

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0927663	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Optum Medical Care Of Nj Pc	Street Address, City, State 18 Railroad Ave, Ste 103, Rochelle Park, 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: Based on surveyor review of the Procedure Manual and interview with the Technical Consultant (TC), the laboratory failed to follow the "Flag Procedure" for flags obtained on Hematology tests performed on the Beckman Coulter AcT Diff analyzer from 1/2/19 to the date of the survey. The finding includes: 1. The PM stated to repeat samples with flags but there was no documented evidence five out of five flagged samples were repeated. 2. The TC confirmed on 3/26/19 at 1:50 pm that the Flag Procedure was not followed.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 surveyor review of the Procedure Manual and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for imminently life-threatening test results, or panic or alert values for tests ran on the Beckman Coulter AcT Diff analyzer from 4/12/17 to the date of the survey. The TC confirmed on 3/26 /19 at 2:10 pm that the laboratory did not establish the above procedure.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Records (TR) and interview with the Technical Consultant (TC), the laboratory failed to maintain positive identification of the specimen for Hematology tests performed on the Beckman Coulter AcT analyzer to ensure positive Identification (ID) of the patient from 4/12/17 to the date of the survey. The finding includes: 1. A review of five Hematology results revealed five out of five were identified by a sequence number generated by the instrument but the sequence number did not match the patient sample. 2. The TC confirmed on 3/26/19 at 1:45 pm that the laboratory did not maintain positive ID of the specimen.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the Technical Consultant (TC), the laboratory failed to follow the Quality Assessment Plan (QAP) procedure in the IQCP in the calendar year 2018. The findings include: 1. A review of the IQPC for Throat Culture media revealed there was no documented evidence the QAP was reviewed in 2018. 2. The TC confirmed on 3/26/19 at 1:40 pm the laboratory did not follow the QAP procedure in the IQCP.

D5801

TEST REPORT

CFR(s): 493.1291(a)

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 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 transcribed accurately and in a timely manner for Throat Culture (TC) tests from January 2019 to the date of survey. The findings include: 1. A review of six FR revealed: a. One of six had a report date three minutes after the specimen collection time. b. One of six had a report date 5 days after the specimen collection time. 2. The TC confirmed on 3/26/19 at 2:45 pm that the laboratory did not transcribe results accurately and in a timely manor.

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. A review of seven Throat Culture FR revealed: a. Seven out of seven did not have the correct name of the laboratory location where tests were performed. b. Seven out of seven did not have the "Test Report Date". c. Four out of seven did not have "Specimen Collection Date". d. Four out of seven did not have "Specimen Source". 2. The TC confirmed on 3/26/19 at 2:55 pm 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 tests from January 2019 to the date of the survey. The finding includes: 1. A review of six FR for Throat Culture results revealed four of six did not have a RR. 2. The TC confirmed on 3/26/19 at 2:20 pm that all Throat Culture tests did not have a RR on the FR.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files, Competency Assessment records and interview with the Technical Consultant (TC), the TC failed to perform CA from 4/12/17 to the date of survey. The findings include: 1. The CA was not performed by the TC but was done by a non qualified Testing Personnel (TP). 2. The TP #1 listed on CMS form 209 performed CA on four of five TP but was not qualified to perform CA. 3. The TC confirmed on 3/26/19 at 1:15 pm that the CA was not performed by the TC.