Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0241840	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wilson Dermatology Clinic, Pa	2874 Ward Blvd, Wilson, NC	

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
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 review of laboratory policies, verification of accuracy records and interview with histology technician (HT #1) and laboratory director (LD) 10/21/21, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH)/Wet Prep and the Mart 1 Immunostain at least twice annually in 2019, 2020 and 2021, a period of approximately 3 years in which verification of accuracy was not performed. 1. The laboratory failed to verify the accuracy of the KOH/Wet Prep at least twice annually in 2019, 2020 and 2021. Review of laboratory policy "General Laboratory Quality Systems" revealed under section 6 "PROFICIENCY TESTING POLICY...For Provider-Performed Microscopies, the laboratory will either be enrolled in proficiency testing or will perform split-specimen testing with another laboratory or between providers." Review of verification of accuracy (proficiency testing) records for the KOH/Wet Prep test revealed no documentation of a twice annual verification of accuracy in 2019, 2020 or 2021, either by being enrolled in proficiency testing or performing split-specimen testing with another laboratory or between providers. Exit interview with HT #1 and LD at approximately 3:00 p.m. confirmed the laboratory failed to verify the accuracy of the KOH/Wet Prep testing at least twice annually in 2019, 2020 and 2021. 2. The laboratory failed to verify the accuracy of the Mart 1 Immunostain at least twice annually in 2019, 2020 and 2021. Review of laboratory policy "Quality Assessments" under section "Analytic Systems #2. "...some type of proficiency program is required." and under "Section V: Proficiency Testing ... Meeting CLIA Requirements When No Commercial Proficiency Testing Service is available...one of the four following methods should be used for bi-annual quality assessment to verify the accuracy of test results." Review of verification of accuracy

	(proficiency testing) records revealed no documentation of a twice annual verification of accuracy in 2019, 2020 and 2021 by either of the four methods under "Section V: Proficiency Testing...". Exit interview with HT #1 and LD at approximately 3:00 p.m. confirmed the laboratory failed to verify the accuracy of the Mart 1 Immunostain at least twice annally in 2019, 2020 and 2021.
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 review of laboratory procedure manual and interview with HT #1 and LD 10 /21/21, the laboratory procedure manual failed to include a procedure for the performance and reporting of KOH/Wet Prep testing. Findings: Review of laboratory procedure manual revealed no procedure for the performance and reporting of KOH /Wet Prep testing. Exit interview with HT #1 and LD at approximately 3:00 p.m. confirmed the laboratory procedure manual failed to include a procedure for the performance and reporting of KOH/Wet Prep testing.
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 review of laboratory policies and procedures, verification of accuracy records, TP training and competency records 10/21/21, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Findings: 1. The LD failed to ensure at least twice annually a verification of accuracy was performed for KOH/Wet Prep and Mart 1 Immunoassay testing for a period of three years. See D5217. 2. The LD failed to ensure the procedure manual included a procedure for the performance and reporting of KOH/Wet Prep testing. See D5403. 3. The LD failed to

	ensure the verification of accuracy policies for Mohs, KOH/Wet Prep, and Mart 1 Immunoassay were adequate and/or established to determine the accuracy of testing performed. See D6086. 4. The LD failed to ensure prior to testing patient specimens, all testing personnel had the appropriate training. See D6102. 5. The LD failed to perform competency assessments at least twice annually during the first year of patient testing for TP #2. See D6120.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory verification of accuracy policies and 2019, 2020 and 2021 verification of accuracy records 10/21/21, the LD failed to ensure verification procedures for the Mohs testing, KOH/Wet Prep and Mart 1 immunoassay are adequate to determine the accuracy of the testing performed. 1. The LD failed to ensure the policy for the verification of accuracy for the Mohs testing was complete. Findings: Review of policy "Quality Assurance" revealed "30th Case review...the frozen sections slides for every thirtieth case are review by a Dermatopathologist. The following is recorded in the Quality Assurance Log Book: Date, Patient's Name (last and first name), Patient MRN, Stage numbers, Slide numbers. If a discrepancy is discovered, the slides and map are returned to the appropriate surgeon who will then make the decision on how to proceed. The policy fails to include what is reviewed on the slides sent to the dermatopathologist. For example: Are they reviewed for correct staining and mapping, are they reviewed for initial diagnosis, and are they reviewed to ensure the final slide contains no cancerous cells. The policy also fails to state the corrective action if discrepancies are discovered. 2. The LD failed to ensure the verification of accuracy performed for the Mohs testing included a review of the final slide to determine if cancerous cells were still present in the patients sample. And also failed to ensure the verification of accuracy included the name of person performing the review, the address of where slides were sent and education documentation on the "dermatopathologist" who performed the review. Findings: Review of verification of accuracy records for slides dated 9/2/21 through 9/29/21 revealed a log with columns for date, patient, stage, slides, comments, and doctor initials. The comments indicated a type of cancer, for example "BCC or SCC, which would correlate to the original diagnosis. The log did not include a review of the final slide to determine if cancerous cells were still present in the patient sample. The log also included initials under the "doctor initials" column but verification records failed to include documentation of the name, address and education of the "dermatopathologist" who performed the review. 3. The LD failed to ensure the laboratory had a policy that stated specifically what the verification of accuracy for KOH/Wet Prep testing would consist of and failed to ensure the laboratory performed a bi-annual verification of accuracy for the KOH/Wet Prep testing. Findings: Review of laboratory policy "General Laboratory Quality Systems" revealed under section 6 "PROFICIENCY TESTING POLICY...For Provider-Performed Microscopies, the laboratory will either be enrolled in proficiency testing or will perform split-specimen testing with another laboratory or between providers." The policy fails to state what method the laboratory will use for the verification of accuracy for KOH/Wet Prep testing. Review of verification of accuracy records for KOH/Wet Prep testing revealed no documentation for the performance of

	a verification of accuracy in 2019, 2020 and 2021. See D5217. 4. The LD failed to ensure the laboratory had a policy that stated specifically what the verification of accuracy for Mart 1 Immunostain would consist of and failed to ensure the laboratory performed a bi-annual verification of accuracy for the Mart 1 Immunostain. Findings: Review of laboratory policy "Quality Assessments" under section "Analytic Systems #2. "...some type of proficiency program is required." and under "Section V: Proficiency Testing ...Meeting CLIA Requirements When No Commercial Proficiency Testing Service is available...one of the four following methods should be used for bi-annual quality assessment to verify the accuracy of test results." The policy fails to indicate which of the "four methods" the laboratory will use for the verification of accuracy for the Mart 1 Immunostain. Review of verification of accuracy records for the Mart 1 Immunostain revealed no documentation for the performance of a verification of accuracy in 2019, 2020 and 2021. See D5217.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 laboratory personnel records, review of laboratory policy, review of LD job description and interview with HT #1 and LD 10/21/21, the LD failed to ensure prior to testing patient specimens that testing personnel (TP) #2 had documented training for the performance of the KOH/Wet Prep test. Findings: Review of personnel records revealed TP #2 was hired in March of 2020. Personnel records also revealed no documentation of training for the performance of the KOH/Wet Prep test. Review of laboratory policy "Wilson Dermatology Quality Assessment Program" revealed "#5. Personnel Competency..."This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens." Review of LD job description revealed "All personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered...". Exit interview with HT #1 and LD at approximately 3:00 p.m. confirmed TP #2 was hired in March of 2020, TP #2 performed KOH/Wet Prep testing and there was no documentation of training for the performance of the KOH /Wet Prep test.
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 review of laboratory competency policies and TP competency assessment records 10/21/21, the LD failed to ensure the competencies of 2 of 2 TP were reviewed to identify needs for remedial training if necessary. Findings: Review of laboratory policy "Wilson Dermatology Quality Assessment Plan" revealed "5. Personnel Competency...At least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory... The written result of the review will be filed in the individual's personnel file. The director will ensure that laboratory personnel are provided with retraining or continuing education if indicated." Review of TP #1 and TP # 2 competency assessment records revealed a quiz for the KOH/Wet Prep testing, which consisted on pictures of slides and multiple choice answers for each picture on the quiz. The assessments (quizzes) failed to indicate a review by the LD and failed to document whether the multiple choice answers were correct or incorrect to identify needs for remedial training if necessary.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of laboratory policy, personnel records, TP competency records and interview with HT#1 and LD 10/21/21, the technical supervisor (TS)(laboratory director) failed to perform competency assessments for TP #2 twice annually during the first year of testing for the KOH/Wet Prep. Findings: The laboratory director (LD) also serves as the TS for the laboratory. Review of laboratory policy "Wilson Dematology Quality Assessment Plan" revealed under #5 "Personnel Competency...At least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency." The policy fails to meet the regulation of a twice annual competency for the first year of TP testing. Review of personnel records revealed TP #2 began testing in approximately March of 2020. Review of TP #2 competency records revealed the TS (LD) performed a competency assessment for KOH/Wet Prep in October of 2021, approximately 19 months after TP #2 began KOH/Wet Prep testing. Exit interview with HT #1 and LD at approximately 3:00 p.m. confirmed TP #2 did not have a competency assessment until October of 2021.