Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0956350	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Optum Medical Care Of Nj Pc	500 Piermont Road, Closter, NJ	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that TR included relevant and necessary information for accurate and reliable testing and reporting from 11/1/16 to the date of survey. The finding includes: 1. A review of five TR revealed five of five did not have the collection date recorded. 2. The TP #1 listed on CMS form 209 confirmed on 10/2/18 at 11:50 am that the collection date was not on the TR.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their PM policy for flagging of all Hematology results run on the Coulter AcT 2 analyzer from 11/1/16 to the date of the survey. The finding includes: 1. The PM stated flagged results will be re-run, if the flag remains specimen will be sent out to a reference laboratory but the laboratory had no documented evidence of above. 2. The TP #1 listed on CMS form 209 confirmed on 10/2/18 at 11:20 am the PM was not followed.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Normal Reference Intervals (NRI) were indicated on the FR for Throat Culture (TC) tests performed in the laboratory from 11/1/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 10/2/18 at 11:45 am that the NRI for TC were not on the FR.
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 review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for one out of four TP from 11/1/16 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 10/2/18 at 10:10 am that all TP did not have education records.