

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0539775	(X3) Date Survey Completed 08/22/2024
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 2600 Mill St Suite 100, Reno, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 22, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of the laboratory's quality monitoring program from July 2023 through July 2024, and an interview with the laboratory manager and accessioning personnel, the laboratory failed to ensure optimum integrity of patient specimens from time of collection through reporting of results. Findings include: 1. A review of the laboratory director approved policy titled "Satellite Laboratory Quality Monitoring Program", states that a quarterly review of the accuracy of testing documentation for four random patients, including requisitions, draw site orders, and results, will be performed in January, April, July and October. The checklist includes review items for Preanalytical, Order Entry, and the Final Report. 2. A review of the quarterly reports from July 2023 through July 2024, found that in the quarterly report for July 2023, the laboratory failed to correctly document where the send out specimen was sent for one of four final patient reports reviewed by the laboratory. The final patient report for accession number 205-408-0003 contained an incorrect message that the split specimen was sent out to the Laboratory Corporation facility in</p>

Phoenix, Arizona. The requisition for accession number 205-408-0003 indicated that the split specimen was to be sent to Renown Medical Center in Reno, Nevada. In an interview on August 22, 2024 at approximately 1:30 PM, the laboratory manager confirmed that the split specimen for accession number 205-408-0003 had been sent to Renown Medical Center. "Flagging and message codes" were marked as correct on the checklist. 3. A review of the quarterly reports from July 2023 through July 2024, found that in the quarterly report for July 2024, the laboratory failed to detect that one of four patient files reviewed by the laboratory did not consistently document the patient's date of birth. The requisition form from the provider for accession number 198-408-0003 documented the patient's date of birth as 12/22/1988. The test order form from the Labcorp collection site documented the patient's date of birth as 9/25/1988. The patient report documented the patient's date of birth as 09/25/1988. "DOB or age" under Order Entry Review and "Client/Patient Demographics match data entry" under Final Report Review were both marked as correct on the checklist. 4. A review of the quarterly reports from July 2023 through July 2024, found that in the quarterly report for July 2024, one of four patient reports reviewed by the laboratory was missing the Labcorp collection site test order indicating the correct specimen collection date and time for accession number 192-408-0011. The manually completed requisition from the provider indicated 7/11/24 as the collection date. The patient report and the instrument data indicate both the specimen collection date and instrument testing date are 7/10/2024. The actual collection date was unable to be verified. "Date Collected" and "Time Collected" under Order Entry Review were marked as correct on the checklist. 5. A review of the quarterly reports from July 2023 through July 2024, found that in the quarterly report for July 2024, the laboratory failed to correctly document the patient's age on the form titled "Order Entry/ Final Report Review Form" for two of four patient files reviewed. a. The patient report for accession number 192-408-0011 documented the patient's age as 53. The Order Entry/ Final Report Review form indicated the patient's age was 54. b. The patient report for accession number 191-408-0001 documented the patient's age as 77. The Order Entry/ Final Report Review form indicated the patient's age was 71. c. "DOB or age" under Order Entry Review was marked as correct on the checklist for both patients. 6. An interview with the laboratory accessioning personnel on August 22, 2024 at approximately 1:30 PM confirmed these findings. The laboratory performs approximately 22,140 chemistry tests and 26,550 hematology tests annually.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of the 12 patient test reports included in the laboratory's quality management audits between July 2023 through July 2024, a random review of five patient reports from July 2024, and an interview with the laboratory manager, the laboratory failed to provide pertinent reference ranges on the test reports. Findings include: 1. A review of the 12 patient test reports included in the laboratory's quality management audits between July 2023 through July 2024, and a random review of five patient reports from July 2024, revealed that six of six patient reports for Complete Blood Counts (CBC) failed to include reference ranges for % Neutrophils, % Lymphs, % Monocytes, % Eos, % Basos. 2. The reference ranges for %

Neutrophils, % Lymphs, % Monocytes, % Eos, % Basos were documented as "Not Estab." 3. An interview with the laboratory manager on August 22, 2024 at approximately 1:30 PM confirmed these findings. The laboratory performs approximately 26,550 hematology tests annually.