Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1033325	02/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
360 Complete Medical Pc	120 East 56th Street, 14th Floor, New York, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on lack of safety standard operating procedures (SOPs) and interview with the testing person (TP), the laboratory failed to draft, approve safety protocols to protect staff from physical, chemical, biochemical, biohazard materials, and electrical hazards. FINDINGS: 1. The laboratory failed to draft, approve safety protocols in compliance with universal precautions. 2. The TP confirmed the findings on February 29, 2024, at approximately 2:00 P.M.
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 review of TP six-month and annual competency evaluation records, lack of training documentation, lack of competency evaluation policy, as well as interview with TP, the LD failed to draft, approve a competency evaluation policy as well as perform, document TP training, six-month, and annual competency evaluations. FINDINGS: 1. The LD failed to draft, approve a competency evaluation policy including the following guidelines: a. Direct observations of routine patient test

	performance, specimen preparation, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of instrument maintenance performance and function checks. e. Assessment of patient test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f. Assessment of problem-solving skills. 2. It was noted that the TP was trained on the TOSOH AIA 900, ABX Horiba Pentra 400, and Micros 60 analyzers when the technical service representative installed the instruments October 24, 2023. 3. There was no documentation of TP training, six-month, and annual competency evaluation from June 2023 hire through date of survey. 4. The TP confirmed the findings on February 29, 2024, at 2:30 P.M.
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 lack of Quality Assessment (QA) policy and interview with the LD, the laboratory failed to draft, approve a QA policy. FINDINGS: 1. The current, approved 360 Complete Medical, PC standard operating procedures (SOPs) did not include a QA policy. 2. The TP confirmed the findings on February 29, 2024, at approximately 2:30 P.M.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's current, approved SOP manual and interview with the TP, the laboratory failed to include written instructions for performing the following activities: FINDINGS: 1. Requirements for specimen labeling, criteria for specimen acceptability, and rejection. 2. The TP confirmed the findings on February 29, 2024, at approximately 2:30 P.M.
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 review of the laboratory's current, approved SOP manual and interview with the TP, the laboratory failed to include written instructions for performing the following activities: FINDINGS: 1. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. Protocol for reporting life threatening results, panic values, and alert values. 3. Course of action if the test systems became inoperable. 4. The TP confirmed the findings on February 29, 2024, at approximately 1:30 P.M.
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 lack of current, approved SOPs, QA policies, TP personnel training records and competency evaluations, as well as interview with the TP, the LD failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The LD failed to ensure: 1. Drafting and approving QA policies for all phases testing. Refer to D6021. 2. Completion and documentation of TP training and competency evaluation. Refer D6029. 3. Drafting and approving policies for monitoring personnel who perform moderate complexity testing to assure training and competency. Refer to D6030. 4. Drafting and approving SOPs for performing all activities. Refer to D5403. 5. Specifying, in writing, the TP duties and responsibilities for all phases of the laboratory testing. Refer to D6032.
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 QA policy and interview with the TP, the laboratory failed to draft, approve a QA policy for all phases of the general laboratory system. Refer to D5291.
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 review of TP six-month and annual competency evaluation records, lack of training documentation, lack of competency evaluation policy, as well as interview with TP, the LD failed to ensure that training and competency evaluation were performed and documented for the TP responsible for moderate complexity testing. Refer to D5209.
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 current, approved SOPs as well as training and competency documentation, the LD failed to ensure that policies and procedures were established for monitoring personnel who conduct specimen testing to assure training and competency. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's current, approved SOP manual and interview with the TP, the laboratory failed to include written instructions for all activities performed. Refer to D5403.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of TP personnel records and confirmed by interview with the TP, the LD failed to specify, in writing, the TP duties and responsibilities for all phases of laboratory testing. Refer to D6000.