

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2270232	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier Genuincare Llc	Street Address, City, State 9610 Medical Center Dr Suite 200, Rockville, MD	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure, the reagent log, and reagent packing slips and interview with the testing person (TP), the laboratory failed to document the lot number and expiration dates of reagents used for reverse transcription polymerase chain reaction severe acute respiratory syndrome coronavirus 2 (RT-PCR SARS-CoV-2) testing. Findings: 1. The laboratory performed RT-PCR SARS-CoV-2 testing that included extracting nucleic acid from patient specimens. 2. The extraction reagent kit included wash buffer, binding buffer, magnetic beads, proteinase K, and elution buffer. The CovidNow SARS-CoV-2 Assay Kit (assay kit) included the primer/probe mix and the positive and negative controls. 3. Procedure "Gen 22" titled "Reagent Receiving and QC" stated that for new reagents to "Open the Lot Verification log and navigate to the appropriate tab to enter the required information (vendor, storage temp, catalog number, lot number, received date, and expiration date)" and to "Document the use of a new reagent lot or shipment by entering the date put into use and the batch number into the Lot Verification log." On 09/26/2023 at 12:15 PM, the TP confirmed that the laboratory did not use a "Lot Verification log." 4. The laboratory had a reagent log titled "Reagents Order" that included the reagent name, lot number, and expiration date. The reagents from the extraction kit were all listed as expired by 01/26/2023 and from the assay kit were all listed as expired by 11/2022. 5. In the laboratory, an opened bottle of elution buffer was found with an expiration date of 12/2023 and a packing slip for assay kit lot 23068 was found showing that the kit was received on 03/14/2023. There was no documentation of when the buffer or assay kit were put into use for patient testing. 6. An image of a packing slip for another</p>

assay kit was emailed to the surveyor on 10/02/2023 and showed that the assay kit was received on 02/21/2023. There was no documentation of when the assay kit was put into use. 7. Accession number 10039 was tested and reported on 02/19/2023. It is unknown what lot number of the extraction and assay kits was used for testing 10039 and whether they were within the expiration dates. 8. During the survey on 09/26/2023 at 1:00 PM, the TP confirmed that the laboratory did not use the Lot Verification log referred to in their procedure, did not have a log or record of all reagents used for patient testing, and did not have documentation when reagent lot numbers were put into use for patient testing.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient test logs, requisition forms, and test reports, and interview with the testing personnel (TP), the laboratory failed to ensure that the specimen collection date was accurately reflected on two of three patient test reports. Findings:
1. The laboratory kept a patient test log that was organized by the date of testing. Each date of testing had a separate sheet of paper that had the barcodes of the patients that were tested on that date affixed to the sheet. 2. Three patients were randomly selected to review the requisition form and patient test report. 3. The requisition forms included a handwritten date and initials of the TP indicating when specimen collection was performed. The collection time was not documented. 4. Data from the requisition form was entered into a laboratory information system (LIS) that indicated which fields were required for entry. There was a section to input the collection date and time, but this was not indicated as a required field. The TP stated that patient data for the test report was pulled from the LIS. 5. The requisition for accession number 10063 showed that the specimen was collected on 03/06/2023. The patient log showed that it was tested on 03/06/2023. The final report showed that the specimen was collected on 03/07/2023 at 7:00 AM. 6. The requisition for accession number 10139 showed that the specimen was collected on 04/13/2023. The patient log showed that it was tested on 04/14/2023. The final report showed that the specimen was collected on 04/15/2023 at 9:00 AM. 7. During the survey on 09/26/2023 at 1:00 PM, the TP confirmed that two out of three randomly selected patient test reports listed an incorrect collection date and time.