Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1006481	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
North County Dermatology Clinic Pa	6500 N Socrum Loop Rd Ste 100, Lakeland, 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 North County Dermatology Clinic PA on 07/25/23 to 07/28/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to ensure the accuracy for twice a year testing for parasitology (Scabies) for 4 (#A, #D, #E, and #G) out of 5 Testing Personnel (#A, #D, #E, #F, and #G) for two out of two years (2021 - 2023) and failed to ensure the accuracy for twice a year testing for histopathology for one out one Testing Personnel (#B) for two out of two years (2021 - 2023). Findings included: Record review of the "Scabies" Log that included columns titled "Primary Reader Initials" and "Initial for QA if agree" revealed: Testing Personnel (TP) #A had verification of accuracy performed one time in 2021 (12/19/21) and one time in 2022 (12/27/22), TP #D had verification of accuracy performed one time in 2021 (12/19/21) and one time in 2022 (1/19/22), and TP #E and TP #G had no documentation for verification of accuracy performed in 2021 and 2022. Record review of the "TC/PC Quality Assurance Peer Review Requisition" for histopathology revealed TP #B had no peer review or verification of accuracy performed in 2021 or 2022. On 07/25/2023 at 1:10 PM, the Laboratory Director confirmed the twice annual verification of accuracy for scabies and histopathology had not been performed for TP #A, #B, #D, #E, and #G.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to follow written procedures for the Microscope Protocol and the Cryostat and Microtome Use Protocol for two out of two years (2022-2023) reviewed. Findings included: On 07/25/2023 at 10:30 AM, observation revealed the Olympus BX41 microscope had a service sticker that documented service was performed and due 03 /21 and the American Optical microscope had a service sticker documenting service was due 11/22. Record review of the microscope service field report for the Olympus BX41 clarified that the service was performed on 03/01/21 and was not due again until 03/01/22. A review of the laboratory's procedure titled "Equipment Quality Control Form 1: Microscope Protocol" revealed the microscope state and ocular eyepieces are to be cleaned every year, and the ocular micrometer is to be calibrated every year. On 07/25/23 at 1:15 PM, the Laboratory Director confirmed that both microscopes had not been maintained in accordance with the protocol and service stickers. Record review of the laboratory's cryostat logs revealed the laboratory had not documented the cryostat's inside chamber temperature or cryostat and microtome maintenance. Record review of the laboratory's procedure "Equipment Quality Control Form 3: Cryostat and Microtome Use Protocol" revealed corrective action is taken and documented if temperature exceeds the range; Defrost of cryostat is done bi-monthly, and a handwritten note under other procedures of "TEMP [temperature] (-) 24 (-)28." On 07/25/23 at 12:40 PM, the histotechnologist confirmed cryostat temperatures had not been documented and maintenance had not been performed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the Technical Consultant failed to ensure that all competency records were retained for 2 (#D and #G) of 4 testing personnel (#D, #E, #F and #G) performing fungi and scabies testing for 2 out of 2 years reviewed (2021-2023). Findings included: Review of the CMS 209, signed by the Laboratory Director and dated 07/14/23, revealed the Laboratory Director was also the Technical Consultant. Record review of the laboratory's procedure titled "General Quality Assurance Plan" revealed employee evaluations will be performed by the Supervisor and/or the Medical Director annually. Review of personnel records revealed Testing Person (TP) #D had no documented evidence of competency records for 2021 and 2022 and TP #G had no competency records for 2022. On 07/25/23 at 1:00 PM, the Laboratory Director confirmed that competency was not completed annually for TP #D and #G.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director did not perform annual histopathology competency for one of one (#B) Testing Personnel (TP) for two out of two years (2021 - 2023). Findings included: Review of the CMS 209, signed by the Laboratory Director and dated 07/14/23, revealed the Technical Supervisor was also TP #B who performed histopathology testing. Review of TP #B's personnel record revealed no competency evaluations had been performed for 2021 and 2022. On 07/25 /23 at 1:05 PM, the Laboratory Director confirmed he had not performed competency evaluations for TP #B.