

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2195062	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Anchor Project Center	Street Address, City, State 2333 Maccorkle Ave, Saint Albans, WV	
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	<p>An announced, on site, initial survey was conducted at Anchor Project Center on March 2, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2020 and 2021 laboratory quality assurance (QA) logs and an interview with the technical consultant (TC), the laboratory failed to monitor and document the (1) water quality (2) temperature and (3) humidity conditions of the laboratory for 2 of 5 months reviewed. Findings: 1. Review of 2020 and 2021 QA logs during the survey at approximately 11:30 AM, revealed no documentation of temperature, humidity, or water quality conditions for 2 of 5 months of patient testing. a. October 2020 and November 2020 had no documentation of temperatures, humidity, and water quality conditions. b. December 2020, January 2021, and February 2021 had documentation of temperatures, humidity, and water quality conditions for each day of patient testing. 2. During an interview with the TC, on 3/3 /2021 at approximately 11:45 AM, the TC stated there was not any documentation of temperatures, humidity, and water quality for October and November 2020.</p>

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory maintenance logs and an interview with the technical consultant (TC), the laboratory failed to document the daily, weekly, and monthly maintenance of the CLC720i analyzer for 2 of 5 months of patient testing. Findings: 1. A review of monthly maintenance logs for the CLC720i analyzer at approximately 11:30 AM, spanning October 2020 thru February 2021, revealed no documentation of daily, weekly, or monthly maintenance on the CLC720i analyzer for October and November 2020. 2. During an interview with the TC, on 3/5/21 at approximately 11:40 AM, the TC stated there was not any documentation of the CLC720i maintenance for October and November 2020.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory 2020 and 2021 quality control (QC) data records, and an interview with the technical consultant, the laboratory failed to perform and document the acceptability of the QC of all analytes before reporting patient results from the CLC720i analyzer. Findings: 1. Review of October 2020 QC data records during the survey at approximately 10:15 AM, revealed 2 of 7 dates of patient testing that no acceptable QC was documented for the 6AM and Ecstasy analytes. a. 10/09/2020 had no acceptable QC for 6AM and Ecstasy. b. 10/22/2020 had no acceptable QC for 6AM and Ecstasy. 2. Review of November 2020 QC records during survey at approximately 10:20 AM, revealed 5 of 7 dates of patient testing that no acceptable QC was documented for 6AM and/or Benzodiazepine. a. 11/3/2020, 11/5/2020, 11/10/2020, 11/12/2020, and 11/19/2020 had no acceptable QC for 6AM. b. 11/10/2020 and 11/12/2020 had no acceptable QC for Benzodiazepine. 3. During an interview with the TC, on 3/2/2021 at approximately 10:30AM, the TC confirmed there was not any acceptable QC for the dates and analytes identified during the QC data record review.