

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0866546	<b>(X3) Date Survey Completed</b>  04/12/2018
<b>Name of Provider or Supplier</b>  Optum Medical Care Of Nj Pc	<b>Street Address, City, State</b>  264 Boyden Avenue, Maplewood, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Physicians Assistant (PA), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from November 2017 to the date of survey. The PA confirmed on 4 /12/18 at 10:00 am that a BA procedure was not established.</p>
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Physicians Assistant (PA), the laboratory failed to check the Immunohistochemical Stains (IS) for positive and negative reactivity from November 2017 to the date of the survey. The findings include: 1. A review of the CD3 QC log revealed QC was</p>

acceptable but did not state which reactivity result was acceptable. 2. The PA confirmed on 4/12/18 at 12:25 pm that IS were not checked for positive and negative reactivity.

**D5603**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(b)(f)

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Histopathology Slides (HS) and interview with the Physicians Assistant (PA), the laboratory failed to retain HS from November 2017 to the date of the survey. The finding includes: 1. A review of twelve patient records revealed that four out of twelve patients' slides were not retained at the time of the survey. 2. A review of twelve patient records revealed slides were not retained to substantiate the reported results as follows: a. Patient 14431 - Source A,B and C had a statement " Myeloperoxidase (MP) immunostain performed but no MP slides were found. b. Patient 14307 - Source C stated " No Heliobacter Pylori (HP) organisms but no HP slide was found for source C. 3. The PA confirmed on 4/12/18 at 12:30 pm that HS were not retained.

**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 Physicians Assistant (PA), the laboratory failed to include the name and address of the laboratory where the technical component for biopsy specimens were processed from November 2017 to the date of survey. The PA confirmed on 4/12/18 at 11:30 am that the laboratory name and address was not on the FR.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the Procedure Manual (PM), Quality Control (QC) Final Reports (FR) and interview with the Physicians Assistant and Office Manager, the Laboratory Director (LD) failed to provide overall management, oversight and direction to the Testing Personnel (TP) for laboratory testing. The findings include: 1. The LD failed to ensure that a Quality Control program was established and maintained. Cross Refer to D6093. 2. The LD failed to ensure that a Quality Assurance program was established and maintained. Cross Refer to D6094.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on surveyors review of the Procedure Manual and interview with the Physicians Assistant (PA), the Laboratory Director failed to establish and maintain a Quality Control (QC) program for Histopathology testing from November 2017 to the date of survey. The findings include: 1. The Technical Consultant stated via telephone at 10:20 am on 4/12/18 that the laboratory did not read or receive a QC slide for Hematoxylin and Eosin (HE) but stain logs revealed QC slides were acceptable on 1/22/18, 1/30/18, 2/6/18, 2/15/18, 2/25/18, 3/1/18,3/10/18,3/15/18 and 4/9/18. 2. The PA confirmed on 4/12/18 at 11:00 am that a QC program was not established and maintained.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the laboratory Procedure Manual and interview with the Physicians Assistant (PA), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from November 2017 to the date of the survey. The PA confirmed on 4/12/18 at 10:45 am the LD did not establish a QA program.