

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0676670	(X3) Date Survey Completed 10/12/2021
Name of Provider or Supplier Colonial Health & Rehab Center	Street Address, City, State 1604 Old Donation Pkwy, Virginia Beach, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (#VA00053192) was conducted at Colonial Health and Rehab Center on October 5, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The investigation also included virtual interviews with the facility's administrator and director of nursing on 10/8/21 and 10/12/21. The laboratory holds a Certificate of Waiver and operates under CLIA # 49D0676670. Based on a tour, review of documents and interviews, the inspector found the pre-analytic and analytic complainant allegations to be substantiated. Specific deficiency cited is as follows:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: A. Based on a complaint investigation review of the Centers for Medicare and Medicaid Services (CMS) Automated Survey Processing Environment (ASPEN) database, interviews, testing personnel (TP) training/competency assessments, tour, review of Food and Drug Administration (FDA) Emergency Use Authorization (EUA) Instructions for Use (IFU), lack of documentation, and resident test logs, the skilled nursing facility failed to provide documentation of training for two (2) COVID-19 EUA test methods per manufacturers' requirement prior to reporting resident results during the review timeframe of November 2020 to the date of the investigation on 10/05/21. Findings include: 1. In a pre-survey review of the CMS ASPEN database on 10/1/21, the inspector noted that the skilled nursing facility reported utilizing BD Veritor System Rapid Detection of SARS-CoV-S and BinaxNOW Antigen card COVID-19 testing under EUA. 2. During an entrance interview, on 10/05/21 at</p>

approximately 3:00 PM, the administrator stated: "This facility changed ownership in November 2020 and I came onboard as the administrator in April 2021. To the best of my knowledge, we are using BinaxNow cards for rapid testing at this time. The staff did use BD Veritor at one time. We had a medical assistant and nursing director who were the primary testing personnel but they are no longer employed. Our new director of nursing is currently documenting training for all nursing staff to test the residents."

3. The inspector requested to review staff training records for the 2 test methods outlined above (timeframe November 2020 to 10/05/21). The facility provided the following BinaxNow Training Checklist competency assessments: TP #1, TP #2, TP #3, TP #4, TP #5 dated 09/21/21; TP #6 dated 09/23/21; TP #7, TP #8 dated 10/05/21; The inspector requested to review training records for the BD Veritor test method. No documentation was available for review.

4. During a tour of the facility at approximately 3:30 PM, the inspector observed four (4) BD Veritor Rapid SARS-CoV-2 test kits (lot number 0330427) and ten (10) Abbott BinaxNow kits (lot numbers 132172, 155373, 158725) stored for use.

5. Review of the FDA's issued EUA grants for the 2 test methods revealed: BD Veritor System for Rapid Detection of SARS-CoV-2 EUA (dated 03/31/21) included a manufacturer's IFU statement that read "Conditions of Authorization for Laboratory and Patient Care Setting: All operators using your product must be trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use the product in accordance with the authorized labeling." BinaxNOW COVID-19 Ag Card EUA (revised 12/2020) included a manufacturer's IFU statement: "Conditions of Authorization for Laboratory and Patient Care Setting: All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling".

6. Review of available rapid COVID-19 test logs revealed: One thousand one hundred six (1,106) resident rapid COVID-19 tests were assayed/reported utilizing BD Veritor method during timeframe of 11/23/21 to 2/10/21. The inspector noted that the facility failed to document staff training prior to reporting the 1,106 BD Veritor test results; One thousand six hundred thirty-eight (1,638) resident rapid COVID-19 tests were assayed/reported from March 2021 to 9/24/21 with no test method mentioned. The inspector inquired regarding the lack of test method identification. No additional documentation was available. The administrator stated, on 10/5/21 at approximately 4:00 PM: "It is my understanding that the staff used the Binax cards after March 2021. I am not aware of anyone using the BD Veritor tests after March." The inspector noted that the facility failed to document their BinaxNow Training Checklist for staff testing personnel prior to 09/21/21.

7. An interview with the administrator on 10/12/21 at approximately 3:00 PM, confirmed the above findings.

B. Based on a review of the facility's policies/procedures, manufacturers' package inserts, resident test logs, and lack of documentation, the skilled nursing facility failed to record documentation of acceptable quality control (QC) for two COVID-19 EUA test methods per manufacturers' instructions during the review timeframe of November 2020 to the date of the inspection on 10/05/21. Findings include:

1. Review of the available policies/procedures revealed the facility lacked general laboratory QC protocols for COVID-19 testing.
2. Review of manufacturer's package inserts revealed: Abbott BinaxNow Ag Card instructions stated under Quality Control: "Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. Each kit contains a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. If the correct control results are not obtained, do not perform patient tests or report patient results."; BD Veritor System

Rapid SARS-CoV-2 instructions stated under Warnings and Precautions: "Do not use this kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results". 3. Review of the facility's resident COVID-19 test logs revealed no record of QC for the BD Veritor or Abbott BinaxNow test kits during the timeframe of November 2020 to 9/24/21 while the facility reported two thousand seven hundred forty-four (2,744) resident results. The inspector requested notation/documentation of acceptable QC for the timeframe outlined above. No QC documentation was available for review. 4. An interview with the administrator on 10/12/21 at approximately 3:00 PM, confirmed the above findings. C. Based on a tour, review of policies/procedures, manufacturers' package inserts, reagent certificate of conformance, and resident test logs, the skilled nursing facility failed to label expired reagents as to "do not use" per manufacturers' instructions while storing four (4) expired BD Veritor Rapid SARS-CoV-S test kits from April 1, 2021 and up to the date of the inspection, 10/5/21. Findings include: 1. During a tour of the facility's COVID-19 kit supply storage areas on 10/05/21 at approximately 3:15 PM, the inspector observed 4 expired BD Veritor Rapid SARS-CoV-2 test kits (lot number 0330427, expiration date 04/01/21) in addition to ten BinaxNOW COVID-19 Ag Card test kits. 2. Review of the BD Veritor package insert revealed instructions stated under Warnings and Precautions: "Do not use this kit beyond the expiration date printed on the outside carton." The inspector inquired regarding the expired reagent and requested if the facility had contacted the manufacturer for an expiration date extension. The administrator stated at approximately 3:30 PM: "I will have to email our supply contact to verify if the expiration date was extended." 3. Review of the emailed supplier's BD Rapid Diagnostics (Suzhou) Co. LTD. Suzhou, Jiangsu China, Certificate of Conformance for Kit Lot 0330427 revealed the manufacturer had not extended the expiration date beyond 04/01/21. 4. Review of the facility's test logs revealed one thousand six hundred thirty-eight (1,638) resident rapid COVID-19 tests were assayed/reported during the timeframe of March 2021 to 9/24/21 with no test method indicated. The inspector inquired regarding if the test method BD Veritor had been used during the seven (7) months reflected on the test logs. No documentation was available to verify the test method or kit lot numbers utilized for reporting the 1,638 COVID-19 test results during the recent 7 months of test reporting. 4. An interview with the administrator, on 10/12/21 at approximately 3:00 PM, confirmed the above findings