Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0980863	09/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adrian L Connolly Md Llc	101 Old Short Hills Road, West Orange, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the MART-1 Manufacturers Package Insert (MPI), observation of the slides and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI instructions for MART-1 slides at the time of the survey. The finding includes: 1. The MPI stated that slides must be positively charged but the StatLab colorview adhesion slides used in the laboratory did not state they were positively charged. 2. The date the slides were opened was not documented. 3. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:10 am that the MPI was not followed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on surveyor review of temperature records and interview with the Testing Personnel (TP) the laboratory failed to record the temperature of the heat block used for MART-1 tests from 9/22/16 to the date of the survey. The findings include: 1. The temperature of the heat block used in MART-1 Histopathology testing must by at 60 degrees. 2. There was no temperature chart for the heat block. 3. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:45 am temperature of the heat block was not recorded.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Histopathology reagents and interview with the Testing Personnel (TP), the laboratory failed to appropriately label the reagents used for Histopathology tests with pertinent information required for proper use on the date of the survey. The findings include: 1. 70% Alochol was prepared in the laboratory and wasn't labeled as to its storage requirements, preparation and expiration dates. 2. Xylene was in a pour off bottle and was not labeled to indicate: a. Concentration b. Storage requirements c. Preparation and expiration dates. 3. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:35 am all reagents were not labeled appropriately.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents and interview with the Testing Personnel (TP), the laboratory failed to check the expiration date for reagents used for Hisotpathology tests on the date of the survey. The findings include: 1. Acetone and Toludin Blue were expired. 2. Approximately 8 to 10 patients were run once a month. 3. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:10 am that the laboratory had expired reagents.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to replace the filter on the Air Filtronix Fume Hood (FH) used in Histopathology testing from 10/17/16 to the day of the survey. The finding includes: 1. The paperwork on the FH stated the filter is to be replaced every six months but the last date it was changed was 10/17/16. 2. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:30 am maintenance was not performed.
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 surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to report Histopathology test results accurately from 9/22/16 to the date of survey. The finding includes: 1. The laboratory performed MART-1 a non Food and Drug Administration cleared tests and there was no statement stating "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration" on FR. 2. The TP #1 listed on the CMS 209 confirmed on 9/27/18 at 12:30 pm that MART-1 test were not reported accurately.
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 surveyor review of the Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that one of two TP had appropriate education prior to patient testing from January 2018 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 9/27/18 at 10:20 am that education was not documented.