



COLLEGE of AMERICAN PATHOLOGISTS

Laboratory Quality Solutions

Information for Virtual Inspection Process Inspector & Laboratory Participants

The College of American Pathologists (CAP) modified the inspection process and now provides the option for a virtual inspection. With prior CAP approval, the virtual inspection process is available to laboratories that are in good standing and meet the following eligibility criteria:

- Have reliable Wi-Fi and a laptop, tablet or smartphone enabled with a camera, microphone and speakers that can be taken into each laboratory area.
- Both the laboratory director and the inspection team must agree to perform the inspection 100% virtually.
- The process will require laboratories to provide electronic documents to the inspection team for review as well as be able to facilitate, and participate in, some method of live video observation of laboratory practices.
- The laboratory director and the team leader will determine which technologies/platforms to use to accomplish the document review and live observation of laboratory practices.
- The inspection team will perform a thorough review of the laboratory through virtual inspection, while not actually going on site.

Laboratories that successfully complete the virtual inspection will be accredited. If significant concerns about the laboratory's ability to maintain continuous compliance are identified through the virtual inspection, the laboratory may have to comply with additional requirements or sanctions, as determined by the Accreditation Committee and depending on the severity of the issues.

Please Note: Initial inspections for CLIA-licensed laboratories using a virtual inspection will require a focused on-site visit when restrictions allow per the Centers for Medicare & Medicaid Services.

Inspection Date(s) and Timeframe

If the inspection is overdue, the inspection team will work with the laboratory to determine preferred inspection date(s) and timeframe for inspection. The laboratory may indicate preferred dates and timeframe however the inspection team will determine the final date(s) of inspection. The inspection team is responsible for sharing the date(s) with the laboratory and the CAP.

If the inspection is on time, the inspection team will select a date and timeframe in the 90-day window. The laboratory's blackout dates and CAP holidays will be honored. The inspection team is responsible for sharing the scheduled date(s) with the CAP and the laboratory.

Document Review Options

Documents can be made available through any mechanism the laboratory is most comfortable using. The laboratory director and team leader will need to determine how to best accomplish document review. The following options are available:

1. Share documents during your virtual inspection.
2. Provide the inspection team with guest access to your document management system to share documents in advance of your inspection.
3. Upload documents in Organization Profile to share with inspection team in advance of your inspection. The list of documents for review is available in Organization Profile.

Note: If the laboratory chooses to share more documentation, they may request a link to a CAP SharePoint folder.

Each inspector should prepare a list of the documents and records they want to review and provide this list to the laboratory contact person in advance of the inspection to allow sufficient time to compile and share the documents.

As stated in the CAP Accreditation Program Policy Manual, Confidentiality of Inspection Findings 2.05, documentation is confidential and should be utilized solely for inspection purposes. Inspectors are prohibited from photographing, copying, or downloading any documents. To preserve the educational exchange of the inspection, inspectors should request that the laboratory share a blank copy of a form or document that they wish to borrow to use in their own laboratory, just like they would during our traditional inspections. Likewise, any recording (video or audio) of the virtual inspection process is prohibited. Laboratories must also comply with the Health Insurance Portability and Accountability Act (HIPAA) and ensure that any documents sent to the inspection team are de-identified and do not contain any protected health information (PHI) as specified under HIPAA (for laboratories subject to US law) or local privacy regulations and laws (non-US laboratories).

Inspection Planning Call

Please note the following recommendations:

- Identify conference platforms to be used (ie Zoom, Microsoft Teams) and who will be responsible for hosting.
- Timing of document review—during inspection, advance document review, or a combination.
- If the laboratory chooses to have advance document review, identify how documents will be shared (upload to CAP Organization Profile, or guest access to laboratory's document management system).
- Utilize the Inspection Planning tool attached to help determine approximate amount of time required for each checklist and which if any documents will be shared in advance.
- Identify laboratory and inspector contacts who will be working with one another throughout the inspection process. We recommend a point person be identified for the laboratory and the inspection team as well.
- Identify a time to test the live video stream either during this call or another time prior to inspection. Live video observation of laboratory practices is a requirement for the virtual inspection.
- There should be a schedule for each day of the inspection indicating which section(s) will be reviewed including any document review, observation of the inspection process and discussions with staff. The

final schedule should be shared with inspection team members and laboratory staff. Please note difference in time zones if applicable.

During the Inspection

Please note the following recommendations:

- Begin the inspection with introductions and agenda for the day including any interviews with the hospital administration and laboratory staff.
- Any deficiencies should be discussed with the laboratory personnel as soon as they are identified

- Schedule a brief meeting at the end of each inspection day with the team leader, laboratory director, and appropriate team members and laboratory staff to review the status of the inspection:
 - Identify any areas that remain to be evaluated.
 - Any outstanding questions or remaining documents needed.
 - Any deficiencies the inspector intends to cite.

- For large, full-service laboratories, identify a few sections to be inspected each day to ensure the personnel's bandwidth for the inspection does not get overwhelmed.
- The inspection team will document any noted deficiencies from the document review and the live video observations on the appropriate inspector summation report (ISR) pages
- The team may allow any non-recurring deficiencies to be corrected on-site up through the last day of the inspection.
- Summation conferences will be completed using either video or conference calls.
- The team leader will scan and email a copy of the completed ISR to the laboratory director at the end of the summation conference for review and signature. *Electronic signatures are accepted.*
- Under no circumstances should any portion of the virtual inspection be recorded (either audio or video). All information regarding the inspection is considered confidential and should not be discussed outside of the inspection process.
- The virtual inspection is the laboratory's actual inspection, and the 30-day deficiency response period begins with the completion of the summation conference and receipt of the ISR.
- The team leader will email a completed copy of the ISR (Part A and all deficiency/recommendation pages) to the CAP Central Office to accred@cap.org .
- Meal reimbursements for the virtual inspection may be completed and emailed to accred@cap.org. Note the meal reimbursable amount remains the same whether it is an in person or virtual inspection.

Anytime you have questions or concerns, please call the CAP office at 1-800-323-4040, extension 6065, and a technical specialist will help you. International customers can email accred@cap.org or call +1-847-832-7000, option 1