Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2190328	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Carestream Medical Ltd	821 Waterway Place, Longwood, 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 February 13, 2023. Carestream Medical Ltd clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation that showed the Laboratory Director approved, signed, and dated the procedure manual from 7/19/2021 to 2/13/2023. Findings: According to the laboratory's response to the Statement of Deficiencies for the survey on 07/16/2021, "A new CMS116 form with a qualified laboratory director has been submitted and communication has been established with the state of Florida, of this forms receipt." The completion date for the deficiency was 07/19/2021. Review of the procedure manuals titled "General Safety Policies and Procedures", "Quality Assurance Program Policies and Procedures", "Analytical (Pre/Post} Procedures", and "General Lab Standard Operating Procedures" revealed that the current Laboratory Director failed to sign the procedure manuals. On 02/13/2023 at 12:11 PM, the Technical Supervisor acknowledged the Laboratory Director had not signed the procedure manuals. Word Key CMS - Centers for Medicare and Medicaid Services
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview the laboratory failed to follow manufacturer's instructions by storing the Hyaluronidase reagent at -20 degrees Celsius (C) on 02/13/2023 Findings: During a tour of the laboratory on 02/13/2023 at 9:34 AM, two bottles of Hyaluronidase lyophilized powder (lot #SLCH0779 and #SLBW4154) were found in the refrigerator with a temperature range of 2-8 degrees C. The label on the bottles indicated the storage temperature is -20 degrees C. Review of the Sigma-Aldrich (manufacturer's) Product Specification sheet lists the "Storage Temperature: -20 degrees C." On 02/13/21 at 9:40 AM, the Technical Supervisor acknowledged the Hyaluronidase was stored at the wrong temperature.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Assistant performed the proficiency testing (PT) for the Fibronectin-Aggrecan Complex Test on 10/01/2021, 05/31/2022, and 10/11/2022, and failed to have a State of Florida Clinical Laboratory Personnel license. (Refer to D6170).
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Assistant performed the proficiency testing (PT) for the Fibronectin-Aggrecan Complex Test on 10/01/2021, 05/31/2022, and 10/11/2022, and failed to have a State of Florida Clinical Laboratory Personnel license. Findings: According to Florida Administrative Code (FAC) Rule: 64B3-5.003, Laboratory Testing Personnel who work in an Independent Laboratory must be licensed in the specialty that testing is being performed (Chemistry). The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed by the Laboratory Director on 02/13/2023 reflects that the laboratory is an independent lab, and the test they are performing is the Fibronectin-Aggrecan Complex Test which is listed as high complexity testing. Review of the PT records showed the laboratory performed split testing on 10/01/2021, 05/31/2022, and 10/11 /2022. The PT records for each date included one sets of test results initialed by the Technical Supervisor and another set initialed by the Laboratory Assistant. Review of Laboratory Assistant's personnel records revealed there was no record of a Florida Laboratory personnel license. Review of the Personnel File Checklist for the Laboratory Assistant showed that the box for "Certificate/license/registry number and

	state registration (as required by position)" was not checked. On 02/13/2023 at 9:30 AM, the Technical Supervisor stated the Laboratory Assistant was performing the PT and that he knew that she was not licensed.