

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0667397	(X3) Date Survey Completed 02/14/2019
Name of Provider or Supplier Optum Medical Care Of Nj Pc	Street Address, City, State 870 Palisades Avenue, Suite 201, Teaneck, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a. Based on surveyor review of the Procedure Manual (PM), review of Quality Control (QC) data and interview with the Technical Consultant (TC), the laboratory failed to follow the "Procedure For Change In Lot Of Control Material" for Hematology tests from 4/13/17 to the date of the survey. The findings include: 1. The PM stated " Prior to use the laboratory should run each level of new control material at least once, to verify that control samples fall within manufactures stated ranges." 2. There was no documented evidence the laboratory followed the procedure stated above. 3. The TC confirmed on 2/14/19 at 11:50 am that the procedure stated above was not followed. b. Based on surveyor review of the PM, and interview with the TC, the laboratory failed to follow the "Flag Procedure" for flags obtained Hematology tests performed on the Beckman Coulter Act 2 Diff analyzer from 4/13/17 to the date of the survey. The findings include: 1. The PM stated to repeat samples with flags but there was not documented evidence flagged samples were repeated. 2. The Testing Personnel stated at the time of the survey that the laboratory does not repeat samples with flags. 3. The TC confirmed on 2/14/19 at 10:50 am that the Flag procedure was not followed. c. Based on surveyor review of the Quality Assurance (QA) procedure and interview with the TC, the laboratory failed to follow the QA procedure in the calendar years 2017 and 2018. The finding includes: 1. The QA procedure stated a QA review is to be performed very six months but there was no documented evidence a QA review was performed. 2. The TC confirmed on 2/14/19 at 12:50 pm that the QA procedure was not followed.</p>

<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview with the Technical Consultant (TC), the laboratory failed to put expiration dates on QC material for Hematology tests at the time of the survey. The findings include: 1. The expiration date of control material shortens once opened. 2. The laboratory did not put new expiration dates on the Coulter 4C control Lot 1685499K in use. 3. The TC confirmed on 2/14/19 at 11:50 am the laboratory failed to put expiration dates on the control material. Note: This was cited on previous survey performed on 4/13/17. Plan of Correction stated: Expiration dates will be paced on controls after opening. Staff members have been retrained to meet this requirement.</p>
<p>D5783</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to take Corrective Action (CA) when controls were out of range for Red Blood Cell (RBC) tests on the Beckman Coulter Act 2 Diff analyzer in June 2018. The findings include: 1. A review of the QC records revealed the Normal and High controls were out of range for RBC on 6/25/18. 2. 11 patients were run and reported. 3. There was no documented evidence CA was taken. 4. The TC confirmed on 2/14/19 at 11:30 am that corrective action on failed QC was not performed.</p>
<p>D5801</p>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt</p>

from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR), work records and interview with the Technical Consultant (TC), the laboratory failed to ensure test results were accurately transcribed on the FR for Throat Culture (TC) tests from January 2019 to the date of survey. The findings include: 1. A review of five FR revealed one of five had an incorrect result. 2. A review of five FR revealed one of five had a result entry at 12:03 am but the office was closed at that time. 3. The TC confirmed on 2/14/19 at 12:45 pm that the laboratory did not transcribe results accurately.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that the FR for Throat Culture tests included all the required information from 4/13/17 to the date of survey. The findings include: 1. The FR did not have: a. The name of the laboratory location where tests were performed. b. The FR did not have the "Test Report Date". 2. The TC confirmed on 2/14/19 at 11:55 am that all the required information was not on the FR.

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 the surveyor review of the Final Reports (FR) and interview with the Technical Consultant (TC), the laboratory failed to have a Reference Range (RR) for all Throat Culture (TC) tests from January 2019 to the date of the survey. The finding includes: 1. A review of five FR for TC results revealed three of five did not have a RR. 2. The TC confirmed on 2/14/19 at 12:20 pm that all TC tests did not have a RR on the FR.