by delivering quality healthcare to thousands of your constituents. I would want to demonstrate some of the diagnostic tests performed in the lab and discuss what I see as the role of pathologists in today's medicine. This educational and entertaining tour will last approximately one hour.

I would appreciate your staff contacting me either by phone at [insert number] or email [insert email] to discuss the preferred date and time for the tour.

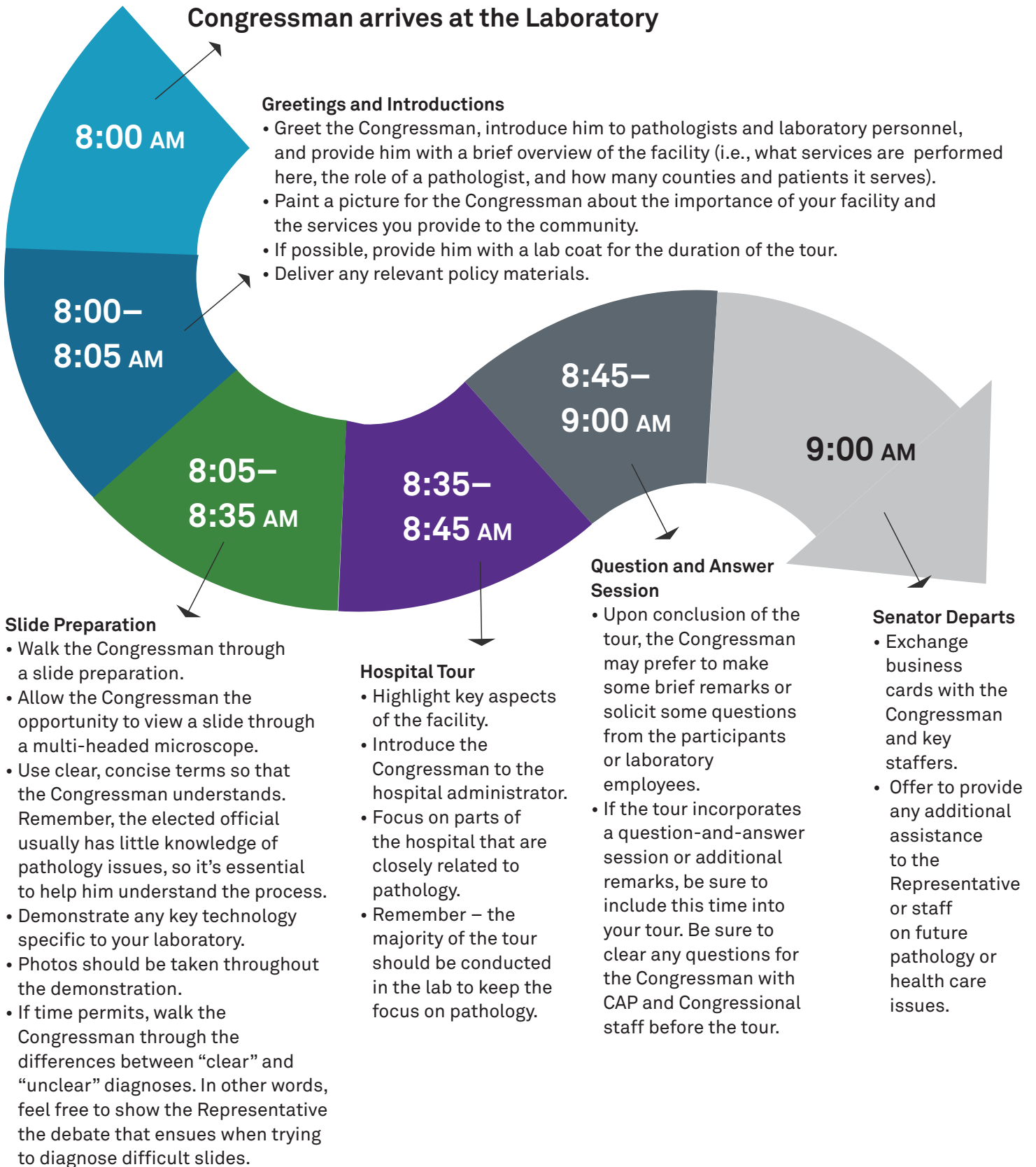
Sincerely,

Your Name  
[Name of Lab]

\* Letter should be placed on your facility's letterhead. Please email a PDF copy to [PathNET@cap.org](mailto:PathNET@cap.org).

## SAMPLE LAB TOUR AGENDA

All times are approximate. Sample agenda items may be amended where appropriate.



## SAMPLE LAB TOUR THANK YOU LETTER FOR MEMBERS OF CONGRESS AFTER THE TOUR\*

[Date]

The Honorable [Member's Name]  
[U.S. House of Representatives] OR [United States Senate]  
Washington, DC 20515 (House Zip) OR 20510 (Senate Zip) Attn: [Scheduler's Name]  
Dear [Representative/Senator Name]:

Thank you for touring the pathology laboratory at [Name of Lab] in [City]. I appreciate you taking time out of your busy schedule to visit this facility and learn more about specific legislation that affects pathology. I sincerely hope that the tour was both educational and entertaining!

I thoroughly enjoyed showing you the inner workings of a pathology laboratory and analyzing different specimen slides. In particular, I hope that our discussion regarding the critical role pathologists plays in the delivery of health care was informative and useful as you and your colleagues work with various regulatory agencies to improve health care in America.

[Please feel free to add any specifics that were discussed during the tour.]

Once again, thank you for touring the pathology laboratory at [insert your lab], and please do not hesitate to contact me either by phone, [insert number], or email [insert email] with any questions or comments pertaining to pathology or health care policy in general. I look forward to working with you in the future.

Sincerely,

Your Name  
[Name of Lab]

\* Letter should be placed on your facility's letterhead. Please email a PDF copy to [PathNET@cap.org](mailto:PathNET@cap.org).



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