QIPMO DON/Administrator Support Group

Information Sharing Series
Presented by Libby Youse, LNHA
Wendy Boren, BSN, RN
Quality Improvement Program for Missouri
Topics for today—Point of Care Testing

- Machines
- Staffing
- Logistical requirements
- Reporting & documentation requirements for Point-of-Care
POINT-OF-CARE TESTING CHECKLIST

- Update Your CLIA Waiver
- Get At Least 2 People Certified To Use Your Machine
- Work Through The Logistics Of The Machine, Supplies, Ordering, Etc.
- Create Your Processes & Procedures For Testing & Reporting
- Create Your Electronic Documentation Log

Cross Your Fingers And Hope It All Goes As Planned!
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 (Abbott, 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.
### CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

#### I. GENERAL INFORMATION

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**CLIA IDENTIFICATION NUMBER**

If an initial application leave blank, a number will be assigned.

#### FACILITY NAME

**FEDERAL TAX IDENTIFICATION NUMBER**

#### EMAIL ADDRESS

**TELEPHONE NO.** (Include area code)

**FAX NO.** (Include area code)

#### FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite)

If applicable) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified.

**MAILING/BILLING ADDRESS** (If different from facility address) send Fee Coupon or certificate.

**NUMBER, STREET** (No P.O. Box)

#### CITY

**STATE**

**ZIP CODE**

#### SEND FEE COUPON TO THIS ADDRESS

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#### NAME OF DIRECTOR

(Last, First, Middle Initial)

#### CREDENTIALS

FOR OFFICE USE ONLY
IMPLEMENTATION AND TRAINING SERVICES

ENSURE A SEAMLESS TRANSITION WITH OUR DEDICATED, PROVEN, AND CUSTOMIZATION IMPLEMENTATION SERVICES

CONTACT US
# What you need to perform test

**Process**  
*Be sure to watch the training video (link above)*

<table>
<thead>
<tr>
<th>What you need to perform test</th>
<th>Process</th>
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| 2 staff—a recorder, and someone to perform the test | Performing the test  
1. Register person being tested according to necessary paperwork, assigning them a patient id#.  
2. Wash hands and properly don PPE.  
3. Perform swab according to directions (this will depend on if you do nasal or nasal-pharyngeal swabs). Swab both nares with the same swab.  
4. Return the swab cotton side down (upside down) to the original packaging.  
5. The sample can be stored at room temperature 59-86 degrees Fahrenheit before running the test. If performing > than 2 hours after the swab, the sample must be stored in refrigeration between 35-46 degrees Fahrenheit. |
| PPE: surgical mask, gloves, gown, eye protection | Running the test—watch the instructional video for specific instructions |

[https://www.youtube.com/watch?v=iHy2StGA_sA](https://www.youtube.com/watch?v=iHy2StGA_sA)

https://www.youtube.com/watch?v=wCGUZ2BI7pg
Sofia, the next generation in diagnostic testing, takes rapid testing to a whole new level. Proven lateral-flow technology and proprietary advanced fluorescence chemistry and assay development techniques are all integrated into two small bench-top analyzers that can be used near patient and in laboratory settings.

Sofia 2 has the power to deliver highly accurate, objective and automated Influenza A+B and RSV results fast. With Sofia 2’s proprietary Advance Result Technology (ART), Sofia 2 can produce and store results in as few as 3 minutes, giving you, your providers and your patients an accurate result, faster than ever before.
Concierge Sites for POC Testing Machines

• 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/
STAFFING FOR TESTING

- How many staff it takes to do the point-of-care testing will really depend on how you plan to run your process—at minimum, plan on 2 people depending on how many people you intend to test at one time.

- Most machines are taking 7-8 minutes/test to process negative results, sometimes up to 15 minutes to process positive results.

- Keep in mind, swabs can be stored at room temperature for 2 hours or refrigerated for up to 24 hours.

- For larger homes with more staff, it may be more efficient to utilize one team for testing staff and a second team to run the tests. That way both things are getting done at one time. Inevitably, it will take much longer to run the tests than it will to collect them.

- You will also need to have one person designated for each process (performing and running) to serve as recorder—this person will do the clerical data prior to the performance of the test collection and includes assigning a patient ID, and during the testing to enter the ID and record the result.
LOGISTICAL REQUIREMENTS FOR POINT-OF-CARE TESTING

Set-Up

1. Designate a place OUTSIDE of patient-care areas where you can utilize a walk-through station system.

2. Place a table at the entry for clerical entry. Make sure you are somewhere you can plug in a power cord for your computer.

3. Place a second table at minimum 6ft from the first to hold the testing supplies.

4. Provide two chairs, one for the tester to rest in (this can be a long process!) and one for the person being tested.

5. Provide a trash can, hand sanitizer, and a box of gloves for the person doing the testing.

6. Use duct tape to mark off social distancing between those being tested.

7. Clearly mark your entry and exit areas. Those exiting should not come into contact with those being tested inside the testing area.

*NOTE—all workers, those performing the tests AND clerical workers should wear proper PPE protection, including eye protection, gown, and surgical mask.

This system can be duplicated to run as many testing stations are necessary.
Table 1 for clerical processing

Please remain here until called

Entry

Table 2 for test sampling

Chair for person being tested

Please remain here until called

Exit

6 ft
LOGISTICAL REQUIREMENTS FOR POINT-OF-CARE TESTING

Process

1. Put up signage requiring everyone entering the testing area to wear a mask (this can be a cloth or surgical mask).

2. Enter one at a time into the testing area. Wait until called to enter by the clerk.

3. Allow the clerk to record the necessary information and assign a patient ID#. See spreadsheet (next slide).

4. Move onto table #2 for the test, removing the mask only for the time of the actual testing.

5. NOTE—it may be helpful to provide tissues for after testing as it can cause nasal dripping or sneezing.

6. Once testing is completed, the person being tested should use hand sanitizer and exit the area.

7. Once the sample is obtained, the person performing the test should place the sample rubber tote (it can be as large or small as warranted) or a cooler for refrigeration, depending on how it will be before the tests are processed.

8. The performer should then change gloves, don new gloves, wipe down the chair and testing area, use hand sanitizer or wash their hands, and don new gloves for the next test.
LOGISTICAL REQUIREMENTS FOR POINT-OF-CARE TESTING

Other things to note:

1. You must have a doctor’s order to perform these tests. Standing orders from your medical director is sufficient for both staff and residents. However, you must include the name brand(s) of the point-of-care machine(s) in the order.

2. You do NOT have to be a nurse to perform the point-of-care nasal swab. However, you must be properly trained.

3. Be aware surveyors may request to watch you perform these tests.

4. Time should be taken to ensure you get a good sample, despite the discomfort experienced in the test sampling.

5. It is very important that those performing the tests where proper PPE to ensure their own safety—including eye protection, surgical or respirator mask, preferably with face shield, gloves, and a gown.
REPORTING REQUIREMENTS FOR POINT-OF-CARE TESTING

- Report per CLIA waiver requirements
- Report to NHSN
- Positive results should continue to be reported via the
  - online CD-1 form portal
  - local public health department
  - regional DHSS office
  - weekly NSHN
DOCUMENTATION REQUIREMENTS FOR POINT-OF-CARE TESTING
(From QSO 28-30-NH, August 26, 2020)

(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.

For symptomatic residents and staff, document
- the date(s) and time(s) of the identification of signs or symptoms,
- when testing was conducted,
- when results were obtained, and
- the actions the facility took based on the results.

Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document
- the date the case was identified,
- the date that all other residents and staff are tested,
- the dates that staff and residents who tested negative are retested, and
- the results of all tests.

All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).
DOCUMENTATION REQUIREMENTS FOR POINT-OF-CARE TESTING

For staff routine testing, document
- the facility’s county positivity rate,
- the corresponding testing frequency indicated (e.g., every other week),
- the date each positivity rate was collected, and
- the date(s) that testing was performed for all staff, and the results of each test.

For staff and residents who refuse, document
- the facility’s procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.

If there is a shortage of testing supplies, document
- that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Documenting how you conduct testing
Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).
1. Are supplies for POC testing provided at no cost?
   No, after your supply from CMS is used, you will have to order from a supplier and your expense. However, be sure that you use your HHS stimulus for cost and/or bill DHSS.

2. So we cannot use the BD machine until CLIA is completed? Is there isn’t a grace period?
   If you already have a CLIA# with a pre-existing CLIA and are just adding COVID-19, you need to update your CLIA, but can start testing as soon as you send Form 116.
TOPICS FOR TODAY

Testing QSO-20-38 NH

Pulling Data

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:
   - Document that testing was completed and the results of each staff test; and
   - 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](#), where the information can be found under the “COVID-19 Testing” paragraph.
COVID-19 Nursing Home Data

The Nursing Home COVID-19 Public File includes data reported by nursing homes to the CDC’s National Healthcare Safety Network (NHSN) system COVID-19 Long Term Care Facility Module, including Resident Impact, Facility Capacity, Staff & Personnel, and Supplies & Personal Protective Equipment, and Ventilator Capacity and Supplies Data Elements.

For a list of Frequently Asked Questions, please click here.

For a full list of variables included in this Public Use File (PUF) and their descriptions, please see the data dictionary. The file contains an individual record for each certified Medicare skilled nursing facility/Medicaid nursing facility and the ending date for each collection week, and is updated weekly. More information on CMS requirements for reporting COVID-19 Information can be found here. We note that the presence of cases of COVID-19 in a nursing home does not automatically indicate noncompliance with federal requirements. This information is used to assist with national surveillance of COVID-19 in nursing homes, and support actions to protect the health and safety of nursing home residents.

NOTE: This is preliminary data and may be subject to fluctuations as facilities are given the opportunity to submit and correct their data on the NHSN website. The first deadline for reporting data was 11:59 p.m. EST Sunday, May 17, 2020. As the number of facilities reporting increases each week, it will increase the reported number of COVID-19 cases, suspected cases, and deaths each week. Additionally, facilities may opt to report cumulative data retrospectively back to January 1, 2020. Therefore, some facilities may be reporting higher numbers of cases/deaths compared to other facilities, due to their retrospective reporting. Numbers for Week Ending 05/24/2020 may include reporting for any time between 01/01/2020 through 05/24/2020. Reporting for subsequent weeks is on a weekly basis.

Additionally, data quality checks were performed to identify instances where facilities may have entered incorrect data, such as entering cumulative counts over time instead of new cases, and other data entry errors. In these cases, we will display facilities as having submitted data, but will not include their data in our dataset or analyses to preserve the accuracy of the data presented. Facilities that have submitted erroneous data will have an “N” displayed in the column titled “Passed Quality Assurance Check.”

Therefore, CMS cautions users to consider these factors when performing any analysis. For example, data reported over the first few weeks should not be used to perform trend analysis and longitudinal analyses. We expect the data to stabilize as nursing homes become more familiar with how to submit data via the NHSN Long Term Care Facility Module. Please view the Data Dictionary for more information about data limitations.

COVID-19 Testing

As part of CMS’ commitment to protecting nursing home residents, and to boost the surveillance of COVID-19, nursing homes are now required to conduct testing of residents and staff. More information about these requirements and guidelines can be found here. These guidelines include testing staff on a certain frequency based on the COVID-19 positivity rate for the county the nursing home resides in. Rates of county positivity are posted here. Facilities should monitor these rates every other week and adjust staff testing accordingly.

Supporting COVID-19 Testing

The Department of Health and Human Services, Office of the Assistant Secretary for Health (OASH), recently announced that we will begin providing nursing homes with a Point of Care (POC) rapid response testing instrument to bolster each facility’s ability to prevent the spread of COVID-19. The data collected through the NHSN system directly supports this initiative by helping to prioritize the nursing homes with testing needs and an increasing number of cases. For the methodology describing how facilities are prioritized, and a listing of the facilities, please click here. A list of frequently asked questions (FAQs) is also available here.
## County Data

https://data.cms.gov/stories/s/bkwz-xpvg

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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

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<td>Bollinger County, MO</td>
<td>29017</td>
<td>MO</td>
<td>Region 7</td>
<td>12,133</td>
<td>18.4%</td>
<td>Red</td>
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<tr>
<td>Boone County, MO</td>
<td>29019</td>
<td>MO</td>
<td>Region 7</td>
<td>180,693</td>
<td>8.2%</td>
<td>Yellow</td>
</tr>
<tr>
<td>Buchanan County, MO</td>
<td>29021</td>
<td>MO</td>
<td>Region 7</td>
<td>87,564</td>
<td>5.5%</td>
<td>Yellow</td>
</tr>
<tr>
<td>Butler County, MO</td>
<td>29023</td>
<td>MO</td>
<td>Region 7</td>
<td>42,478</td>
<td>15.8%</td>
<td>Red</td>
</tr>
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<td>Caldwell County, MO</td>
<td>29025</td>
<td>MO</td>
<td>Region 7</td>
<td>9,020</td>
<td>6.5%</td>
<td>Yellow</td>
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<tr>
<td>Callaway County, MO</td>
<td>29027</td>
<td>MO</td>
<td>Region 7</td>
<td>44,743</td>
<td>24.6%</td>
<td>Red</td>
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<tr>
<td>Camden County, MO</td>
<td>29029</td>
<td>MO</td>
<td>Region 7</td>
<td>46,305</td>
<td>10.6%</td>
<td>Red</td>
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<tr>
<td>Cape Girardeau County, MO</td>
<td>29031</td>
<td>MO</td>
<td>Region 7</td>
<td>78,871</td>
<td>13.0%</td>
<td>Red</td>
</tr>
<tr>
<td>Carroll County, MO</td>
<td>29033</td>
<td>MO</td>
<td>Region 7</td>
<td>8,679</td>
<td>4.4%</td>
<td>Green</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%</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>10.9%</td>
<td>Yellow</td>
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<tr>
<td>Cedar County, MO</td>
<td>29039</td>
<td>MO</td>
<td>Region 7</td>
<td>14,349</td>
<td>0.0%</td>
<td>Green</td>
</tr>
<tr>
<td>Chariton County, MO</td>
<td>29041</td>
<td>MO</td>
<td>Region 7</td>
<td>7,426</td>
<td>&lt;10 tests</td>
<td>Green</td>
</tr>
<tr>
<td>Christian County, MO</td>
<td>29043</td>
<td>MO</td>
<td>Region 7</td>
<td>88,595</td>
<td>12.3%</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%</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>12.9%</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%</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%</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>12.9%</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%</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%</td>
<td>Green</td>
</tr>
</tbody>
</table>
AND...THE DATA CHANGES QUICKLY

**08/26/2020 MAP**

**08/30/2020 MAP**

Coronavirus Disease 2019 (COVID-19)
Current consecutive days of downward trajectory, by county
26 Aug, 2020

Days in downward trajectory
- 1-6 days
- 7-13 days
- 14-20 days
- 21-41 days
- ≥42 days
- Not in downward trajectory
- 1-5 cases in the past two weeks
- 0 cases in the past two weeks
- No reported cases

Source: CDC analysis of USAFacts data

Coronavirus Disease 2019 (COVID-19)
Current consecutive days of downward trajectory, by county
30 Aug, 2020

Days in downward trajectory
- 1-6 days
- 7-13 days
- 14-20 days
- 21-41 days
- ≥42 days
- Not in downward trajectory
- 1-5 cases in the past two weeks
- 0 cases in the past two weeks
- No reported cases

Source: CDC analysis of USAFacts data
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
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”):

### Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

<table>
<thead>
<tr>
<th>Community COVID-19 Activity</th>
<th>County Positivity Rate in the past week</th>
<th>Minimum Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt;5%</td>
<td>Once a month</td>
</tr>
<tr>
<td>Medium</td>
<td>5% - 10%</td>
<td>Once a week*</td>
</tr>
<tr>
<td>High</td>
<td>&gt;10%</td>
<td>Twice a week*</td>
</tr>
</tbody>
</table>

*This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.

- October 2nd
- September 9th
- September 5th
DISCUSSION
• Who do we contact for state health department?
https://health.mo.gov/living/lpha/lphas.php

• So we need to contact both local and state?
Yes, you have to report to DHSS within 24 hours of an outbreak and also to your local health department.

• What is meant by contractors? Agency? Physicians?
Anyone that comes in your building for business purposes have to be tested. Even if they come in once a month. They can be tested at their place of business as long as it coincides with the testing you are doing in your building.

• Does testing include anyone in your facility from 9/2 until you do testing? for example if you do not have to test until 10/2 if someone in our facility during that time? Is there a look back?
There is not a look back unless you have an outbreak and then survey will look at your processes.
• What about surveyors?
Surveyors do not have to be tested for COVID, however be sure to assess all surveyors that come to your building and if they have any signs and symptoms they do not proceed into your building.

• Is the testing facility wide or % of staff?
If you are testing for an outbreak or to move into Phase II would require a full facility wide test of all staff and residents. If you are testing to meet the CMS county requirement you will only test all staff.
Region 1 - Ruth Tuttle
149 Park Central Square, Suite 412
Springfield, MO 65806
(417) 895-6435

Region 2 – Cindy Rexroad
1903 Northwood, Suite 4
Poplar Bluff, MO 63901
(573) 840-9580

Region 3 – Michele McElroy-Otis
1410 Genessee, Suite 136
Kansas City, MO 64102
(816) 889-2818

Region 4 – Candice Talbot
207 East McElwain Drive
Cameron, MO 64429
(816) 632-6541

Region 5 Amy Rehard Region
1716 Prospect Drive, Suite C
Macon, MO 63552
(660) 385-5763

Region 6- Laura Smith
920 Wildwood Drive
Jefferson City, MO 65102
(573) 751-2270

Region 7 - Michael Ponder
815 Olive Street, Suite 10
St. Louis, MO 63101
(314) 340-7360