Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0696040	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Optum Medical Care Pc	107 Northern Boulevard, Suite 201, Great Neck, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of the CAP Proficiencies Testing records, the laboratory failed to retain copies of the signed attestation forms, test result forms, and a signed PT summary report. Confirmed findings on an interview with office manager on 3/9/2023 about 11:15am. Findings: The laboratory failed to retain copies of the above documents and records; therefore, it could not determine if the proficiency testing samples were tested in the same manner as patient specimens. And rotated among six testing personnel.
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 review of the Quality Assessment (QA) policy, the laboratory failed to perform and document annual QA review for calendar year 2022. Confirmed findings on an interview with office manager on 3/9/2023 about 10:30am.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of laboratory's Standard Operating Procedure (SOP), the laboratory director failed to perform annual review and sign the procedure manual as required by the SOP. Confirmed findings on an interview with office manager on 3/9 /2023 about 11:30am.
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 the review of thermometer calibration certificate, the room temperature /humidity thermometer calibration expired on 2/22/2023. Confirmed findings on an interview with office manager on 3/9/2023 about 11am.
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 on review of hematology calibration records, the laboratory failed to perform calibration of the hematology analyzer at the frequencies required by the laboratory's

	calibration policy. Confirmed findings on an interview with office manager on 3/9 /2023 about 11am.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Sysmex XN-430. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The general office manager confirmed during interview on 3/9/2023 at 10:45 am, the new lot to lot validation of QC material for hematology analyzer was not performed.
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 review of the laboratory's Quality Assessment (QA) procedure, it failed to perform and document annual QA review and confirmed in an interview with the general office manager, the laboratory director failed to establish a maintain QA for all phases for the general laboratory system. Refer to D5291.