Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0975603	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
New York Dermatology Pc	23-83 Bell Boulevard, Bayside, NY	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory competency records and an interview with the clinical consultant/owner of the Physician Office Laboratory (POL), the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing when they began in the 2016. Findings Include: It was confirmed by the clinical consultant /owner of the POL on April 5, 2018, at approximately 1:30 pm, that the director of the laboratory acting as the technical consultant failed to have documentation of semi-annually competency for two of two Histo-technician's who performs Moh's surgery tissue processing and pathology grossing. And one of one new testing person who performs processing of patient specimen for pathology.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records for histopathology stained slides and an interview with the clinical consultant/owner of the the POL, the laboratory failed to document the results of the positive and/or negative control slides. Findings Include; It was confirmed by the clinical consultant/owner of the POL on April 5, 2018 at approximately 2:30 PM, that QC has not been performed/documented for Immohistochemistry and Special stain slides from June 2016 through the date of this survey. Approximately 6000 patient slides were read and result released for IHC, and Special stains during the above time period. THIS IS A REPEAT CITATION FROM THE MAY 18, 2016 SURVEY.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of QC records, and an interview with the clinical consultant/owner of the POL, the laboratory director failed to ensure that the QC program for histopathology was followed to assure the quality of laboratory services. Refer to D5601 THIS IS A REPEAT CITATION FROM THE MAY 18, 2016 SURVEY.
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 a review of personnel records and an interview with the clinical consultant /owner of the POL, the laboratory director failed to ensure that appropriate training was documented for two of two new testing personnel who perform high complexity Moh's surgery tissue processing and pathology grossing. In addition, documentation of training is needed for the new testing person who only performs processing of tissue for pathology specimens. Refer to D5209
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the clinical

	consultant/owner of the POL, the laboratory director, acting as the technical supervisor, failed to perform the semi-annual evaluation for two of two new testing personnel who perform high complexity Moh's surgery tissue processing and pathology grossing and in addition for one of one new testing person who performs processing of tissue for pathology specimens during the first year of patient testing. Refer to D5209