

Reimbursement & Policy

New surveyor guidance for lab compliance

CMS recently issued new surveyor [guidance](#) for COVID-19 laboratory test result reporting for Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories. The new guidance complements a Sept. 2 [interim final rule](#). Laboratories are expected to be in compliance with the new requirements no later than Sept. 23.

The new requirements state:

- All laboratories that perform or analyze any COVID-19 test (molecular, antigen, antibody, etc.) must report data, regardless of the type of CLIA certificate the laboratory has. In addition, all negative and positive test results, irrespective of method, must be reported. Any facility using point-of-care COVID-19 testing devices under a CLIA waiver also is required to report.
- Failure to comply with the reporting requirements will result in a mandatory citation.
- All laboratories must have documentation demonstrating compliance.
- After Sept. 23, a laboratory's failure to report COVID-19 test results will result in a condition-level violation of the CLIA regulations.
- For laboratories not in compliance after Sept. 23, CMS will impose a \$1,000 civil monetary penalty for the first day of noncompliance and a \$500 penalty for each subsequent day of noncompliance.

AHA addresses the "up-coding" myth

Last week, the American Hospital Association [spoke out against](#) remarks being made that hospitals are "up-coding" patients to reflect a COVID-19 diagnosis for financial gain. In his comments, AHA President Rick Pollack aimed to "set the record straight" by explaining coding guidelines and the penalties for not adhering to them. He also describes the current financial position many hospitals are facing.

Quality & Patient Safety

How long after potential exposure should we test HCWs?

Reverse transcriptase polymerase chain reaction (RT-PCR) tests for SARS-CoV-2 are being used to "rule out" infection among high-risk persons, e.g. healthcare workers. Understanding how the predictive value of the test varies with time from exposure and symptom onset is critical to avoid false reassurance from a negative test result. The study [Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction–Based SARS-CoV-2 Tests by Time Since Exposure](#) pooled data from 7 previous studies to estimate the false-negative rate by time since exposure.

As the pandemic progresses, hospitals increasingly have to decide how to respond when a healthcare worker has a known exposure to SARS-CoV-2. The most conservative options – 14 days of airborne precautions or quarantine – is not feasible for many hospitals. A more judicious balance of personnel time and transmission interruption is SARS-CoV-2 testing, which would help facilities determine if that exposed health care worker is infected. The Annals of Internal Medicine study above demonstrates that testing and results should consider time since exposure.

Among infected persons, probability of a false-negative result decreased during the 4 days prior to median time of symptom onset (day 5) – from 100% on day 1 to 68% on day 4. On the day of symptom onset, the median false-negative rate was 38%. This decreased to 20% on day 8 (3 days after symptom onset) then began to increase again, from 21% on day 9 to 66% on day 21. **The false-negative rate was minimized 8 days after exposure—that is, 3 days on average after the onset of symptoms. As such, this may be the optimal time for testing if the goal is to minimize false-negative results.**

Care must be taken in interpreting RT-PCR tests for SARS-CoV-2 infection—particularly early in the course of infection—when using these results as a basis for removing precautions intended to prevent onward transmission. This study showed that testing done immediately after exposure provides no additional information about the likelihood of infection. If clinical suspicion is high, infection should not be ruled out on the basis of RT-PCR alone.

Virtual Meetings & Education

FDA discusses gowns and gloves

The FDA will present information on both the enforcement policy and the EUA for gowns, gloves and other apparel used by healthcare workers. FDA representatives along with individuals from the CDC and OSHA will be available to answer your questions. Registration is not necessary for this event.

Tuesday, Sept. 15 ~ 11a-12p MTN / 10a-11a PAC
800.455.1392 / conference number: **PWXW-1662301** / passcode: **7621596**

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