COVID-19 Webinar for Laboratory Accreditation

Q&A With The Joint Commission

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Panel

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Today’s webinar will be focused solely on laboratory accreditation program related questions as they relate to COVID-19 and The Joint Commission.

For questions related to other accreditation or certification programs, please join us for those webinars.
Recovery and The Joint Commission
The Joint Commission return to survey activity

- In addition to conducting accreditation surveys and certification reviews, we have been advocating for the safety and wellbeing of healthcare workers at the highest levels of policy making.

- We want to assure you that we want to work together to reduce your risk and ours during the onsite survey/review process.
Your questions

You have had a number of questions about our return to survey:

- How or when will we get a survey?
- What will that survey process look like, any differences?
- What type of instruction have you provided to the surveyors?
- What will the surveyors focus on?
When and how will survey activity resume?

- Survey/review activity has started in low risk areas – includes all programs
- Low Risk Criteria
  - Number of COVID-19 cases are lower and less impact to organizations
  - The # cases/thousand population and new cases within the county
  - Determination that our staff can travel to that area safely and find appropriate accommodations.
- We are aware that surveys are past their due dates; CMS is also aware – we will conduct those surveys when possible
- Prioritized initials and past due organizations. We will also be looking for organizations due in the next few months that meet the low risk criteria and are currently ready for survey.
What instructions have been provided to surveyors?

- Do not travel if you are sick
- Do not travel if you have been in close contact with known or suspected COVID-19 patients
- When traveling they are required to wear a mask/face covering
- **Required to wear a mask on survey and follow an organization's guidelines. The organization will provide the PPE to the surveyor as required by their policy.**
- Practice physical distancing
- Practice good hand hygiene
- Follow CDC guidelines
What has changed about the survey process?

The survey process and its components will remain the same however here are some guidelines for the survey:

- Limiting the number of individuals in group sessions
- The use of audio or videoconferencing could be incorporated to safely expand the number of attendees for sessions
- Use of masks will be a routine practice
- Maximize the use of technology to eliminate the number of people needed to sit directly next to an individual for an extended period of time (For example, screen sharing or projecting medical records)
- Interviewing patients and staff by telephone
- Driving in separate cars to offsite or patient homes
Survey process - continued

- We will NOT Enter at risk or confirmed COVID-19 rooms.
- We will avoid visiting a unit with any confirmed COVID-19 patients when possible.
- Limited physical review of high risk and aerosol generating procedures
- Consider using a simulation and/or distant review of certain activities/procedures
- Practice social/physical distancing during the survey
- Follow PPE and risk reduction strategies as established by the CDC
- Limit attendance at group sessions e.g., opening, briefings, system tracers
- Limiting observers or scribes to avoid additional exposure during the survey
Additional information

- We would ask that you do not provide additional avoid dates due to the difficulty in scheduling surveys – avoid dates already submitted will be honored to the extent we can

- **Virtual surveys** – For Lab, initial surveys and reaccreditation surveys are occurring in No-Go Zones

- Virtual event is a combination of:
  - Secure Zoom technology for the survey and facility review
  - Use of a secure SharePoint site for document upload to review pre survey
  - A follow up on-site survey to be scheduled after the PHE is over.
  - Organization is contacted to verify ability and willingness to participate
What will be the focus of survey activities?

- During the opening conference we will have a discussion with you about the impact of the current pandemic and your organization’s response.
- We will discuss both Infection Control and Emergency Management.
- The focus of our survey will not be the timeframe of the public health emergency but the current situation within your organization.
Pre-Submitted Questions

Our Lab survey is likely to be 9-12 months later than due. Would we expect surveyors to review documentation since the previous survey even though it may be 3 years?
Pre-Submitted Questions

Our 2 year survey was due in March 2020. When we do have the survey, will they be looking at the 3/18-3/20 data only? Or a different timeframe?
Pre-Submitted Questions

Are we getting notifications for surveys announced or unannounced? To be specific, do we get a call from Joint Commission representatives inquiring COVID status prior to inspections?
Pre-Submitted Questions

Will we receive notification if our survey is pushed out beyond our open dates?
Pre-Submitted Questions

Is a survey timeframe supposed to be provided once a readiness call is made by the account executive and the organization is determined to be ready, or does the survey remain unscheduled and unannounced?
Pre-Submitted Questions

Should we expect the survey to be longer or shorter?
Pre-Submitted Questions

Our laboratory reaccreditation survey is due within the next 6 months; will our lab's accreditation be extended beyond 2 years if the survey ends up being delayed?
Pre-Submitted Questions

If the survey is to include a tour and review of the point of care testing sites, how will that occur?
Pre-Submitted Questions

How long is the gap between the scheduling call and the visit?
General Questions
Pre-Submitted Questions

Please explain the process regarding the government supplying POC instruments to LTC facilities. Do they need a CLIA Waived license?
Pre-Submitted Questions

To what extent are you looking for validation studies on instrumentation and/or test kits implemented in a laboratory with a 1135 waiver?
Pre-Submitted Questions

Please speak to the QC and IQCP requirements for tests under Emergency Use Authorization.
Pre-Submitted Questions

Please confirm what validations are expected for EUA waived tests.
Pre-Submitted Questions

Will the regulatory compliance expectations for EUA tests change once they are no longer considered EUA?
Pre-Submitted Questions

Is FDA authorization needed if planning to do COVID testing as in-house test if the manufacturer of the machine was already approved for EUA?
Pre-Submitted Questions

As a CLIA licensed lab, are we required to submit an EUA for our own LDTs? How about if the LDT is simple modification of an existing EUA?
Pre-Submitted Questions

What is the status of saliva testing?
Pre-Submitted Questions

What should we do for competency for collection of swabs?
Pre-Submitted Questions

What medical personnel are qualified to be collecting the NP swabs for COVID-19 testing?
Pre-Submitted Questions

How does validation compare to proficiency?

Do we need both?
Pre-Submitted Questions

How could we transition from a CLIA waived facility to moderate complexity?
Pre-Submitted Questions

Does Joint Commission require a specific method to document our COVID activities at our facility such as an action plan versus a COVID management plan or a COVID policy?
Pre-Submitted Questions

What are testing personnel qualifications for "off label" procedures?
Pre-Submitted Questions

What standards do you expect to change or be emphasized in 2021 due to COVID-19?
Can you explain the laboratory's role in reporting COVID-19 results? If the lab reports it to their health department, do they need to report it to HHS? If the lab processes the sample but then sends it to another lab, who reports the COVID result?
Pre-Submitted Questions

As a testing lab for COVID, we report all the results to Department of Public Health and they report to State of CA. Does anybody know if California state reports to Federal government, so we don't need to do?
Pre-Submitted Questions

Do we have to correlate different COVID-19 PCR methods when each method is detecting different genes?
CMS 1135 Waivers
The Department of Health and Human Services released a statement on Friday, 10/02/20 stating the PHE was extended.

The renewal effective date is Friday, 10/23/20 and will last for 90 days.

This is the third extension of the PHE.

1135 Waivers will remain in effect during the declared PHE.
Looking for more information on CMS 1135 Waivers?

Accredited organizations can learn more by visiting Resources and Tools > Tools > Learn More in their Joint Commission Connect® extranet site.
Pre-Submitted Questions

Are there testing waivers on any current COVID-19 tests? What about antigen tests?
Pre-Submitted Questions

What documentation should be kept to support/reflect changes that occurred during the pandemic (waivers, policy etc.)?
By chance, have you heard of any updates to extending the EUAs on COVID testing? Especially since some expired in October.
Pre-Submitted Questions

Will the regulatory compliance expectations for EUA tests change once they are no longer considered EUA?
Infection Control Practices
Pre-Submitted Questions

What are the disinfection requirements for point of care testing devices that are used for testing of COVID patients?
How long should an employee who tests positive for COVID-19 stay home?

How do labs practice "social distancing" if the lab is not physically designed to allow for 6 foot separation?

Pre-Submitted Questions

What is the effect of using powdered gloves during Covid-19 sample collection?

COVID-19 resources

What Your Organization Needs to Know About the Coronavirus

Trusted Guidance. Trusted Resources.

View resources
Thank You

We support your efforts in response to the COVID-19 pandemic and hope to provide helpful resources.
Resources

- COVID Resources
  - https://www.jointcommission.org/covid-19/

- Standards Interpretation
  - https://www.jointcommission.org/standards/standard-faqs/