Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2221790	03/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Indian River Memorial Hospital Inc	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	(Amended) An initial certification survey was conducted on March 29, 2022. Indian River Memorial Hospital Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and follow written policies and procedures to assess employee initial training that included six month, and annual competency assessment for one of one testing personnel from 10/04 /2021 to 03/29/2022. Findings: Review of the laboratory's procedure manual showed there was no procedure for competency assessments. Review of the laboratory personnel records showed there was no record of an initial competency assessment on the histology technologist. Review of the laboratory's quality control logs with the current location of the laboratory listed, noted the first date the quality control logs were completed was 10/04/2021. On 03/29/2022 at 3:11 PM, the Histology Technologist stated there was no initial training competency assessment performed on him. On 03/29/2022 at 3:59 PM, the Histology Technologist said there was no policy for competency assessments.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory did not have a written quality assessment procedure that described the laboratory's process for proficiency testing from 09/21/2021 to 03/29/2022. Findings: Review of the procedure manual showed the manual was signed by the Laboratory Director on 09/21/2021. The procedure manual failed to include a procedure on the performance of proficiency testing for the reading of the Hematoxylin & Eosin (H & E) stains performed by the Mohs Surgeon and the Potassium Hydroxide (KOH) testing performed by the Laboratory Director. On 03/29/2022 at 3:58 PM, the Histology Technologist stated there was no procedure on the proficiency testing for the H&E stains. On 03/29/2022 at 4:18 PM, the Histology Technologist said there was no procedure on the proficiency testing for the KOH testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 was incomplete from 09/21/2021 to 03/29/2022. Findings: Review of the procedure manual showed the manual was signed by the Laboratory Director on 09/21/2021. The procedure manual failed to include what the laboratory was doing regarding the stain quality control for their Hematoxylin and Eosin Staining (H&E). The procedure manual failed to include the performance for documenting the quality control logs. The procedure manual also failed to include the room temperature and humidity ranges required for laboratory's Avantik QS12 Cryostat and the operating temperature range of the cryostat. On 03/29/2022 at 3:45 PM, the Histology Technologist acknowledged the procedure manual was missing information on the above procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to record the humidity of room where testing was performed from 10/04/2021 to 03/29/2022. Findings: Review of the instruction manual for the laboratory's Avantik QS12 Cryostat noted the maximum humidity of the room was 60% (percent) and up to 35 degrees Celsius. A review of the laboratory's quality control logs showed the laboratory was not recording the humidity of the room where testing was performed. Review of the laboratory's quality control logs with the current location of the laboratory listed, noted the first date the quality control logs were filled was 10/04/2021. On 03/29/2022 at 2:40 PM, the Histology Technologist stated they were not recording the humidity levels
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure the Bluing Reagent used in their Hematoxylin and Eosin Staining (H&E) was not expired prior to patient testing from 10/04/2021 to 03/29/2022. Findings: Observations made during a tour of the laboratory on 03/29/22 at 1:15 PM, showed the opened bottle dated 09/01/2021 of Bluing Reagent expired on 09/2021. The laboratory used the Bluing Reagent in their H&E stained slides from their Mohs surgical procedures. Review of the laboratory's quality control slide log with the current location of the laboratory listed, noted the first date the quality of the stain was evaluated was 10/04 /2021. On 03/29/2022 at 1:20 PM, the Histology Technologist stated the bluing reagent was expired.
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 record review, and interview, the laboratory failed to document the lot

	number, expiration date, and open dates for reagents used in their Hematoxylin & Eosin (H & E) stains from 10/04/2021 to 03/29/2022. Findings: Review of the laboratory's quality control logs showed the laboratory did not have a reagent log. Review of the laboratory's quality control logs with the current location of the laboratory listed, noted the first date the quality control logs were filled in was 10/04 /2021. On 03/29/2022 at 2:57 PM, the Histology Technologist acknowledged they did not have a reagent log.
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 laboratory failed to provide all required information for the Mohs surgical reports for three of three sampled patients, (#1, #2, #3). Findings: The laboratory provided a copy of the After Visit Summary for the Mohs surgical procedures to patients if requested. Review of After Visit Summary showed the name of the laboratory as it appeared on the CLIA (Clinical Laboratory Improvement Amendments) certificate was missing from the report. On 03/29/2022 at 4:12 PM, the Office Manager stated they gave a copy of the After Visit Summary to patients if they requested it, and the full name of the laboratory was not on the summary.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6094. Based on record review and interview, the Laboratory Director failed to ensure a quality assessment (QA) program was established and maintained to assure quality of laboratory services were provided from 09/21/2021 to 03/29/2022.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on record review, and interview, the Laboratory Director failed to ensure a quality assessment (QA) program was established and maintained to assure quality of laboratory services were provided from 09/21/2021 to 03/29/2022. Findings: Review of the procedure manual signed by the Laboratory Director on 09/21/2021 showed there was no QA program procedure. Review of the laboratory's binder with the quality control logs and procedure manual showed the laboratory did not have any documentation of QA being performed. On 03/29/2022 at 3:50 PM, the Histology Technologist stated they did not have a QA policy or a QA checklist.