Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2141888	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clermont Urgent Care	1675 Hancock Rd Ste 300, Clermont, FL	

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	A recertification survey was conducted on September 21, 2021. Clermont Urgent Care clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to comply with Federal and State regulations in the disposal of the Corona Virus Disease 2019 (COVID-19) test vials for the Quidel QuickVue SARS Antigen Test. Findings: On 09/21/2021 at 11:14 AM and 11:36 AM, Testing Personnel B was observed throwing away COVID-19 test vials in the regular trash can lined with a clear plastic trash bag. Review of the package insert from the Quidel QuickVue SARS Antigen Test noted "Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements." The laboratory had also used CareStart Rapid COVID-19 Antigen Test, the Veritor Rapid SARS-CoV-2 Test, and the Visby Medical Rapid Covid Point of Care. Review of the package inserts for the other three tests used by the laboratory noted to dispose of contents as biohazardous waste. The Occupational Safety and Health Administration (OSHA) regulation 1910.1030(b) defined regulated waste as a "liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials." OSHA regulation 1910.1030(d)(4)(iii)(B)(1) - (d)(4)(iii)(B)(1)(iii) read, "Regulated

	waste shall be placed in containers which are: Closable; Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping." OSHA regulation 1910.1030(g)(1)(i)(A) read, "Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material." OSHA regulation 1910.1030(g)(1)(i)(C) - (g)(1)(i)(E) noted, "These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Red bags or red containers may be substituted for labels." The Florida Department of Health's Best Practice for COVID-19 Disposal letter dated May 5, 2020, posted on the Florida Department of Health's website, noted "COVID-19 is a Category B infectious substance, and is not required to be handled differently than any other regulated medical waste per the Occupational Safety and Health Administration, and the Centers for Disease Control and Prevention." Florida Statute Chapter 381.0098 read, "Biomedical waste means any solid or liquid waste which may present a threat of infection to humans." Florida regulations 64E-16.004 2C, showed " Biomedical waste, except sharps, shall be packaged and sealed at the point of origin in impermeable, red plastic bags or, at the discretion of the generator, into sharps containers." On 09/21 /2021 at 11:36 AM, Testing Personnel B stated they were told to throw the vials in the regular trash can. On 09/21/2021 at 12:55 PM, the Laboratory Directory stated the trash in the can that Testing Personnel B put the COVID-19 test vials in, was thrown out with regular trash. On 09/21/2021 at 3:15 PM, the Laboratory Director stated they started COVID-19 testing on 11/20/20 and performed 623 tests in 2020 and 3200 test in 2021.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure confidentiality of patient information by discarding labeled specimen test vials in the regular trash can. Findings: On 09/21/2021 at 11:14 AM and 11:36 AM, Testing Personnel B was observed throwing away Corona Virus Disease 2019 (COVID-19) test vials which contained patient label in the regular trash can lined with clear plastic trash bag. Review of patient's label showed the patient's name, date of birth, date of the test, account number, and home phone number. On 09/21/2021 at 11:36 AM, Testing Personnel B stated they were told to throw the vials in the regular trash can. On 09/21/2021 at 12:55 PM, the Laboratory Directory stated the trash can that Testing Personnel B put the labeled vials in, was thrown out with the regular garbage. On 09 /21/2021 at 3:15 PM, the Laboratory Directory stated they started COVID-19 testing on 11/20/20 and performed 623 tests in 2020 and 3200 test in 2021.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow the manufacturer's instructions by not performing calibrations on the Sysmex XP-300 hematology analyzer every six months from 08/03/2019 to 08/25/2020. Findings: Review of the manufacturer's operations manual on the Sysmex XP-300 noted, "Calibration is required minimally every six months." Review of the quality control documents for the Sysmex XP-300 showed documentation of a calibration between 08/03/2019 to 08/25/2020 was missing. During an interview on 09/20/2021 at 12:53 PM, the Laboratory Director stated the calibration due in February 2020 was not done.