COVID-19 Webinar for Laboratory Accreditation

Q&A With The Joint Commission

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Panel

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General Questions
Are rural health clinics with a CLIA Certificate Of Waiver (COW) required to perform proficiency testing if they want to provide COVID testing?
Pre-Submitted Questions

Have you heard of any updates to extending the Emergency Use Authorization (EUA) on COVID testing?
Pre-Submitted Questions

If a vendor added the SARS-CoV2 test to a test cartridge with RSV and FLU, does that invalidate the IQCP completed for the RSV FLU cartridge?
When validating new COVID tests/analyzers, what is the minimum number of correlations required during the EUA?
Pre-Submitted Questions

During our Joint Commission laboratory survey, what documentation will the surveyor expect to see regarding COVID method validation, quality control, staff training, etc.?
Pre-Submitted Questions

What validation is required for the government provided Abbott BinaxNow Antigen Card?
Pre-Submitted Questions

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

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

Are Individualized Quality Control Plans (IQCP’s) needed for EUA tests?
Pre-Submitted Questions

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

When performing pool testing on an EUA, do laboratories have to submit a separate EUA for the testing method if pooling is outside the manufacturer’s EUA?
Pre-Submitted Questions

How do we cover proficiency testing when our PT Testing lab has only 2 events and we have 3 different platforms?
Pre-Submitted Questions

EUA approved COVID PCR tests -- can RNA extraction be modified? Can we use different instrument as long as we validate as LDT requirement including sensitivity, specificity and in the results field have comment as extraction modified?
Is a Laboratory Risk Assessment required for COVID-19?
Infection Control Practices
Can you provide a template for an after action review so organizations can debrief on their COVID response work?
Pre-Submitted Questions

How can we assess for and prevent COVID infection in the Laboratory and what do we do if a laboratorian is diagnosed with COVID despite our best efforts?

Resources:
https://www.osha.gov/coronavirus/control-prevention/laboratory#:~:text=Until%20more%20is%20known%20about,with%20exposure%20to%20the%20virus

After testing positive for COVID-19, when is it appropriate for a health care professional to return to the workplace?

Resource:
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 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 your surveyors?
• What will the surveyors focus on?
When and how will survey activity resume?

- Survey 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.
- In addition, your AE will contact you to determine your readiness.
- We are aware that surveys are past their due dates, CMS is also aware – we will conduct those surveys when we are able to do so.
- 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 our field staff?

- 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 the organizations’ 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 or homes.
• 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
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.
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 do so
- Offsite/virtual activity continues to expand
- We will work with you to ensure you are ready and prepared.
Offsite (Virtual) Survey

- **Offsite (virtual) survey**— may be scheduled for some organizations who meet eligibility criteria
- Eligible organizations will be contacted via a Qualtrics survey or other outreach from our staff (phone call or email) to confirm their ability to participate
- Offsite 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 dry run test of technology will be conducted prior to the event
- Most offsite events will have a follow-up onsite event.
I recently heard from a third party that The Joint Commission has been approved by CMS to perform accreditation (e.g. for deemed status) surveys virtually. Can you confirm this?
What is the deadline for surveying those facilities that are overdue?
Our labs were virtually surveyed in August/September of 2020 and are awaiting onsite follow-up surveys. What will be the "lookback" dates for the onsite reviews of records?
How long do you expect clearing the inspection backlog?
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?
Can our laboratory be excluded from the triennial survey if they will be receiving their own Lab survey the same year?
Will surveys look different in 2021? (still onsite, Zoom call, etc.?)
Pre-Submitted Questions

Should we expect the survey to be longer or shorter?
How much emphasis will be placed on the EOP plan and will scoring apply?
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/