

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0864861	(X3) Date Survey Completed 11/05/2021
Name of Provider or Supplier Greenleaf Medical Associates	Street Address, City, State 401 S Greenleaf Ave, Ste 1, Park City, IL	
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
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: Based on direct observation, record review, and interviews, the laboratory failed to follow the emergency use authorization (EUA) and the instructions for use (IFU) for SARS-CoV-2 Antigen testing as required, affecting 2218 patients' results. Findings include: 1. The CareStart COVID-19 Antigen EUA and IFU, correspondences with Midwest COVID Testing representative, and laboratory reporting procedures were reviewed. 2. The CareStart COVID-19 Antigen EUA and IFU listed the following requirements under "CONDITIONS of AUTHORIZATION for LABORATORY" *Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. * Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted. *Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing. *Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. *All operators using your product must be appropriately trained in performing and interpreting the results of our product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. *Do not use the kit contents beyond the expiration date. *After swabbing both of the patient's nostrils, place the patient's swab into the extraction vial. 3. On 11/05/2021 at 12:22 PM during a tour of the laboratory, the surveyor observed a blue basket of 17 CareStart COVID-</p>

19 Antigen test devices with Lot #CH21B24, Expiration date July 2021 in-use. 4. On 11/05/2021 at 1:15 PM via telephone interview with the Midwest COVID Testing employee and manager, the following was revealed: *The laboratory failed to provide each patient receiving the COVID-19 Antigen test with an authorized FACT SHEET. *The laboratory failed to ensure 'operators' or employees' training were performed and documented, prior to testing patients. *Testing personnel (TP) failed to follow collection procedures by taking patients' swabs after collection and returning them to their swab sleeves; the EUA states these swabs are to be place into the extraction tubes. *The laboratory failed to ensure testing kits were not expired prior to use. 5. 2215 patients were tested from August 1, 2021 through November 5, 2021 with the expired COVID-19 Antigen test devices. 6. An On-site Complaint survey was conducted on 11/05/21 at 1:00 PM, the laboratory director confirmed the above findings.

D5980

PPM LABORATORY DIRECTOR
CFR(s): 493.1355

The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.

This CONDITION is not met as evidenced by:

Based on direct observation, record review, and interviews, the laboratory director (LD) failed to provides overall management and direction in accordance with 493.1359 to ensure SARS-CoV-2 Antigen testing is performed in accordance with the Emergency Use Authorization (EUA) and performed by qualified and trained individuals (D5987), affecting 2218 patients' test results.

D5987

PPM LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1359(b)

The laboratory director must-- (b) Ensure that any procedure listed under 493.19(c)-- (b)(1) is personally performed by an individual who meets the qualification requirements in 493.1363; and (b)(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

This STANDARD is not met as evidenced by:

Based on direct observation, record review, and interviews, the laboratory director (LD) failed to ensure the emergency use authorization (EUA) for SARS-CoV-2 Antigen testing is performed in accordance with it's EUA and the Clinical Laboratory Improvement Amendments (CLIA) requirements, and performed by qualified and trained individuals, affecting 2218 patients' results. Findings include: 1. Correspondences with Midwest COVID Testing representative, the CareStart COVID-19 Antigen EUA, and laboratory reporting procedures were reviewed. 2. The LD authorized Midwest COVID Testing to provide the following services: *To establish and maintain an electronic medical record system for patients receiving COVID-19 testing. *To provide and manage personnel to perform COVID-19 testing. *To provide COVID-19 test kits and supplies. *To report patient results to Public Health Agencies and authorized providers. 3. The LD failed to ensure the CareStart COVID-19 Antigen EUA procedures were followed by Midwest employees; failed to ensure Midwest employees were qualified and trained prior to testing patients; failed to ensure test kits were not used passed their expiration dates; and failed to ensure each

tested patient received information as required by the CareStart EUA. See D1001. 4. 2215 patients were tested from August 1, 2021 through November 5, 2021 with the expired COVID-19 Antigen test devices. 5. An On-site Complaint survey was conducted on 11/05/21 at 1:00 PM, the laboratory director confirmed the above findings.