

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2221790	(X3) Date Survey Completed 04/15/2026
Name of Provider or Supplier Indian River Memorial Hospital Inc	Street Address, City, State 1155 35th Lane Suite 202, Vero Beach, 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 announced CLIA recertification survey was conducted at Indian River Memorial Hospital Inc on April 15, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, observation, and interview, the laboratory failed to have a procedure on specimen labeling, slide labeling, and step-by-step procedure for their Hematoxylin and Eosin (H&E) stain of from 04/11/2022 to 04/15</p>

/2026. Findings Included: A1. Review of the procedure titled, Mohs Procedure SOP (standard operating procedure), with an effective date 04/11/2022 and approved, reviewed, and signed by the Laboratory Director on 04/13/2026, noted, "The specimen will be given to the tech with a patient label attached to the specimen map." A2. During an interview on 04/15/2026 at 1:18 PM, the Mohs Technician acknowledged the procedure did not contain what patient information was on the label. B1. Review of the procedure titled, Mohs Procedure SOP (standard operating procedure), with an effective date 04/11/2022 and approved, reviewed, and signed by the Laboratory Director on 04/13/2026, noted, "Slide labels with print for each slide." B2. Observation on 04/15/2026 at 2:10 PM, revealed slides for Patients #1 - #5 had handwritten patient identification on the slides. B3. During an interview on 04/15/2026 at 1:19 PM, the Mohs Technician acknowledged the procedure did not include patient labeling information. C1. Review of the procedure titled, Mycology Slide Examination SOP, with an effective date 04/11/2022 and approved, reviewed, and signed by the Laboratory Director on 04/13/2026, revealed the procedure failed to include the labeling of the patient slides. C2. During an interview on 04/15/2026 at 1:42 PM, the Mohs Technician acknowledged there was no instructions on labeling of patient slides. D1. Review of the procedure titled, Mohs Lab Slide Stainer SOP, with an effective date 04/14/2022 and approved, reviewed, and signed by the Laboratory Director on 04/13/2026, revealed there were no instructions that listed the reagents and the amount of time the slides spent in each of the reagents used in their H&E stain. D2. During an interview on 04/15/2026 at 1:35 PM, the Mohs Technician acknowledged they did not have a list of what reagents were in each compartment of the stainer and did not have the amount of time the slides were in each container.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, review of the quality control records and interview, the laboratory failed to document quality control information including lot numbers, expiration dates, and open dates for all the reagents used in their Hematoxylin and Eosin (H&E) stain from 02/01/2024 to 03/12/2026. Findings: 1. Review of the procedure title Mohs Lab Slide Stainer SOP, approved by the Laboratory Director on 04/13/2026, revealed the laboratory used the following reagent for their H&E stain: Hematoxylin, Eosin, 100% Alcohol, Xylene, and Bluing Reagent. 2. Review of the Reagent Log revealed the log only contained reagent received in the lab on 03/11/2026 and 03/29/2026. 3. During an interview on 04/15/2026 at 1:35 PM, the Mohs Technician stated they only kept a list of the current reagents being used.