

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2251032	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier Cleveland Clinic Florida Coral Springs Family	Street Address, City, State 5701 N University Dr, Coral Springs, 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 conducted at CLEVELAND CLINIC FLORIDA CORAL SPRINGS HEALTH CENTER on 10/25/2022 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to dispose the 100% Reagent Alcohol, Hematoxylin Stain Solution, Eosin Y Stain Solution and Xylene Substitute according to manufacturer's instruction since August 2022. Findings include: Observation of reagents in the flammable cabinet on 10/25/2022 at 11:40 AM revealed the labels on the 100% Reagent Alcohol, Hematoxylin Stain Solution, Eosin Y Stain Solution and Xylene Substitute noted "Dispose of contents/container to an approved waste disposal plant." During an interview on 10/25/2022 at 12:30 PM, the MOHS Technician confirmed that the observed reagents were not disposed as per manufacturer instructions.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory's procedure manual failed to include instructions for making the 95% alcohol solution used in the Hematoxylin and Eosin staining in the manual Stainer since August 2022. Findings include: Review of the procedure titled, "Procedure Manual H & E Staining Procedure" approved by the Laboratory Director on 08/02/2022, showed there were no instructions for making the 95% alcohol solution used in the Hematoxylin and Eosin staining in the manual Stainer. During an interview on 10/25/2022 at 12:30 PM, Testing Person A confirmed that the laboratory prepared the alcohol solution of reference and that the instructions were not included in the procedure manual.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview, the Technical Supervisor (TS) failed to sign initial competency for one out of four Testing Personnel (TP) in August 2022. Finding include: Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 10/25/2022 revealed that: - The LD, Clinical Consultant (CC), TS, General Supervisor (GS) and TP# D was the same person and that the laboratory had four TP (TP# A, TP# B, TP# C and TP# D). - Review of personnel records revealed that TP# B had no initial competency since August 2022 when the laboratory started testing. During an interview on 10/25/2022 at 01:00 PM, the TS confirmed that he failed to do initial competency on TP# B.