Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0671012	07/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Optum Medical Care Pc	2 Lincoln Avenue, Suite 301, Rockville Centre, 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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology quality control (QC) records and an interview with the laboratory administrator and the laboratory supervisor, it was determined that the laboratory failed to ensure that hematology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Review of QC records found and it was confirmed with the laboratory supervisor on July 18, 2018 at approximately 11:30 AM during review of QC data that the following levels of control materials were out of acceptable range and remediation was not performed: 1. On 11/8/2017, 12/1/2017, 12/30/2017, 1/2, 3, 6, 10, 26, 27, 29, 31/2018, 3/21, 26, 27/2018, 5/12, 14, 31/2018, 6/20, 25/2018 two out of three hematology controls were out of range. 2. On 5/18, 19, 21, 22/2018 three out of three hematology controls were out of range 3. No records of hematology QC were found for October 2017. 4. Approximately 100 patient specimens were tested and results reported for hematology testing during this time period. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON MARCH 28, 2017.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the hematology QC records and an interview with the laboratory administrator and the laboratory supervisor, the laboratory failed to perform and document corrective action when QC results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Approximately 100 patients specimens were tested and reported during this time. Refer to: D5481 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON MARCH 28, 2017.
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 findings and interview with the laboratory administrator and the laboratory supervisor, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. maintained the plan of correction from the survey conducted on March 28, 2017 2. maintained the laboratory's QC program for hematology; refer to D6020. 3. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON MARCH 28, 2017.
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 the surveyor's review of the laboratory's quality control (QC) records and confirmed in an interview at the time of this survey with the laboratory administrator and the laboratory supervisor, the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality of laboratory services. Refer to: D5481, D5783 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON MARCH 28, 2017.
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 a review of the laboratory quality assessment records (QA), and interview with the laboratory administrator and the laboratory supervisor, the laboratory director failed to follow their QA procedure for having an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for hematology. Findings Include: It was confirmed with the laboratory administrator on the day of the survey at approximately 11:30 AM that although the QA reviews were performed in 12/2016, 7/2017 and 6/2018, the QA reviews failed to identify and address ongoing hematology quality control issues. Refer to: D5481, D5783