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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D2166979 | (X3) Date Survey Completed 01/22/2020 |
| Name of Provider or Supplier Surviving Our Losses And Continuing | Street Address, City, State 729 6th Street, Portsmouth, OH | |
| 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 |
|---------------------------|---|
| D2000 | <p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Technical Supervisor, the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialty of toxicology. All patient toxicology testing performed in this laboratory from 08/13 /2019 to 01/22/2020 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to enroll in a proficiency testing (PT) program for the regulated toxicology analytes. (Refer to D2001)</p> |
| D2001 | <p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> |

This STANDARD is not met as evidenced by:
Based on an interview with the Technical Supervisor (TS), the laboratory failed to enroll in a proficiency testing (PT) program for the regulated toxicology analytes. All patient toxicology testing performed in this laboratory from 08/13/2019 to 01/22/2020 had the potential to be affected by this deficient practice. Findings Include: 1. The Inspector requested the laboratory's PT enrollment records for toxicology from the TS. The TS confirmed the laboratory was not enrolled with a PT provider for toxicology and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/22/2020 at 11:15 AM. .

D5413

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

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.

This STANDARD is not met as evidenced by:
Based on record reviews and an interview with the Technical Supervisor (TS), the laboratory failed to follow the manufacturer's requirements for the room temperature and humidity for the AB Sciex 4500 Series LC-MS in 2019 and 2020. All patient toxicology testing between 08/13/2019 to 01/22/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the manufacturer's requirements found the following statements: "Environmental Requirements... An ambient temperature of 15C to 30C (59F to 86F) Over time, the temperature must remain within a range of 4C (7.2F), with the rate of the change in temperature not exceeding 2C (3.6F) per hour. Ambient temperature fluctuations exceeding the limits might result in mass shifts in spectra." C; degrees Celsius F; degrees Fahrenheit 2. Review of the laboratory's temperature charts revealed no room temperatures recorded. 3. Review of the laboratory's untitled policy and procedure manual approved, signed and dated by the Laboratory Director on 10/28/2019 did not find a room temperature policy or procedure. 4. The TS confirmed the laboratory did not follow the manufacturer's requirements for room temperature monitoring for the AB Sciex 4500 Series LC-MS. The interview occurred on 01/22/2020 at 1:20 PM.

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 record review and an interview with Technical Supervisor (TS), the laboratory failed to include on the final test report the units of measure for patient results. All patients tested under the subspecialty of toxicology from 08/13/2019 to 01/22/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of two out of two of the laboratory's final test reports did not find any units of measure for toxicology patient results or reference range results. 2. The TS confirmed no units of measure were indicated on patient reports for toxicology testing. The interview occurred on 01/22/2020 at 12:30 PM.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure the employment of qualified testing personnel. All patients tested between 08/13/2019 to 10/04/2019 had the potential to be affected by this deficient practice. Findings include: 1. Review of 2019 competency assessment records found an initial competency assessment record for Testing Personnel (TP#5) not listed on the form CMS 209. 2. The TS stated TP#5 was no longer employed by the laboratory and therefore was not listed on the form CMS 209. 3. The inspector requested education documents from the TS for TP#5. 4. The TS was unable to provide the requested education documents and confirmed no education documents were available for TP#5. The interview occurred on 01/22/2020 at 10:45 AM.