Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1096403	09/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Johns Creek Dermatology And Family Medicine Pc	6300 Hospital Parkway Suite 100, Duluth, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on Sept. 4, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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. This STANDARD is not met as evidenced by: Based on Standard Operators Procedure (SOP) review and staff interview, the laboratory failed to have a policy/procedure with the description of the course of

	action to take if a test system becomes inoperable. Findings include: 1. SOP review reveals the laboratory does not have a written procedure for steps to take if the Leica CM 1860 UV cryostat or the Leica ST 4020 slide stainer become inoperable. 2. Interview with the lab director (LD) and the histotechnician (CMS 209) on 9/4/25 at 1 p.m. in the LD's office confirmed the lack of laboratory policy and procedure for the aforementioned procedure.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with the lab director (LD), the LD failed to ensure that all TP received the appropriate training and demonstrated competency prior to performing patient testing. Findings: 1. Review of testing personnel (TP) documents revealed no documentation of training/initial competency for the TP performing mycology slides. 2. Interview with the LD in her office, on 09/04/25, at 12:10 PM confirmed the aforementioned finding.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with the lab director, the technical supervisor failed to perform semiannual competency on testing personnel performing mycology slides. Findings: 1. Review of testing personnel (TP) documents revealed no documentation of semiannual competency for the TP performing mycology slides. 2. Interview with the LD in her office, on 09/04/25, at 12: 10 PM confirmed the aforementioned finding.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with the lab director (LD), the Technical Supervisor failed to ensure that all TP received annual competency. Findings: 1. Review of testing personnel (TP) documents revealed no documentation of annual competency for the TP performing mycology smears. 2. Interview with the LD in her office, on 09/04/25, at 12:10 PM confirmed the aforementioned finding.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 review of the CMS 116, patient result log sheets, and interview with the lab director (LD), the LD failed to ensure the testing personnel (TP) performed and documented QC for mycology slides. The findings include: 1. Review of the CMS 116 revealed the lab performed 120 Potassium Hydroxide (KOH) slides annually 2. Review of patient result log sheets revealed the lack of QC documentation for KOH slides. 3. Interview with the LD (CMS 209), on 09/04/25 , at 12:15 pm , in the LD's office, confirmed the TP failed to perform and documented QC for mycology (KOH).