

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0909286	<b>(X3) Date Survey Completed</b>  02/24/2021
<b>Name of Provider or Supplier</b>  Fountainbleau Nursing Center	<b>Street Address, City, State</b>  1349 Highway 61, Festus, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<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: Based on review of the manufacturer's instructions for use (IFU) for the BinaxNOW COVID-19 Ag Card, lack of product notification to CLIA state agency, COVID-19 test records/medical records documentation for 2020, facility policies and procedures and interview with the Assistant Director of Nursing, the Fountainbleau Nursing Center laboratory failed to follow the manufacturer's IFU. Findings: 1. The manufacturer's IFU, "Conditions of Authorization for Laboratory and Patient Care Settings" states the following: a) " Authorized laboratories that receive your product (BinaxNOW COVID-19 Ag Card) must notify relevant public health authorities of their intent to run your product prior to initializing testing" b) "Authorized laboratories using your product (BinaxNOW COVID-19 Ag Card) must have a process in place for reporting test results to healthcare providers and releveant public heathlth authorities, as appropriate." c) "...authorized laboratories using your product (BinaxNOW COVID-19 Ag Card) must ensure that any records associated with this EUA are maintained until authorized by the FDA" 2. Review of facility information in the CLIA database revealed no documentation to show the nursing center notified the state CLIA agency of their intent to use the BinaxNOW COVID-19 Ag Card product for COVID-19 testing. 3. Review of patient COVID-19 test records/log dated November 18, 2020 revealed a positive (+) COVID-19 test result for patient (B). No documentation was available in the DHSS EpiTrax system to show a positive result for patient (B) was reported for test performed November 18, 2020 (Refer to D1002). 4 .Review of medical records revealed patient (B) had onset of COVID-19 Saturday November 21, 2020. No COVID-19 test result log was retrievable for November 21,</p>

2020 to show whether the test was performed on patient (B). 5. Policy and Procedure "Outbreak Management" states, "Notify the Public Health Agency and DHSS section for Long Term Care Regulation" and " within 24 hours of positive results." 6. Phone interview February 17, 2020 at 12:28 PM, with the Assistant Director of Nursing confirmed the nursing center laboratory failed to follow manufacturer's IFU and written policies and procedures.

**D1002**

**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.

This CONDITION is not met as evidenced by:  
Based on review of reporting documentation from Missouri Department of Health and Senior Services (DHSS) Epidemiology ( EpiTrax), COVID-19 patient (B) testing records/medical records for November 2020, nursing center policies and procedures, COVID-19 reporting requirements and interview with EpiTrax staff (M) and Assistant Director of Nursing for the Fountainbleau Nursing Center, the nursing center laboratory failed to report SARS-CoV-2 test results. Findings: 1. Review of COVID-19 patient test records (log) dated November 18, 2020 revealed a COVID-19 positive (+) test result for patient (B) was documented on the daily patient log. There was no documentation to show the nursing center reported the positive result obtained on patient (B) November 18, 2020 to the DHSS EpiTrax system. 2. Review of medical records showed patient (B) had a principal diagnosis of COVID-19 with onset date of November 21, 2020 The nursing center could not provide a COVID-19 testing log for Saturday, November 21, 2020 to show whether the nursing center laboratory tested patient (B) and obtained a positive result. On phone interview the Assistant Director of Nursing said the facility does not maintain a COVID-19 testing log on weekends (Saturday, Sunday) unless the patient exhibits signs or symptoms. There was no documentation to show the nursing center reported the positive results purportedly performed on the onset date of November 21, 2020 to the DHSS EpiTrax system. 3. The nursing center policies and procedures for reporting COVID-19 test results states, "Within 24 hours of positive results, complete Electronic COVID-19 Case reporting including staff and residents. Notify the DHSS section for Long Term Regulation." 4. Phone interview with EpiTrax staff (M) on February 11, 2021 at 1:17 PM confirmed the system did not show positive COVID-19 test results for patient (B) performed on November 18, 2020 and purportedly performed on November 21, 2020. 5. Phone interview with the Assistant Director of Nursing on February 17, 2021 at 12:28 PM confirmed, the nursing center laboratory failed to report all COVID-19 tests.