QIPMO Administrator Support Group

Information Sharing Series
September 3, 2020
Meeting 21

Topics for today

Testing QSO-20-38 NH

CLIA QSO-20-37-CLIA,NH

Updates-Missouri Information

Discussion-Questions and Comments
F886

483.80(h) COVID-19 Testing. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary.
(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;
(3) For each instance of testing:
   (i) Document that testing was completed and the results of each staff test; and
   (ii) Document in the resident records that testing was offered, completed (as appropriate to the resident’s testing status), and the results of each test.
(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.
(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.
(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results. (p. 2)
**TYPE OF TESTING AND FREQUENCY**

For the testing requirements, either PCR or antigen can be used antibody tests are not permitted. Facilities will be required to conduct three types of testing:

- **Symptomatic Testing:** Test any staff or residents who have signs or symptoms of COVID-19 (facility must continue screening all staff, residents and other visitors).

- **Outbreak Testing:** Test all staff and residents in response to an outbreak (defined as any single new infection in staff or any nursing home onset infection in a resident) and continue to test all staff and residents that tested negative every 3-7 days until no news cases for at least 14 days since the most recent positive result.

- **Routine Testing:** Test all staff based on the extent of the virus in the community using CMS’ published county positivity rate in the prior week as the trigger for staff testing frequency. CMS will publish reports of COVID-19 county-level positivity rates [here](https://www.cdc.gov/coronavirus/2019-ncov/index.html), where the information can be found under the “COVID-19 Testing” paragraph.

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**Testing Triggers**

<table>
<thead>
<tr>
<th>Testing Trigger</th>
<th>Staff</th>
<th>Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic individual identified</td>
<td>Staff with signs and symptoms must be tested</td>
<td>Residents with signs and symptoms must be tested</td>
</tr>
<tr>
<td>Outbreak (Any new case arises in facility)</td>
<td>Test all staff that previously tested negative until no new cases are identified⁰</td>
<td>Test all residents that previously tested negative until no new cases are identified⁰</td>
</tr>
<tr>
<td>Routine testing</td>
<td>According to Table 2 below</td>
<td>Not recommended, unless the resident leaves the facility routinely.</td>
</tr>
</tbody>
</table>
Reports of COVID-19 county-level positivity rates will be available on the following website by August 28, 2020 (see section titled, “COVID-19 Testing”):

## County Positivity Rates

<table>
<thead>
<tr>
<th>County</th>
<th>FIPS code</th>
<th>State</th>
<th>FEMA region</th>
<th>Population</th>
<th>Percent Positive In prior 7 days</th>
<th>Test Positivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adair County, MO</td>
<td>29001</td>
<td>MO</td>
<td>Region 7</td>
<td>25,343</td>
<td>0.0% Green</td>
<td>Green</td>
</tr>
<tr>
<td>Andrew County, MO</td>
<td>29005</td>
<td>MO</td>
<td>Region 7</td>
<td>17,712</td>
<td>6.8% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Alameda County, MO</td>
<td>29002</td>
<td>MO</td>
<td>Region 7</td>
<td>5,343</td>
<td>0.6% Green</td>
<td>Green</td>
</tr>
<tr>
<td>Audrain County, MO</td>
<td>29007</td>
<td>MO</td>
<td>Region 7</td>
<td>25388</td>
<td>0.0% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Barry County, MO</td>
<td>29006</td>
<td>MO</td>
<td>Region 7</td>
<td>35,704</td>
<td>8.1% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Barton County, MO</td>
<td>29001</td>
<td>MO</td>
<td>Region 7</td>
<td>14,754</td>
<td>0.6% Green</td>
<td>Green</td>
</tr>
<tr>
<td>Bates County, MO</td>
<td>29013</td>
<td>MO</td>
<td>Region 7</td>
<td>16,172</td>
<td>1.7% Green</td>
<td>Green</td>
</tr>
<tr>
<td>Benton County, MO</td>
<td>29015</td>
<td>MO</td>
<td>Region 7</td>
<td>19,443</td>
<td>5.3% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Bollinger County, MO</td>
<td>29017</td>
<td>MO</td>
<td>Region 7</td>
<td>12,133</td>
<td>18.4% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Boone County, MO</td>
<td>29019</td>
<td>MO</td>
<td>Region 7</td>
<td>180,466</td>
<td>2.2% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Buchanan County, MO</td>
<td>29021</td>
<td>MO</td>
<td>Region 7</td>
<td>87,364</td>
<td>5.9% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Butler County, MO</td>
<td>29025</td>
<td>MO</td>
<td>Region 7</td>
<td>42,476</td>
<td>15.6% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Caldwell County, MO</td>
<td>29028</td>
<td>MO</td>
<td>Region 7</td>
<td>9,620</td>
<td>6.5% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Callaway County, MO</td>
<td>29027</td>
<td>MO</td>
<td>Region 7</td>
<td>44,743</td>
<td>24.6% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Camden County, MO</td>
<td>29020</td>
<td>MO</td>
<td>Region 7</td>
<td>46,205</td>
<td>10.6% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Cape Girardeau County, MO</td>
<td>29031</td>
<td>MO</td>
<td>Region 7</td>
<td>78,671</td>
<td>13.0% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Carroll County, MO</td>
<td>29033</td>
<td>MO</td>
<td>Region 7</td>
<td>8,673</td>
<td>4.4% Green</td>
<td>Yellow</td>
</tr>
<tr>
<td>Carter County, MO</td>
<td>29035</td>
<td>MO</td>
<td>Region 7</td>
<td>5,982</td>
<td>0.0% Yellow</td>
<td>Green</td>
</tr>
<tr>
<td>Cass County, MO</td>
<td>29037</td>
<td>MO</td>
<td>Region 7</td>
<td>105,780</td>
<td>10.0% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Cedar County, MO</td>
<td>29029</td>
<td>MO</td>
<td>Region 7</td>
<td>14,349</td>
<td>0.6% Green</td>
<td>Green</td>
</tr>
<tr>
<td>Charlton County, MO</td>
<td>29041</td>
<td>MO</td>
<td>Region 7</td>
<td>7,426</td>
<td>&gt;10.0% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Christian County, MO</td>
<td>29043</td>
<td>MO</td>
<td>Region 7</td>
<td>88,595</td>
<td>12.7% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Clark County, MO</td>
<td>29045</td>
<td>MO</td>
<td>Region 7</td>
<td>6,797</td>
<td>27.8% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Clay County, MO</td>
<td>29047</td>
<td>MO</td>
<td>Region 7</td>
<td>249,948</td>
<td>12.5% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Clinton County, MO</td>
<td>29049</td>
<td>MO</td>
<td>Region 7</td>
<td>20,387</td>
<td>7.2% Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Cole County, MO</td>
<td>29051</td>
<td>MO</td>
<td>Region 7</td>
<td>76,745</td>
<td>14.3% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Cooper County, MO</td>
<td>29053</td>
<td>MO</td>
<td>Region 7</td>
<td>17,709</td>
<td>12.5% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Crawford County, MO</td>
<td>29055</td>
<td>MO</td>
<td>Region 7</td>
<td>23,920</td>
<td>15.0% Red</td>
<td>Red</td>
</tr>
<tr>
<td>Dade County, MO</td>
<td>29057</td>
<td>MO</td>
<td>Region 7</td>
<td>7,561</td>
<td>4.2% Green</td>
<td>Green</td>
</tr>
</tbody>
</table>

### Effective Date

- **Low <5%**
  - Once per week-Testing completed by **09/09/2020**

- **Medium 5%-10%**
  - Twice per week-First round of testing by **09/05/2020**
  - Once a month-Testing Completed by **10/02/2020**

- **High >10%**
  - *Assumes availability of POC testing on-site at the NH or off site where a turnaround time is <48 hrs.*
Testing QSO-20-38 NH

• Begin testing on or soon after 09/02/2020. Effective date 09/02/2020.YESTERDAY!!
• Monitor positivity rate every other week.
• Adjust testing accordingly:
  – If the positivity rate increases, adjust testing frequency as soon as criteria are met (immediately).
  – If the positivity rate decreases, continue at the highest frequency until positivity rate has remained at the lower activity for two weeks.
• Are there other state or local factors that influence testing? Contact your public health department.
• Must have an order from provider for both residents and staff—can be a standing order

Documentation QSO-20-38 NH

For each round of testing completed:

RESIDENTS-IN THE MEDICAL RECORD

• Dates/times identification of signs and symptoms
• Testing was offered (date, refusal or accepted)
• Completed (date)
• Results (date received)
• Actions based on the results

STAFF, VOLUNTEERS, CONTRACTORS, CONSULTANTS

• Testing completion date
• Results
  – Documentation must be done in a secure manner—HIPAA
• Remember to check EEOC, ADA guidelines when establishing staff testing policies
**SYMPTOMATIC**
- Date and time of identification of signs or symptoms
- Date of test & date results obtained
- Results and actions taken

**OUTBREAK**
- Date first case was identified
- Dates and results of initial testing and retesting for all residents & staff

**ROUTINE**
- County positivity rate and testing frequency required
- Date the positivity rate was checked on the CMS website
- Dates and results of all tests

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**CDC: Considerations for Interpreting Antigen Test Results in Nursing Homes**

- **SYMPTOMATIC**
  - POC Antigen Test
    - **POSITIVE**
      - No confirmatory test needed; isolate/exclude from work. If index case, initiate outbreak response.
    - **PREVIOUSLY NEGATIVE**
      - Perform confirmatory RT-PCR test immediately; isolate/exclude from work until RT-PCR results. Actions dependent on RT-PCR test alone.

- **ASYMPTOMATIC**
  - Facility with an outbreak (Resident and HCP serial testing):
    - POC antigen testing every 3-7 days**
    - **POSITIVE**
      - No confirmatory test needed; isolate/exclude from work.
    - **PREVIOUSLY NEGATIVE**
      - Continue serial testing until no new positives for 14 days; consider performing confirmatory RT-PCR test within 48 hrs. Exclude from work, pending confirmatory test.
  - Facility without an outbreak (HCP serial screening testing):
    - **POSITIVE**
      - Especially in high-incidence counties, consider performing confirmatory RT-PCR test; continue serial testing.
    - **PREVIOUSLY NEGATIVE**
      - Allow HCP to continue work.

- **RT-PCR TEST POSITIVE**
  - Initiate outbreak response.
- **RT-PCR TEST NEGATIVE**
  - Discuss with public health.*
Updated survey tools

- Standard and Transmission-Based Precautions (review care of a resident under observation, suspected of, or confirmed to have COVID-19 infection);
- Quality of resident care practices, including those under observation, suspected of, and confirmed to have COVID-19 infection, if applicable;
- The surveillance and testing process;
- Actions taken to prevent transmission, such as cohorting and managing care for residents suspected of having or confirmed to have COVID-19;
- The infection preventionist role.
- The survey team will select a random sample of three residents, and if not already sampled, add one additional resident who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.
- The survey team will select a random sample of three staff, and if not already sampled, add one additional staff who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

10. Infection Preventionist (IP):
Did the facility designate one or more individual(s) as the infection preventionist(s) who are responsible for the facility’s IPCP?

Yes  No  F882

11. Staff and Resident Testing
Review the facility’s testing documentation (e.g., logs of county level positivity rate, testing schedules, staff and resident records, other documentation).
If possible, observe how the facility conducts testing, including the use of PPE and specimen collection. If such observation is not possible, interview an individual responsible for testing and inquire how testing is conducted (e.g., “what are the steps taken to conduct each test?”).
Did the facility conduct testing of staff based on the county level positivity rate according to the recommended frequency?
Based on observation or interview, did the facility conduct testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests?
Did the facility’s documentation demonstrate the facility conducted testing of residents or staff with signs of symptoms of COVID-19 in a manner that is consistent with current standards of practice for conducting COVID-19 tests?
DISCUSSION

New and/or Modified CLIA Regulations for SARS-CoV-2 Test Results

These new or modified CLIA regulations apply to all CLIA-certified laboratories performing SARS-CoV-2 testing. New or updated language is in italics.

New/Modified Requirements

§ 493.2 Definitions. *(Modified)*

Condition level requirements means any of the requirements identified as “conditions” in § 493.41 and subparts G through Q of this part.

§ 493.41 Condition: Reporting of SARS-CoV-2 test results. *(New)*: During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.
REPORTING QSO-20-38 NH; QSO-20-37-CLIA, NH

§ 493.555(c) Federal review of laboratory requirements. [New]
(c) The organization’s or State’s agreement with CMS that requires it to do the following:
(6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).

§ 493.1100 Condition: Facility administration. [New]
(a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

§ 493.1804 General considerations. [Modified]
(c) Imposition of alternative sanctions. (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)

§ 493.1834 Civil money penalty. [New]
(d)(2)(iii) For a condition level deficiency under §§ 493.41 or 493.1100(a), a CMP of $1,000 for the first day of noncompliance and $500 for each additional day of noncompliance.

UPDATE YOUR CLIA WAIVER

Homes that currently hold a CLIA waiver will need to update CLIA Form CMS 116 to include testing for COVID-19 NH. If you do not have a CLIA waiver, you will need to get one.

Send the new application/updated form to:

DHSS - Bureau of Diagnostic Services
CLIA Program
PO Box 570
Jefferson City, MO 65102
E-mail: CLIA@health.mo.gov
Fax: 573-751-6158

Additionally, you will need to include the platform you will be using. If you are unsure which platform device, list all POC testing platforms (Abbot, Quidel Sofia 2 Instrument or Becton, Dickinson and Company (BD) Veritor™ Plus System) in order to ensure the platform, you have or will receive, is listed.
Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM)

- Generally, laboratories that have a CoW or PPM certificate are not routinely surveyed. For the duration of the PHE, on-site surveys of 5% of CLIA CoW and PPM laboratories will be conducted for the purpose of determining compliance with:
  - Implementing the new CLIA Condition-level regulation (493.41) pertaining to COVID19 reporting requirements;
  - Confirming that laboratories hold the appropriate type of CLIA certificate (i.e., not testing outside certificate)
- The 5% of these laboratories will be spread over the three years of the PHE, rather than 5% annually.
- The caveat: It is recommended that new and updated CLIA applications that indicate testing for SARS-CoV2, as well as communication from laboratories indicating the addition of this testing received since February 1, 2020, be used to prioritize surveys.

Report Long-Term Care Enforcement Regulations

- Imposition of CMP for Failure to Report COVID-19 data to CDC NHSN May 6 QSO-20-29-NH
- New regulation at § 488.447 that codifies this process for enforcing the reporting requirement using a CMP for each week a facility fails to report in the CDC NHSN system.
  - 1st Occurrence=$1000;
  - $500 each subsequent occurrence;
  - Maximum amount $6500 per citation
- Will continue to be in effect for up to one year beyond the end of the PHE
WHERE TO REPORT

- NHSN: Per DHSS—Prefer daily reporting. Mandated weekly—keep doing what you are doing.
- DHSS: Use the online portal to report all positive cases at https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/. Use the "Electronic COVID-19 Case Reporting" button.
- CLIA Lab Program: This may be new to you and when you begin using your POC Platform for testing is an additional reporting process you should use. All test results, positive and negative results, must be reported. Results are then sent to LPHA's.
  - Methods of Reporting Laboratory COVID-19 Test Results
  - Laboratories are encouraged to report via electronic means.
    - Submitting spreadsheets to BRDI by secure file transfer protocol (sFTP)
    - Please call 573-526-5271. The sFTP option functions as a secure online folder where files may be submitted with no wait. In order to use this option, at least one contact e-mail address for the submitting organization must be provided. Further instructions will be sent to the indicated e-mail address(es) once an account is set up for the organization.
    - Format:
      - Laboratories may use their own format OR
      - Laboratories may use our template.
      - Submit individual laboratory reports in portable document format (PDF) files sent to BRDI by secure file transfer protocol (sFTP)
  - Alternatively, laboratories may submit via fax to BRDI at 573-751-6417. Please note that this fax line experiences high volume during normal business hours.

CONCIERGE SITES FOR POC TESTING MACHINES

- Concierge sites for point-of-care testing devices:
- If you have a Quidel machine: https://togetheragain.quidel.com/
- If you have a BD machine: https://www.bdveritor.com/long-term-care-facilities/system-overview/
Unanswered Questions

1. How far apart do these tests have to be performed? What if there are circumstances that they cannot get here to be tested on the set days?
2. What if employees are on vacation and out of town?
3. Employees that work another job – can their results work for both facilities?
4. PRN employees that do not work very frequently like once a week or once a month? Do they still have to come in twice per week.
5. Do physicians have to be tested in order to perform visits with residents? Medical directors, resident physicians, NPs, etc. Sending to CMS.
6. How will it work for contract staff that work in multiple buildings? I.e. Therapists. They will not want to be repeatedly tested by each home they go into. Work this out between themselves and the contractors. Sending to CMS.

Missouri Guidance Updates
Updated Reopening Guidance

Updated Missouri Interim Guidance for Long Term Care Facilities with Confirmed COVID-19

What's New:

- Added antigen POC testing platforms as an option for testing staff and residents. My interpretation: RT-PCR is the preferred method for testing if results can be received <48 hours of the test, especially for residents.
- Link to the county map information can be found on the Missouri COVID-19 Dashboard

Missouri COVID-19 Dashboard: The Spread of COVID-19 in Missouri

Daily Percent Increase In Cases

Consecutive Days of Downward Trajectory by County Map

Top 10 Counties - Total Cases

County: ST LOUIS - 18,920

Reopening Testing vs. CMS testing

Two different triggers

State: Baseline testing and subsequent testing if moving from phase 1 to phase 2 or already in phase 2/3 per the MO Reopening Guidance Downward Trajectory Map

Federal: County Positivity Rate

MO uses the County Downward Trend Map for Reopening

CMS Positivity Rate
Reopening Questions?

• We got your back. We are here to help you move through the phases of reopening. You may receive calls or emails from us asking where you are in the process, how your testing is going, and so on. We are staying in contact with health departments to see what county LPHAs are recommending in regards to opening up your homes. Moving through the phases is voluntary.

• Visit our reopening page for more information and our contact information.
OTHER INFORMATION

QIPMO Statewide DON Meeting Tuesday, September 8, 202 at 1:30 pm register [here](#)

Nursing Homes CMS Calls
- **Wednesday, September 9; 4:30 – 5:00 PM Eastern**
  - Toll Free Attendee Dial-In: 833-614-0820
  - Access Passcode: 5475686Audio Webcast Link:
- **Wednesday, September 23; 4:30 – 5:00 PM Eastern**
  - Toll Free Attendee Dial-In: 833-614-0820
  - Access Passcode: 5839938Audio Webcast Link:
    [https://protect2.fireeye.com/url?k=17d68a30-4b82a31b-17d6bb0f-0cc47a6d17cc-b3c6f167a0366d03&u=https://engage.vevent.com/rt/cms2/index.jsp?seid=2509](https://protect2.fireeye.com/url?k=17d68a30-4b82a31b-17d6bb0f-0cc47a6d17cc-b3c6f167a0366d03&u=https://engage.vevent.com/rt/cms2/index.jsp?seid=2509)


DISCUSSION
LET US KNOW HOW WE CAN HELP

EVALUATIONS


LTC LEADERSHIP COACHES

• Nicky Martin, BSA, LNHA, CDP, QIPMO Team Leader
  573-217-9382
  St. Louis/Southeast/Southwest
  martincaro@missouri.edu

  Mark Francis, MS, LNHA
  417-499-9380
  Kansas City/West/Southwest
  francismd@missouri.edu

• Libby Youse, BGS, LNHA, CDP
  660-651-3778
  Central/Midwest/North
  youseme@missouri.edu

Nursing Home Help
We can do virtual visits via zoom!