**DO results need to be routinely reported to local as well as state?**

For the new guidance in QSO-20-38-NH says “Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested (p. 8)” QSO-20-37-CLIA, NH says:

All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing. All negative and positive SARS-CoV-2 results must be reported irrespective of the method (e.g., molecular, lateral flow) used. Molecular (RT-PCR) tests detect the virus’s genetic material and antigen tests detect specific proteins on the surface of the virus. Both types of tests are used to detect active or acute infection with SARS-CoV-2 (p.3).

Additionally, CMS notes that “health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation”.

Missouri specific reporting information: The [Electronic COVID-19 Case Reporting System](https://www.health.mo.gov/coronavirus) can be found on DHSS’ main COVID-19 webpage: www.health.mo.gov/coronavirus. Please do not enter lab result information unless you are a reporting laboratory or you are entering on behalf of the laboratory. Testing spreadsheets should continue to be provided by facilities to the Division of Regulation and Licensure. Testing spreadsheets can be uploaded at: [https://health.mo.gov/safety/longtermcare.php](https://health.mo.gov/safety/longtermcare.php).

**WHAT IS MEANT BY CONTRACTORS? AGENCY? PHYSICIANS?**

The IFC used hospice as an example of a contractor. QSO-20-38-NH states on page 3 that “Facility staff includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility’s nurse aide training programs or from affiliated academic institutions”.

**CAN WE WAIT TO TEST UNTIL WE GET THE POC MACHINE FROM THE STATE?**

No, the testing requirement became effective 09/02/2020 and your testing should begin immediately according to the required frequency outline in QSO-20-38-NH. Arrangements with a lab for testing will be necessary if your POC Antigen testing platform has not arrived.

How often will the excel sheet be updated from CMS?

QSO-20-38-NH says that “Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month)” (p. 5).

**DID YOU SAY THERE HAS TO BE A DOCTOR ORDER FOR STAFF TESTS?**

Yes, “rapid POC testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual” (QSO-20-38-NH, p. 7)

**DOES THIS APPLY TO ASSISTED LIVING COMMUNITIES?**

No. Assisted living communities need to follow Missouri guidance in regards to testing.
**CAN WE USE THE POC TO DO THE TESTING OR DO WE HAVE TO USE A LAB?**

You may use either the POC platform or a laboratory to perform your testing. A CLIA Waiver is required to use the POC platform. Instructions to update your CLIA waiver are below: In response to the ongoing pandemic, the Centers for Medicare and Medicaid Services (CMS) is requesting that all facilities (whether Long Term Care, pharmacy, or any other entity) that wish to begin testing for COVID-19 under their existing CLIA Certificate of Waiver (CoW), alert their state CLIA program so this can be appended to their CLIA certificate for public health and epidemiological reporting/tracking purposes. If you have not already been in contact with the MO CLIA program to update your certificate, please see below:

To add COVID-19 testing to your existing CLIA Certificate of Waiver (CoW), you may do one of the following:

1. Either submit a Form 116 indicating OTHER CHANGES: COVID 19 Testing to your CoW. This will require a signature from the lab director or facility owner. (The form can be downloaded here: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf)

OR (typically much easier)

2. You may complete the email table template below and send the email FROM the lab director’s email account. Send the Email to CLIA@health.mo.gov

Subject: Add COVID-19 Testing to existing CLIA Certificate for [FACILITY NAME]

<table>
<thead>
<tr>
<th>Lab/Facility Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing CLIA Waived Lab #:</td>
<td></td>
</tr>
<tr>
<td>Lab Director Name:</td>
<td></td>
</tr>
</tbody>
</table>
| Which COVID-19/ SARS-CoV-2 Waived Test system added? Check [X] all that may apply. | [ ] Abbott BinaxNOW COVID-19 Ag Card  
[ ] Quidel Sofia 2 SARS-CoV-2 Antigen assay  
[ ] Becton Dickinson Veritor™ Plus Antigen test kit  
[ ] Abbott ID Now  
[ ] OTHER Waived test approved by FDA EUA (specify below): |

As the Laboratory Director of record for the CLIA facility holding a Waived Certificate identified above, I wish to append my facility’s existing CLIA# to include testing for COVID-19. I attest that my facility will provide reasonable assurances that:

- All testing personnel for COVID-19 will be provided adequate and documented training
- All Manufacturer’s Instructions for Use (IFU) will be strictly adhered to

All tests results (both positive and negative) will be reported to the proper public health entities under federal and state requirements. See MO DHSS link regarding reporting: https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/how-to-report-lab-results.php

Created by MU MDS and Quality Research Team, September 2020
**NHA SUPPORT GROUP MEETING (9/3/20) FAQ**

**DO WE TEST A CERTAIN PERCENTAGE OF STAFF AND PERCENTAGE OF RESIDENTS?**

No, *routine* testing of residents is not required by the new guidance. Resident testing is only required if there is an outbreak in the building or a resident becomes symptomatic. For routine staff testing described in QSO-20-38-NH, you will test all staff according to the frequency required based on the county positivity rate. Testing requirements are outlined in pages 3-5 of QSO-20-38-NH.

**CAN THE LAB RESULT WHICH STATES DATE COMPLETED AND RESULT RECEIVED DATE BE THE DOCUMENTATION?**

Yes, lab results would suffice as documentation as long as they are placed in the resident’s medical record and the staff member’s file. Documentation requirements are outlined in pages 9-10 of QSO-20-38-NH. If you are using the POC machine and it does not print off results, you will need to manually document all results in the resident’s medical record and employee file.

**IS IT OK WITH THE CENTERS THAT ARE WEEKLY, TO COMPLETE THE TESTING ON 9/9 FOR THE 1ST ROUND?**

Yes, the testing would need to be completed on or before 09/09/2020.

**IF YOU HAVE A CONTRACTOR/VENDOR SUCH AS AN ELECTRICIAN COMES IN AND HAS NO CONTACT WITH STAFF OR RESIDENTS IN A RED COUNTY, DO THEY HAVE TO TEST TWICE PER WEEK?**

No, the electrician is not performing a service the nursing home would perform (i.e. resident care) or on your behalf; therefore, they would not be required to be tested. Precautions should be taken to limit travel throughout the building as much as possible.

MO DHSS on their guidance they stated to every 2 weeks test 10% of staff… this CMS guidance states all staff monthly. Do we need to continue to follow both and do all staff monthly along with the 10% every other week?

Testing schedules should be based on the more stringent guidance. The MO DHSS Reopening guidance says 10% of staff bi-monthly testing must be completed if you are in phase 2 or phase 3. The CMS guidance states all staff must be tested based on the frequency outlined in table 2 of QSO-20-38-NH (p. 5). For instance, if you are in Phase 2 based on the MO DHSS Reopening Guidance and performing twice a month testing of 10% of staff but are in a county that is only required to test once a month based on the county positivity rate released by CMS, then at least one round of testing would need to be all staff and the second round could be 10% of staff. In the previous scenario the state guidance would be the more stringent. On the other hand, if you are in phase 2 and in a county that is required to test twice a week or once a week based on the CMS data, 10% staff testing would not need to be completed because you are following the more stringent guidance and already testing all staff twice a week, which in this case is the federal guidance.

**WHAT ARE THE STATE EXPECTATIONS FOR FIT TESTING ON N95s?**

An initial fit test should be performed according to OSHA standards and CDC recommendations. A fit testing resource may be found at [https://www.mhanet.com/mhaimages/COVID-19/Respiratory%20Protection%20companies.pdf](https://www.mhanet.com/mhaimages/COVID-19/Respiratory%20Protection%20companies.pdf)

**HAVING ISSUES WITH THE HEALTH DEPARTMENT WITH DIFFERENT TIME FRAMES FOR ISOLATION FOR STAFF. IS IT 14 DAYS OR 10 DAYS?**

The CDC Return to work guidance is outlined [here](https://www.mhanet.com/mhaimages/COVID-19/Respiratory%20Protection%20companies.pdf). Local public health authorities (LPHAs) may have more restrictive guidance depend on local case activity.
**Do you retest a positive staff with the POC machine/lab or not retest at all required? Throughout process?**

QSO-20-38-NH says “in keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances” (pp.6-7).

The following questions have been sent to CMS for clarification:

- Is pooled testing an acceptable approach to testing?
- Do those who provide services occasionally (i.e. physician) need to be included in the routine staff testing?
- How will it work for contract staff that work in multiple buildings (i.e. therapists)?
- Do EMS staff need to be included in the routine staff testing?

As soon as we have answers to these questions, we will update!