Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2221790	01/31/2024
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	Recertification survey was conducted from 1/11/2024 to 1/31/2024. Indian River Memorial Hospital Inc clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to locate Potassium Hydroxide (KOH) patient records for 2022 and 2023. Findings Included: On 1/11/2024 at 1:10 PM, a bottle of KOH 10% with expiration date of 10/31/2025 was located in the lab. Review of KOH log indicated there was no documentation of patients recorded for KOH testing in 2022 and 2023. Review of Mycology Slide examination SOP signed by Laboratory Director on 4/19/2023 revealed no written policy on how patient records would be monitored for KOH. On 1/11/2024 at 2:45 PM , the Director of Lab Operations and Practice Manager confirmed the lab could not locate KOH patients in their laboratory record computer system as physician wrote patient results in notes not easily traced. Annual testing volume for Mycology is 15.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to perform twice annual peer- review verifications for micrographically oriented histographic surgery (MOHS) testing in 2023. Finding included: Review of Peer Reviews revealed no documentation for 2 out of 2 MOHS peer review verifications in 2023. Review of MOHS Lab Surgery Proficiency Monitoring Program (Peer Reviews) SOP signed by the Laboratory Director on 1/5/2024 read, "All peer reviews will be selected at random for physicians. A total of 5 cases will be reviewed annually. The cases will be read by another MOHS surgeon (annually) to assure that both physicians concur that tumor has been removed. (This process is known as peer-review)." The policy did not contain documentation of twice annual reviews. On 1/11/2024 at 2:44 PM the Director of Lab Operations confirmed 2 out of 2 MOHS peer- review verifications were not completed in 2023.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 consultant failed to perform annual Potassium Hydroxide (KOH) competency assessments for 1 out of 3 Testing Personnel in 2022 and 2023, (C). Findings Included: The Laboratory Personnel Report revealed employee C was Testing Personnel C. Review of Competency assessments revealed no documentation of annual KOH competency assessments performed for Testing Personnel C in 2022 and 2023. Review of MOHS Lab Competency Assessment of Testing Personnel SOP signed by Laboratory Director on 4/19/2023 read, "Annually: with the calendar year. Competency: the ability of the employee to apply their skill knowledge, and experience to perform their job duties correctly and as they were initially trained." On 1/11/2024 at 2:44 PM the Director of Lab Operations confirmed the technical consultant failed to perform annual KOH competency assessment for 1 out of 3 Testing Personnel, C in 2022 and 2023.