Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1078005	01/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Western New York Immediate Medical Care Llc	4988 Harlem Rd, Amherst, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's procedure manual and an interview with the site administrator, the laboratory failed to retain the current copies of the manufacturers package inserts. FINDINGS The site administrator confirmed on 01/29 /2018 at approximately 2:00 PM, that the laboratory did not retain copies of the following manufactures package inserts for these test kits: a. Henry Schein One Step + Rapid Strep A, Henry Schein One Step + Influenza A & B , Henry Schein One Step + Respiratory Syncytial Virus and the Alere Uhcg. b. The laboratory changed to these current test kits in 01/2016.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) policy and lack of 3rd event 2017 MLE PT 2017 records and confirmed in an interview with the site administrator, the laboratory failed to retain copies of the MLE records and documentation to include signed attestation forms, test result forms, insturment printouts and PT summary reports for the 2017 third event. FINDINGS The site administrator confirmed on 1/29/2018 at approximately 3:00 PM that the

	laboratory failed to retain copies of the MLE records and documentation to include signed attestation forms, test result forms, insturment printouts and PT summary reports for the 2017 third event.
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 surveyor's review of the laboratory's policies and procedure manual and confirmed in an interview with the site administrator, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components to assess testing personnel's competency. FINDINGS The site administrator confirmed on 1/29/2018 at approximately 2:00 PM, that the laboratory failed to retain a copy of their competency assessment policy for all testing personnel, clinical consultants and the laboratory director, therefore there was no policy available at survey. The laboratory failed to include the following six criteria: 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem solving skills.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of MLE PT reports and confirmed in an interview with the site administrator, the laboratory director failed to review and evaluate the PT summary reports for all three events in 2016 and 1st & 2nd events of 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) polices

	/procedures and confirmed in an interview with the site administrator, the laboratory failed to follow the laboratory's written QA policy and perform QA reviews for the general laboratory systems for hematology testing in calendar years 2016 and 2017.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based of surveyor's review of the hematology calibration records and confirmed in an interview with the site administrator, the laboratory failed to perform the required six-month calibration for the hematology analyzer. FINDINGS 1. The site administrator confirmed on 1/29/2018 at approximately 3:30 PM, that the laboratory failed to calibrate the Coulter Act Diff hematology analyzer at the required six-month period. The last recorded date of calibration was 2/18/16 therefore, the analyzer was out of calibration in 2016 until the laboratory performed a calibration on 2/9/17. 2. The laboratory's calibration policy and the manufacturer of the hematology analyzer requires calibration every six months. 3. Approximately 104 patient specimens were tested and reported for CBC, when analyzer was out of calibration.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and confirmed in an interview with the site administrator, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. MLE PT reports were reviewed and evaluated, refer to D6018; 2. QC program for hematology was maintained, refer to D6020; 3. laboratory's QA program maintained, refer to D6021; 4. corrective action was taken and documented, refer to D6024; 4. testing personnel newly hired had the appropriate training, refer to D6029; 5. newly hired testing personnel had a six month competency evaluation, refer to D6053; 6. routine testing personnel had their annual competency reviews, refer to D6054.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor's review of the MLE PT records for all three test events in 2016 and 2017 and confirmed in a interview with the site manager, the laboratory director failed to evaluate the scored PT results and take corrective action when failures were identified. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's hematology calibration & QC records and confirmed in an interview with the site administrator, the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality of laboratory services. Refer to: D5437
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of a QA policy and confirmed in an interview with the site administrator, the laboratory director failed to establish a written QA policy. Refer to D5291.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on the surveyor's review of the hematology calibration records, QC records, lack of QA policy/records and lack of PT records and confirmed in an interview with the site administrator, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D3037, D5209, D5211, D5291, and D5437.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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's review of the testing personnel education records, training and competency evaluation records and confirmed in an interview with the site administrator, the laboratory director failed to ensure that the new testing personnel had the appropriate training, prior to patient testing. Refer to D5209.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 surveyor's review of personnel records and confirmed in an interview with the site administrator, the laboratory director (acting as the technical consultant), failed to perform and document semi-annual competency evaluations of six of the new hires. Refer to D5209.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's personnel records and confirmed in an interview with the site administrator, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for the eleven of eleven testing persons for the calendar years 2016 and 2017. Refer to D5209