Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2278069	06/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Zaki Badawy Md Pc	8100 Oswego Road Suite 140b, Liverpool, 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 the review of the laboratory's standard operating procedures as well as training and competency documentation, the laboratory failed to establish written policies and procedures for personnel training and competency. Confirmed findings by interview with the technical consultant on June 8, 2023, at approximately 6:00 P. M. Refer to D6030.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on direct observations of the WallarGe digital thermometer, lack of thermometer calibration procedures and records, and an interview with the technical consultant, the laboratory failed to retain approved instructions for the calibration of thermometers. FINDINGS: 1. The technical consultant confirmed on June 8, 2023, at approximately 5:30 P.M. that the procedure manuals did not include written, approved instructions for performing calibrations of thermometers. 2. The technical consultant confirmed on June 8, 2023, at approximately 5:30 P.M. that the laboratory did not retain thermometer calibration certificates and the manufacturer's instructions for calibration of thermometers.
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 direct observations, review of the Material Safety Data Sheets (MSDS), reagent manufacturer's storage requirements, and an interview with the technical consultant, the laboratory failed to properly store flammable reagents in the supply storage room and specimen processing laboratory as required by the MSDS. FINDINGS: 1. The surveyors' observations in the supply storage room and specimen processing laboratory confirmed on June 8, 2023, at approximately 2:00 P.M. the following reagents and processing materials were not properly stored in the flammable materials storage cabinet as required by the MSDS and the manufacturer's storage requirements: a. Eight 16 fluid ounce units of Swan Ethyl Rubbing Alcohol 70% lot: 0581886318 were stored on a rack in the supply storage room. b. One 32 fluid ounce unit of Belle Chemical Hand Sanitizer Grade 95% Ethanol lot: 857329007865 was stored on the backsplash of the sink located in the specimen processing laboratory.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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 the review of the laboratory's standard operating procedures as well as training and competency documentation, the laboratory director failed to ensure that policies and procedures were established for monitoring personnel who conduct specimen testing to assure training and competency. Confirmed findings by interview with the technical consultant on June 8, 2023, at approximately 6:00 P.M. Refer to D5209.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on the review of the training and competency documentation as well as educational records, the technical consultant (TC) did not meet the qualification requirements for performing moderate complexity testing. Confirmed findings by

	laboratory's failure to submit sufficient documentation of at least one year laboratory TC training or experience and competency assessments for virology moderate complexity testing on June 23, 2023, at approximately 12:30 P.M.