



**CAP Laboratory Accreditation Program
Virtual Inspection FAQs
June 23, 2021**

General Topics

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

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

- Document review (which may be done concurrently with the livestream component or advance file sharing)
- Virtual livestream

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.

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 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 advance file sharing and/or screensharing on the day of the virtual inspection. 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. When will the first virtual inspections be initiated?

The virtual inspections began in November 2020.

8. 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.



9. 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 be further delayed until an on-site inspection can be scheduled.

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

Pre-recorded informational or introductory videos may be used during the opening conference. Pre-recorded video is not acceptable for inspecting laboratory operations. This inspection must be done in real-time using live streaming.

11. 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.

12. 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.

On-site Visits Following *Initial* Virtual Inspections for CLIA-licensed Laboratories

13. Why is an on-site visit required for CLIA-licensed Laboratories who had their *initial* inspection virtually?

This is a requirement from the Centers for Medicare and Medicaid Services

14. How will the number of inspectors be determined for the on-site visit?

Most In-Person visits (if required) will consist of 1-2 inspectors.

15. What should I expect during the on-site visit?

When the on-site visit 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 items such as cytology slides (for laboratories with that discipline).

16. Will every checklist be used for this on-site visit or will only certain checklists be used?

Components of all the laboratory's checklists will be used during the virtual inspection.

17. Is the on-site visit announced?

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

18. Will the accreditation decision notification for *initial* inspections include information regarding additional requirements to maintain accreditation and a statement about the required on-site visit within six months?

Yes, the CAP accreditation letter will specify that an on-site visit is required and that it should take place within six months of a virtual inspection, or whenever it is safe to do so.



19. 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.

20. Will the same inspection team that conducted the *initial* virtual inspection for CLIA-licensed laboratories conduct the follow up on-site visit?

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

21. Will international laboratories qualify for virtual inspections?

Yes, international laboratories qualify for virtual inspections. International laboratories with a CLIA certificate who have their *initial* inspection virtually will be required to have a follow up on-site visit when travel restrictions are lifted.

22. 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 visit if that is acceptable for the inspected laboratory.

23. 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.

24. 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.

25. How do we budget for virtual inspection compared to an in-person inspection?

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

26. 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.

27. 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. For example, advance document review, if applicable, may be performed over two weeks in small blocks of time prior to the scheduled virtual inspection. The virtual inspection may be performed in small blocks of time over a one-week period.