Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1058391	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Margaret Ravits & Associates	721 Summit Avenue, Hackensack, NJ	

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 surveyor review of the Competency Assessment (CA) records and interview with the Histotech on phone, the laboratory failed to perform CA accurately on one of one Histotech in 2016 and 2017. The finding include: 1. The CA documentation sheet did not include how CA was accessed, what and when records were reviewed. 2. The Histotech confirmed via phone conversation on 7/25/18 at 11:30 am that CA was not done accurately.
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: a) Based on surveyor review of the Procedure Manual (PM), observation of Staining Station (SS) and interview with the Medical Assistant (MA) and phone interview the Histotech, the laboratory failed to have correct procedure for Hematoxylin and Eosin Staining (HES) from 7/6/16 to the dayteof survey. The finding includes: 1. The HES procedure stated two 100% alcohol steps but the SS had three 100% alcohol

	containers. 2. The MA and Histotech stated on 7/25/18 at 11:15 am that it was an error in HES procedure. b) Based on surveyor review of the PM and interview on phone with the Histotech, the laboratory failed to have a procedure on how to prepare 0.05% Acid Alcohol from 7/6/16 to the date of survey. The Histotech stated during phone conversation on 7/25/18 at 11:15 am that the laboartory did not have a written procedure mentioned above.
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 surveyor review of an accession log, Quality Control (QC) slides and interview with the Medical Assistant (MA), the laboratory failed to document reaction of QC slide on 5/30/17. The finding includes: 1. The laboratory ran and reported eight patient results without evaluating QC on 5/30/17. 2. The MA confirmed on 7/25/18 at 11:30 am that the laboratory did not document QC reaction. b) Based on surveyor review of an accession log, QC slides and interview with the MA, the laboratory failed to stain QC slide on 3/5/17. The MA stated on 7/25/18 at 11:30 am there was no QC slide for 3/5/17.
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 surveyor review of the Procedure Manual (PM) and interview with the Medical Assistant (MA), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the applicable elements for Mohs technician from 7 /6/16 to the date of survey. The MA confirmed on 7/25/18 at 10:30 am that a CA procedure was not established.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

	supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Medical Assistant (MA), the Laboratory Director (LD) failed to specify in writing the list of job responsibilites for LD from 7/6/16 to the date of survey. The MA confirmed on 7 /25/18 at 11:30 am that job resposibilites were not established for LD.