

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2190328	(X3) Date Survey Completed 07/16/2021
Name of Provider or Supplier Carestream Medical Ltd	Street Address, City, State 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	An initial certification survey was conducted on June 28 to July 16, 2021. Carestream Medical Ltd clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to meet the qualification requirements to function as laboratory director according to Florida state law Findings: Cross Reference D3009. Based on record review and interview, the Laboratory Director failed to meet the qualification requirements to function as laboratory director according to Florida state law.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to meet the qualification requirements to function as laboratory director according to Florida state law from 08/05/2020 to 07/16/2021. Findings: Review of Florida state law 64B3-5.007 Director; Limitations and Qualifications read "at least one of the following requirements must be met for specific areas of licensure. In some cases, there are multiple options for meeting the requirements." The following are the options available : 1. Certification in Clinical Pathology by the ABP (American Board of Pathology) or AOBP (American Osteopathic Board of Pathology). 2. Certification in the pertinent laboratory specialty by ABIM (American Board of Internal Medicine), AOBIM (American Osteopathic Board of Internal Medicine), ABMM (American Board of Medical Microbiology), ABCC (American Board of Clinical Chemistry), ABNM (American Board of Nuclear Medicine), AOBNM (American Osteopathic Board of Nuclear Medicine), ABMG (American Board of Medical Genetics and Genomics), ABB (American Board of Bioanalysis), ABMLI (American Board of Medical Laboratory Immunology), or ABHI (American Board of Histocompatibility and Immunogenetics). 3. Four years of pertinent clinical laboratory experience (post-graduate), with two years experience in the specialty to be directed Review of the Laboratory Director's CV (Curriculum Vitae) showed the Laboratory Director, listed on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed on 06/28/2021, was not a pathologist or certified by one of the above mentioned organizations. The CV did not include any evidence of four years of pertinent clinical laboratory experience. According to CLIA Application for Certification signed and dated by the Laboratory Director on 06/28/20, the laboratory had an estimated annual test volume of 600 tests per year. On 06/30/2021 at 3:10 PM, the Technical Supervisor stated the CV provided was the current CV for the Laboratory Director and he did not believe the Laboratory Director had four years of pertinent laboratory experience.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to provide complete documentation of performance specifications for the Fibronectin Aggrecan Complex (FAC) laboratory developed test from 08/05/2020 to 07/16/2021. Findings: Review of the validation plan for the FAC test showed the plan did not include analytic sensitivity, analytic specificity including interfering substances, and information on

how the laboratory determined what was considered a positive and a negative test result. On 07/16/2021 at 5:33 PM, the Technical Supervisor stated the above mentioned performance specifications were not included in the validation.

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 interview, the patient test reports failed to provide all required information for laboratory test reports for 3 of 3 patients, (#1, #2, #3). Findings: Review of the patients #1, #2, and #3 test reports showed the name and address of the laboratory was not listed on the reports. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the acting Laboratory Director on 06/28/2021, the laboratory annual estimated hematology test volume was 600 tests. During an interview on 07/07/21 at 9:37 AM, Technical Supervisor stated the patient test reports did not have the name or address of the laboratory.