Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0686745	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mathias Zemel Md	381 Chestnut Street, Union, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log and interview with the Testing Personnel (TP), the laboratory failed to retain analytic system records for Mohs testing from 10/27/16 to the date of the survey. The findings include: 1. A review of laboratory records revealed Quality Control results, Instrument Maintenance and Temperature records were not retained in 2017. 2. Patient work records (Mohs maps) were not on site at the time of the survey and had not been received by fax the next day. 3. The TP confirmed at 12:10 pm 7/31/18 analytic system records were not retained.
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 the lack of Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on two out of two Testing Personnel (TP) from 10/27/16 to the date of the survey. The TP confirmed on 7/31/18 at 10:25 am that CA was not performed annually.

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 lack of Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Histopathology testing twice annually from 10/27/16. The findings include: 1. This was cited on the previous survey performed on 10/27/16. 2. The Plan of Correction approved 1/23/17 stated "an alert has been placed in our calendar system to remind us when proficiency testing is due, every six months. This will be monitored by our head Mohs technician to ensure completion in a timely manner." 3. The TP confirmed on 7/31/18 at 11:45 am the laboratory did not verify the accuracy of Histopathology testing.
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 Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the applicable elements for Mohs technicians from 10/27/16 to the date of survey. The findings include: 1. This was cited on the previous survey performed on 10/27/16. 2. The Plan of Correction approved on /1/23/17 stated "We have all new proper documentation moving forward in our lab. This includes proper procedure and log for our Competency Assessment. The Director will be responsible for completing a CA on each lab personnel." 3. The TP confirmed on 7/31 /18 at 10:30 am that a CA procedure was not established.