Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0686569	06/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Group, Pc-North Wales, The	1140 Welsh Rd Suite 130, North Wales, PA	

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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of scabies and KOH slide examinations quality control (QC) records, and interview with the laboratory director (LD), the laboratory failed to document QC procedures performed for 31 of 272 patient specimens examined for scabies and KOH microscopic examinations from 09/28/2017 to the 12/31/2018. Findings Include: 1. On the day of survey, 06/13/2019, review of scabies and KOH microscopic examinations QC records revealed the laboratory did not document QC performed each day of patient testing from 09/28/2017 to the 12/31/2018. - 14 of 66 KOH examination in 2017. - 16 of 205 KOH examinations in 2018. - 1 of 5 scabies examinations in 2018. 2. The LD confirmed the findings above on 06/13/2019 around 10:30 am. ***KOH= Potassium Hydroxide
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of histopathology patient test reports and interview with the laboratory director, the laboratory failed to include on 3 of 3 test reports reviewed at the time of survey, the location where Tissue Pathology slides were read from 07 /2018 to the date of survey. Finding Include: 1. On the day of survey, 06/13/2019, review of some test reports (3 of 3) revealed the test reports did not include the correct address where the slides were read. 2. The top of the final pathology reports states the address, 311 North Sumneytown Pike, Suite 1D &1E, North Wales PA 19454. 3. The LD confirmed on 06/13/2019 around 12:20 pm, the test reports did not reflect the site where the slides were read, 1140 Welsh Road, Suite 130, North Wales PA, 19454.
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 review of testing personnel records and interview with the laboratory director (LD), the technical consultant (laboratory director failed to evaluate the competency of 2 of 3 TP who performed scabies and KOH microscopic examinations in 2018. Findings Include: 1. On the day of survey, 06/13/2019, the LD could not provide the following competency documents for 2 of 3 TP in 2018: - Documentation of performance through testing previously analyzed specimens for 1 of 3 TP who performed KOH microscopic examinations. - Documentation of performance through testing previously analyzed specimens for 2 of 3 TP who performed scabies microscopic examinations. - Competency assessment records for 2 of 3 TP who performed scabies microscopic examinations. 2. In 2018 (01/01/2018 to 12/31/2018) 5 scabies microscopic examinations were performed. 3. In 2018 (01/01/2018 to 12/31 /2018) 205 KOH microscopic examinations were performed. 4. The LD confirmed the findings above on 6/13/2019 around 11:30 am. ***KOH = Potassium Hydroxide *** REPEAT DEFICIENCY***
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 laboratory records and interview with the Laboratory Director (LD), the LD failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided from 09/28/2017 to the date of survey. Findings Include: 1. On the date of survey, 06/13/2019, review of laboratory records revealed: - A policy to assess the test performance of testing

	personnel through testing previously analyzed specimens for KOH and scabies was not established. - Criteria for reagents kept at room temperature, were not established. - Quality assurance programs were not established to cover Dermatopathology testing performed onsite. 2. The LD confirmed the findings above on 06/13/2019 around 12: 00 pm. *** KOH= Potassium Hydroxide