

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0878205	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier American Family Medical Center	Street Address, City, State 1254 Ogden Ave, Downers Grove, 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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.</p> <p>This CONDITION is not met as evidenced by: Based on direct observation, laboratory records, and interview with laboratory testing personnel (LTP); the laboratory failed to meet the requirements of this condition. The laboratory failed to provide a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (Refer to D3005).</p>
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's emergency use authorization (EUA), and</p>

interview with laboratory testing personnel (LTP); the laboratory failed to maintain a unidirectional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection for SARS-CoV-2 in 2023. Findings Include: 1. Review of the "GeneFinder COVID-19 Plus RealAmp Kit FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY - Instructions for Use; 7. Warnings and Precautions" revealed the following: a. "Separate laboratory areas, dedicated to performing predefined procedures of the assay, are required. a) 1st Area: Preparation Area-Prepare testing reagent: b) 2nd Area: specimen processing-Process the specimen and controls: c) 3rd: Amplification Area-PCR conducted." b. "All materials used in one area should remain in that area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected immediately." c. "Immediately after the addition of the Nucleic Acid reaction Mix, the 96 well plate for real-time PCR should be covered and transferred to a separate specimen processing area." d. "To prevent contamination from exogenous RNA, samples should be prepared in the following sequence: 1) no template (negative) control, 2) specimen RNA, and 3) positive control." 2. Direct observation on 04/26/2023 at 12:53 p.m., of LTP #4 demonstrating the testing procedures for the GeneFinder COVID-19 Plus RealAmp Kit (GCP) assay revealed the following: a. Review of the EUA Warnings and Precautions listed in Finding #1(a), direct observation, and interview with LTP #4 revealed the laboratory failed to provide separate laboratory areas for preparing GCP testing reagents, processing patient sample plates, and the processing of positive and negative assay controls. An interview with LTP #4 on 04/26/2023, at 12:53 p.m. revealed; "One hood is used for everything". (Biosafety cabinet marked, "SSII VP"). b. Review of the EUA Warnings and Precautions listed in Finding #1(b), direct observation, and interview with LTP #4 revealed the laboratory failed to maintain one area for the multichannel pipettes utilized for the addition of positive and negative control samples to patient test plates. i. Three of three single pipettes were observed in the biosafety cabinet "SSII VP" revealed in Finding #2(a). ii. Four of four multichannel pipettes (Integra) were observed on a shelf outside of the biosafety cabinet "SSII VP". iii. An interview with LTP #4 on 04/26/2023 at 1:14 p.m. revealed; "The multichannel pipettes (Integra) are used to add the positive and negative controls. c. Review of the EUA Warnings and Precautions listed in Finding #1(c), direct observation, and interview with LTP #4 revealed the laboratory failed to provide a separate specimen processing area after the addition of the Nucleic Acid reaction Mix to the 96 well plate for GCP assay patient testing. An interview with LTP #4 on 04/26/2023, at 12:53 p.m. revealed; "One hood is used for everything". (Biosafety cabinet marked, "SSII VP"). d. Review of the EUA Warnings and Precautions listed in Finding #1(d), direct observation, and interview with LTP #4 revealed the laboratory failed to follow the order of sequence for preparing the GCP assay samples to prevent ribonucleic acid (RNA) contamination. An interview with LTP #4 on 04/26/2023, at 12:53 p.m. revealed; "The sample is added, then master mix; at the end of the plate, the positive and negative controls are added at the same time." 3. On 04/26/2023 at 1:14 p.m., LTP #4 confirmed the above findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

use.

This STANDARD is not met as evidenced by:

Based on laboratory records, direct observation, and interview with laboratory testing personnel (LTP); the laboratory failed to identify, label, and date one of three reagents utilized for the patient testing of SARS-CoV-2 in 2023. Findings Include: 1. Review of the "GeneFinder COVID-19 PLUS RealAmp Kit Emergency Use Authorization (EUA), Instructions for Use" revealed the following: a. "7. Warnings and Precautions - All contents in this package are prepared and validated for the intended testing purpose. Replacement of any of the package contents will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots." 2. On 04/26/2023 at 12:47 p.m., direct observation revealed one of three reagents stored in the "GeneFinder COVID-19 PLUS RealAmp Kit - Lot #: 2201-R45-02, Expiration date: 2023-01-18", stored in "Freezer #3 (Accucold)", failed to reveal any markings for identity, storage requirements, lot number, or expiration date. 3. On 04/26/2023 at 12:47 p.m., LTP #4 confirmed the above findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, direct observation, and interviews with laboratory testing personnel (LTP) and the laboratory consultant; the laboratory failed to discontinue the use of two of two expired reagent test kits for the testing of SARS-CoV-2 from 01/19/2023 to 04/26/2023. Findings Include: 1. Review of the "American Family Medical Center GeneFinder COVID-19 PLUS RT-PCR Assay Procedure" revealed the following: a. "6. Reagent - a. Storage and Stability (iii): Do not use after expiration date." 2. On 04/26/2023 at 12:47 p.m., direct observation revealed two of two "GeneFinder COVID-19 PLUS RealAmp Kits - Lot #: 2201-R45-02, Expiration date: 2023-01-18" in use on the date of survey (04/26/2023). 3. Surveyor review of the expiration dates of the reagent kits identified in Finding #2 revealed the following: a. "Expiration date: 2023-01-18" 4. Review of the "American Family Medical Center COVID-19 PCR test - Reagents in Use" form revealed the following: a. Reagent: GeneFinder; Lot Number: 2201-R45-02; Expiration Date: _____, Open date: 3-1-23; By: SMK". b. Reagent: GeneFinder; Lot Number: 2201-R45-02; Expiration Date: _____, Open date: 3-16-23; By: SSK". c. Reagent: GeneFinder; Lot Number: 2201-R45-02; Expiration Date: _____, Open date: 4-10-23; By: SMK". 5. On 04/26/2023 at 12:53 p.m., an interview with LTP #4 revealed, "Ok to use expired kits, the laboratory consultant is calling the company to confirm." 6. On 04/26/2023 at 3:30 p.m., an interview with the laboratory consultant revealed a total of 427 patient samples were tested for SARS-CoV-2 from 01/19/2023 to 04/26/2023. 7. On 04/26/2023 at 3:30 p.m., the laboratory consultant confirmed the above findings.