



**CAP Laboratory Accreditation Program
Virtual Inspection FAQs
November 24, 2020**

General Topics

1. What will be the composition of the virtual inspection?

A **virtual inspection** consists of three components:

- Document review (which may be done concurrently with the livestream component or file sharing)
Virtual livestream
- An on-site, focused inspection,
 - The Centers for Medicare and Medicaid Services (CMS) requires the on-site, focused inspection for all Clinical Laboratory Improvement Amendments (CLIA) laboratories and the CAP will schedule the on-site, focused inspection within six months, or as soon as it is safe to do so.
 - It is not mandatory for non-CLIA laboratories, but the CAP reserves the right to require one if needed.

2. What does the laboratory need to be inspected virtually?

To be successful, the laboratory needs to be able to display evidence of compliance electronically for the inspection team. The laboratory will need computers with cameras to interact with the inspection team and exchange information like what happens in traditional inspections. One or more mobile devices (ie, laptops, tablets, or smartphones) with a camera, microphone, and speakers are needed to allow inspectors to observe testing and the environment.

3. We are in a hot zone and trending upward. May we be exempt from inspection?

The CAP cannot exempt laboratories from their 2020 inspections. Virtual inspections are designed to address concerns and logistical restrictions for performing inspections during the COVID-19 pandemic.

Virtual Inspections

4. How will the inspection team and laboratory perform the document review?

Document review will be done using file sharing and/or screensharing. The team leader and laboratory director will determine which combination of technologies and platforms are optimal to complete document review.

5. If my laboratory is in an area with low COVID-19 prevalence or has safety concerns with an on-site inspection, could we request a virtual inspection even though we do not meet all the eligibility requirements?

The CAP will honor all requests for virtual inspections.

6. We are a US Department of Defense laboratory. Do we qualify for the virtual inspections?

Yes, US Department of Defense laboratories qualify for virtual inspections.

7. Who received the initial email communication regarding information related to virtual inspections?

The CAP sent an [email](#) in October 2020 to CLIA directors, accreditation contacts, laboratory managers, quality assurance contacts, section directors, and section supervisors.



8. When will the first virtual inspections be initiated?

The virtual inspections began in November 2020.

9. Are there certain criteria the laboratories must meet to qualify for the virtual inspection process?

Yes, to participate in virtual inspections, laboratories must be in good standing and meet the following 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.

10. Internet reception is spotty within our laboratory. May we still participate in a virtual inspection?

The process requires laboratories to have some method of live-video observation of laboratory practices. Laboratories with inconsistent internet reception would not allow for live streaming video, so it is recommended that in this situation, check with your information technology department to determine if it is possible to obtain a Wi-Fi signal booster. If Wi-Fi coverage cannot be fixed, the inspection may need to wait for the health care emergency to end.

11. Will pre-recorded video be acceptable for the virtual inspection?

The CAP and its inspectors will not accept any pre-recorded video for any portion of the inspection.

12. Are there training modules and tools available for the virtual inspection process?

A training course, [Performing Virtual Inspections: Being the CAP's "Eyes and Ears" From Home](#), is available plus additional inspection tools have been added to the [Inspector Tools and Training section](#) of the Accreditation Resources on e-Lab Solutions Suite (ELSS) on cap.org.

13. Your instructions require the laboratory director to work with the inspection team in the planning of the virtual inspection. Our director is not full-time onsite. Can he or she delegate these functions?

Yes, the laboratory director can delegate the planning for the virtual inspection. You must ensure the laboratory director is fully aware of decisions made by the designee and the inspection team.

Non-routine, On-site Inspections

14. If the CAP virtually inspects a laboratory, how will the CAP prioritize the completion of the required subsequent on-site inspection?

Prioritization is influenced by several factors associated with individual laboratories. Most importantly, the CAP will schedule the on-site inspection only when it is safe for both the laboratory and the inspection team to participate in an on-site visit.

15. How will the number of inspectors be determined for the on-site inspection?

Most on-site inspections will consist of 1-2 inspectors.



16. What should I expect during the on-site component of my inspection?

When the on-site inspection occurs (ideally within six months after the virtual inspection) we will not reinspect the original findings of the virtual inspection but will focus on the environment of care, direct observation of test performance, labeling, reagent storage, and infection control. On-site inspectors will also review cytology slides for laboratories with that discipline.

17. Will every checklist be used for this non-routine, on-site inspection or will only certain checklists be used?

All the laboratory's checklists will be used during the virtual inspection.

18. Is the on-site component announced?

The pre-notification of the on-site component will be determined nearer to the time of the event.

19. Will the accreditation decision notification include information regarding additional requirements to maintain accreditation, including a statement regarding the required subsequent on-site inspection within six months?

The CAP accreditation letter will specify that an on-site inspection is required and that it should take place within six months or whenever it is safe to do so, if an on-site inspection did not take place.

Inspection Teams

20. What if my inspection team cannot travel due to national, state, or local mandate or institutional restrictions?

The CAP will work with your laboratory inspection team to arrange an inspection that best fits your situation. Virtual inspections do not require travel, so your team should consider performing your assigned inspection using this process.

21. Will the same inspection team that conducted the virtual inspection conduct the on-site inspection?

On-site inspectors preferably will come from the virtual inspection team, but other inspection teams may be used to complete the inspection when it will allow the inspection to be completed in a timelier way.

International Inspections

22. Will international laboratories qualify for virtual inspections?

Yes, international laboratories qualify for virtual inspections. International laboratories will not be required to have an on-site inspection component after the virtual inspection unless they possess a CLIA certificate.



23. Will the CAP conduct international virtual inspections using the international laboratory's time zone or the inspection team's time zone?

Our preference is that the inspection team inspects using the laboratory's time zone. The laboratory director or designee and the inspection team leader will work together to determine the best timing for the inspection. We ask all parties to be flexible in making these arrangements. Efforts will be made to use acceptable regional or local inspectors for the on-site component if that is acceptable for the inspected laboratory.

24. If we are an international laboratory and prefer having a US-based CAP inspector coming to our site, could that be accommodated?

With the current COVID-19 pandemic situation, US inspectors are unable to travel internationally. If the laboratory prefers a US inspector for the onsite, this request will be honored but may delay completion of the inspection.

25. For the virtual inspection, we are concerned with language barriers, could we hire an interpreter to facilitate the inspection?

The laboratory being inspected is responsible for hiring interpreters if needed.

26. How do we budget for virtual inspection and modified inspection compared to on-site inspection?

There are no additional costs associated with the virtual inspection, and travel expenses will be substantially reduced.

27. Could our laboratory reject the inspection request given other priorities in this special time? If so, what is the allowed extension?

The inspection process is an integral part of the CAP Accreditation Programs. To ensure that the CAP Accreditation Standards are being maintained an inspection must occur once every two years. The CAP will work with your laboratory and the inspection team to complete the inspection with as little disruption as possible.

28. How long will the virtual inspection take?

The virtual inspection process will take approximately the same amount of time overall but may be spread out over several days to accommodate time zone differences and prevent laboratory staff and inspector fatigue.