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# FRIENDS & FAMILY COVID-19 CHRONICLE

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## Visitation Letter from Regency Integrated Health Services



August 11, 2020

Dear Residents, Families and Friends,

Thank you for your support and patience as we continue to navigate through the COVID-19 pandemic. We know being separated from your loved ones over the past few months has been very difficult and that each of you are eagerly waiting to find out when facilities will re-open to visitors.

As you may know, last week we received guidance from the Texas Health and Human Services Commission regarding visitations. While we are very pleased to get the information, there are still many questions that must be answered before we can determine when visitors will be allowed and what protocols will be put in place to ensure your safety as well as the safety of our residents and staff.

Although we have not received the final order, some of the guidelines will include:

### **Nursing Facilities**

For the health and safety of facility residents and staff, public visitation is limited to outdoor visits only. Physical contact between residents and visitors is not permitted. Additional conditions a facility must meet to conduct limited outdoor visitation include:

- No confirmed positive COVID-19 cases in staff in the last 14 days.
- No active positive cases in residents.
- Any facility previously experiencing an outbreak that has fully recovered must be adequately staffed and following adequate infection control procedures.
- Facility staff are being tested for COVID-19 weekly.

We will continue to offer virtual visitation and window visits while we work with local and state authorities to address this important reopening policy in Texas.

We appreciate your patience and understanding during this time and we remain committed to keeping you and your loved ones informed as we learn more information.

Sincerely,

## Regency Integrated Health Services Is Fully Stocked on PPE

Regency's Facility Management department continues the enormous task of ordering and distributing PPE (personal protective equipment) to all facilities across the state of Texas and keeping the company's regional warehouses full.

The Regency facilities are now able to order PPE for themselves as the normal supply chains are opening up from the back log experienced during April, May, and June of this year. Likewise the corporate warehouse, which was once the major source of PPE supplies, is now able to take more of a tertiary support role, while the regional warehouses occupy the secondary position to fill any holes that might be experienced in facility ordering.

During the COVID-19 pandemic, Regency has been able to keep adequate protective gear available for all residents and employees due to long hours and selfless dedication from the Facility Management staff. A HUGE thank you goes out to them for all of their hard work!



## COVID-19 Antigen Machines From The Center for Medicare & Medicaid Services, Have Arrived

Recently, Regency Integrated Health Services was notified by CMS (Centers for Medicare & Medicaid Services), that some of their nursing facilities were selected to receive a COVID-19 antigen machine and supplies. Below are some questions and answers from CMS about those machines.

### 1. Who will receive the testing platforms and U.S. Food and Drug Administration (FDA)-authorized antigen diagnostic tests?

Nursing homes will receive either a Quidel Sofia 2 Instrument or Becton, Dickinson and Company (BD) Veritor™ Plus System over the coming months along with the associated FDA-authorized antigen diagnostic tests. To be eligible, nursing homes must have a current CLIA Certificate of Waiver AND meet certain epidemiological criteria. The U.S. Department of Health and Human Services (HHS) will distribute the testing platforms and FDA-authorized antigen diagnostic tests to all nursing homes with a CLIA Certificate of Waiver over the next few months.

### 2. How is distribution of the testing platforms and FDA-authorized antigen diagnostic tests being determined? Will these devices be sent directly to the nursing homes or to states for distribution?

Distribution of instruments and tests are prioritized for facilities based on Centers for Disease Control and Prevention (CDC) epidemiological hotspot data and facilities whose data indicate an elevated risk for COVID-19 transmission. Devices will be sent directly to nursing homes to

ensure that nursing homes can begin testing as soon as they receive the devices and complete the requisite training.

Shipping schedules are based on the availability of instruments and test kits. Facilities that have been prioritized to receive early shipments (within the first 3 weeks) are located in CDC epidemiological hotspot counties. Most shipments will occur in the first 4 weeks, although it may take up to 14 weeks for all nursing homes to receive their shipment due to supply availability.

### 3. When will the testing platforms and authorized point-of-care tests be distributed?

Instruments and authorized diagnostic antigen tests will begin shipping the week of July 20 and shipments will continue over the course of 14 weeks. Supplies will arrive in a single shipment directly from the manufacturer and/or distributor.

### 4. How many COVID-19 test kits will nursing homes receive?

Allotments of instruments and test kits are determined by the estimated volume of tests needed for the facility to test all staff and residents at least once and enable a pathway to conduct ongoing testing according to public health guidelines. This estimated volume is based on the average number of weekly staff, and the average resident census for each facility reported by CMS. All facilities will receive at least one instrument. A second instrument will be allocated to facilities that were identified to receive 900 tests (facilities identified as major outliers).

Nursing homes were categorized into 5 groupings based on their estimated testing needs:

- ★ Small facilities – 150 tests, 1 instrument;
- ★ Small-medium facilities – 240-250 tests, \* 1 instrument;
- ★ Medium facilities – 325-330 tests, \* 1 instrument;
- ★ Large facilities – 600 tests, 1 instrument;
- ★ Major outlier facilities – 900+ tests, 2 instruments.

\*Note: The range accounts for variations in kit size between BD and Quidel. Tests for the BD Veritor™ Plus come in kits of 30 and those for the Quidel Sofia 2 in kits of 25.

### 5. How were nursing homes prioritized to receive a testing platform and FDA-authorized antigen diagnostic tests?

The prioritization is based on CDC epidemiological hotspot data, as well as nursing homes that reported the following information to the CDC by July 5th:

- ★ Current CLIA Certificate of Waiver;
- ★ Three or more confirmed or suspected new cases of COVID-19 in the last 7 days;
- ★ At least one new COVID-19 case in the last 7 days after having zero previous COVID-19 cases;
- ★ Inadequate access to testing in the last 7 days;
- ★ At least one new resident death due to COVID-19 in the last 7 days;
- ★ At least one new confirmed or suspected COVID-19 case among staff in the last 7 days.

6. Will every nursing home receive a point-of-care instrument and associated tests?

CMS has prioritized > 3,900 nursing homes to receive instruments and tests in the coming weeks. Once those shipments are complete, HHS will continue a phased distribution of antigen testing supplies to nursing homes with a current CLIA Certificate of Waiver and based on updated epidemiological data.

7. Which nursing homes will receive instruments and tests in the first wave of shipments?

Regency Integrated Health Services has received 25 COVID-19 antigen testing machines across the company from CMS.

8. When will my nursing home receive the shipment of testing platforms and FDA-authorized antigen diagnostic tests?

Instruments and tests will be shipped on a weekly basis directly to CMS-prioritized nursing homes. Instruments and tests will begin shipping the week of July 20 and shipments will continue over the course of 14 weeks. Each nursing home will receive one shipment that includes supplies to facilitate baseline testing among nursing home residents and staff and enable a pathway to conduct ongoing testing according to public health guidelines.

9. What are antigen tests? Is it required to retest negative results with a PCR test?

Antigen diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs.

Negative results should generally be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. If necessary, confirmation with a molecular assay for patient management may be performed. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

10. How many tests can be conducted with the Quidel Sofia 2 Instrument and the BD Veritor™ Plus System testing platforms?

Each test takes about 20 minutes to perform from start to finish. However, it is possible to run tests in an assembly line fashion to test 20 – 30 samples per hour. To use this strategy, the start time for each test is staggered by a few minutes. Next, at the end of the test incubation period, each test is read one by one every few minutes. Instructions for using batch mode are included with the Instructions for Use and vendor training.

11. Why is the federal government sending antigen testing supplies to nursing homes if they cannot be used to rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment?

Fighting this global pandemic requires an array of different technologies, including antigen testing. In areas of high prevalence or for patients with known risk factors, positive results from an antigen



test can be considered confirmatory and used for diagnostic purposes. In areas of high prevalence, confirming negative results using an alternate form of testing is recommended. In low-prevalence areas where the patient is asymptomatic, results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

12. Are nursing homes required to report results of any COVID-19 tests?

Yes. All laboratories must have a CLIA Certificate and report the results of the COVID-19 tests that they conduct to the appropriate federal, state, or local public health agencies. Laboratories must report data for all testing completed, for each individual tested. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual's residence. Testing sites must report all diagnostic test data in accordance with the HHS Lab Data Reporting Guidance for COVID-19 issued June 4, 2020 and meet these reporting requirements by August 1, including providing your facility name and CLIA number when reporting results.

13. Can nursing homes keep the testing platforms?

Yes. Upon receipt, the instrument(s) become the property of the nursing home and can be used in accordance with the conditions of authorization for the test.

14. Do facilities need a provider order to conduct the test?

These 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.

## COVID-19 Chronicle New Distribution Schedule

At Regency Integrated Health Services, we try to keep families, friends, and employees abreast of any new or helpful information while we are all navigating COVID-19 during this unprecedented time. One component of these efforts has been to publish a weekly newsletter. As the COVID-19 landscape is not changing as frequently as it once was, we will begin publishing the COVID-19 Chronicle and the Family & Friends COVID-19 newsletters monthly going forward.

## Guadalupe Valley Nursing and Rehabilitation Center Circus

Guadalupe Valley Nursing and Rehabilitation in Seguin, TX hosted a circus for the residents. They had clowns and wild (stuffed) animals to show off.

The circus traveled the halls delivering popcorn and fun for all the residents!

