Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1006481	07/23/2025
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 07/10/2025 - 07/11/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 493.1230 Condition: General Laboratory Systems D6076 493.1441 Condition: Laboratory Director
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to establish and maintain chemicals in a manner to ensure protection from hazards by failing to store 100% Reagent Alcohol in a flammable liquids storage area and storing incompatible reagents, bleach (sodium hypochlorite) and 10% Formalin Fixative together. Findings included: 1. A tour of the laboratory was conducted beginning at 10: 00 a.m. on 07/10/2025. 100% Reagent Alcohol was observed stored on a shelf in a regular cabinet, bleach was observed stored next to 10% Formalin Fixative. No flammable storage cabinet was observed in the lab. 2. Interview with Testing Person (TP)) #C during the tour confirmed the above. 3. The Safety Data Sheet (SDS) for 100% Reagent Alcohol, with a revision date of 07/15/2015 was reviewed. The SDS indicated "Highly flammable liquid and vapor" and "Store in an approved Flammable Liquids storage area." 4. The SDS for bleach, with a revision date of 08/17/2018, was reviewed. The SDS had a pictogram reflecting the chemical is corrosive. The SDS stated "Store away from other materials." The pH was documented as 12.1, which is a strong base. 5. The SDS for 10% Formalin Fixative was reviewed. The SDS had a pictogram reflecting the chemical is corrosive. The SDS stated the reagent was

	incompatible with "Bases" and hazardous decomposition products included "formaldehyde, carbon monoxide and carbon dioxide."
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure continuing compliance with the requirements for general laboratory systems with previously identified non-compliance (07/28/2023) regarding verifying the accuracy of slide interpretation for the subspecialty of Histopathology for one (2024) of two years (2023, 2024) reviewed. (See D5217)
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, the laboratory failed to verify the accuracy twice annually for one (2024) of two years reviewed (2023-2024) for Testing Person (TP) #B for testing performed in the subspecialty of Histopathology. This deficiency was previously cited at the 07/28/2023 recertification. Findings included: 1. The plan of correction dated and signed by the Laboratory Director on 08/11/2023 for the recertification survey conducted 07/28/2023 was reviewed. The plan stated six slides would be sent out for peer review (verification of accuracy of slide interpretation for stained tissue for the subspecialty of Histopathology) would occur in January and July of each year. The plan stated the lab would be in compliance by 08/08/2023. 2. Peer Review records were reviewed for 2023 and 2024. For the year 2024 peer review for TP #B was documented one time, 11/21/2024. 3. Interview with the Laboratory Director on 07/10/2025 at 1:00 p.m. stated they were unaware the documentation to support peer review was not present. 4. Electronic communication from the Office Manager on 07/11/2025, 4:52 p.m., provided additional confirmation that the peer review for January 2024 was not present.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 lab utilized an expired reagent, for the subspecialties of Mycology for four months (03/2025 - 07/2025). Findings included: 1. Observation of the work station where testing occurs for the subspecialty of Mycology and Parasitology were conducted on 07/10/2025 at 12:39 p. m. One bottle of Potassium Hydroxide (KOH) reagent, lot #3074, with an expiration date of 03/15/2025, was next to the microscope. No other bottles of KOH could be located. 2. No reagent log could be found. 3. The KOH Log (accession log) with a revision date of 08/2024 was reviewed. The bottom of the log had the statement "Check KOH Exp. Date". The abbreviation exp. stands for expiration. There were 33 Patients tested from 03/20/2025 through 07/10/2025. The log reflected Testing Personnel (TP) #A, who is also the Laboratory Director, and TP #D performed the Mycology tests. 4. The Laboratory Director was interviewed on 07/10/2025 at 1:00 p. m. and stated they were not aware they were using an expired reagent.
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, observations, and interviews, the Laboratory Director failed to provide overall management from 09/2023 through 07/2025 by failed to establish a policy to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities (See D6080), failed to establish and maintain chemicals in a manner to ensure protection from hazards by failing to store 100% Reagent Alcohol in a flammable liquids storage area and storing incompatible reagents, bleach (sodium hypochlorite) and 10% Formalin Fixative together (See D6084), failed to maintain an effective quality assessment program to identify failures and address issues that could affect the accuracy of test results (See D6093), and failed to perform an initial, or six month competency on one Testing Person (TP) #C of two Testing Persons (#B & #C) performing testing for the subspecialty of Histopathology (See D6103).
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to reflect the requirement of being onsite once every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities. Findings included: 1. The policy and procedure manual, signed &

	dated by the Laboratory Director 01/31/2025, was reviewed. No policy could be found regarding documenting being on site every 6 months to include evidence of performing activities that are part of the Laboratory Director's responsibilities. 2. An interview was conducted with the Laboratory Director on 07/10/2025 at 1:00 p.m. stated they were not aware of this requirement.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to establish and maintain chemicals in a manner to ensure protection from hazards by failing to store 100% Reagent Alcohol in a flammable liquids storage area and storing incompatible reagents, bleach (sodium hypochlorite) and 10% Formalin Fixative together. Findings included: See D3011.
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 observation, record review, and interview, the Laboratory Director failed to maintain an effective quality assessment program to identify failures and address issues that could affect the accuracy of test results. Findings include: 1. The laboratory policy and procedure manual, dated and signed by the Laboratory Director on 01/31 /2025, 03/22/2024 and 01/25/23 was reviewed. The table of contents listed 7 sections to include "Quality Management, General Quality Assurance, Pre-Analytic Quality Assessment, Analytic Systems Quality Assessment, Post Analytical Systems Quality Assessment, Quality Assessment/Control Forms," and "Lab Director Responsibilities". 1(a). Section 6 "Quality Assessment/Control Forms" was reviewed. There were no completed Quality Assessments for the dates reviewed, 09/2023 through 06/2025. 1(b). An interview was conducted with the Laboratory Director on 07/10/2025 at 1:00 p.m. revealed they had no explanation for no Quality Assessment. 2. Record review and interview revealed the laboratory failed to verify the accuracy twice annually for one (2024) of two years reviewed (2023-2024) for Testing Person (TP) #B for testing performed in the subspecialty of Histopathology. This deficiency was previously cited at the 07/28/2023 recertification. (See D5217). 3. The laboratory utilized an expired reagent, for the subspecialties of Mycology for four months (03 /2025 - 07/2025) on 33 Patients. (See D5417). 4. Record review and staff interview, revealed the Laboratory Director failed to perform an initial, or six month competency on one (TP #C) of two testing persons (TP #B & #C) performing testing for the subspecialty of Histopathology. This is a repeat deficiency cited at the previous recertification survey on 07/28/2023. (See D6103).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) 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 staff interview, the Laboratory Director failed to perform an initial, or six month competency on one Testing Person (TP) #C of two Testing Persons (#B & #C) performing testing for the subspecialty of Histopathology. This is a repeat deficiency cited at the previous recertification survey on 07/28/2023. Findings included: 1. The plan of correction signed and dated by the Laboratory Director 08/11/2023 was reviewed. The plan stated "The lab director/Technical consultant is responsible for ensuring that all testing personnel have competency records...reviews annually on or before the anniversary date of employment." The plan indicated the lab would be in compliance on 08/11/2023. 2. The Quality Management Manual, dated and signed by the Laboratory Director on 01/31/2025 and 03/22/2024 was reviewed. The "General Systems Quality Assurance Personnel Competency" policy stated "Lab personnel will be assess for their ability to perform all aspects of the job description to which they are assigned within the first 90 days after completion of training." Besides ongoing monitoring during monthly quality assurance activities, the policy did not specify additional competencies would be performed or documented after the 90 day competency. 3. Review of the CMS-209, Laboratory Personnel Report (CLIA), signed and dated by the Laboratory Director 07 /10/2025 revealed TP #B and TP #C performed high complexity testing. 4. Review of TP #B's competency assessments for 2023 and 2024 revealed no annual competency assessment for 2024. TP #B performed slide interpretations (microscopic) of stained tissue. 5. TP #C was interviewed on 07/10/2025 at 10:15 a.m. They stated their date of hire was 03/01/2024, they performed grossing (macroscopic) of tissue for Histopathology, and they only had one competency completed since date of hire. They stated competencies were only performed as needed. 6. TP #C's records were reviewed. A competency assessment for TP #C, titled "Employee Performance Evaluation - Histotechnician" and a "Statement of Competency" form, both signed by the Laboratory Director on 07/01/2025 were found and reviewed. Neither the Evaluation or the Statement of Competency contained an evaluation of the grossing performed by TP #C. The Histotechnician Job Description, undated, did not include grossing of tissue. 7. An interview was conducted with the Laboratory Director on 07 /10/2025 at 1:00 p.m. stated they did not have an explanation for the above issues identified.