Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0952462	(X3) Date Survey Completed 02/15/2018
Name of Provider or Supplier Optum Medical Care Of Nj Pc	**Street Address, City, State** 3200 Sunset Avenue, Ocean, 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
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (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. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, accession log, and interview with the Office Manager (OM), the laboratory failed to document the reactions of the QC slides for Periodic acid-Schiff (PAS), Helicobacter pylori (HP), Trichrome, Alcian blue/ Periodic acid-Schiff (ALB/PAS) stains used for Biospy slides from June 2017 through December 2017. The findings include: 1.There was no QC documented for H&E, PAS, ALB/PAS, Trichrome stains on 12/15/17. 2. There was no QC documented for H&E, PAS, Trichrome stains on 6/6/17. 3. Approximately 20 Patients were treated and reported. 4. The OM confirmed on 2/15/18 at 9:45am that the QC reactions were not documented.
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 Office Manager (OM), the laboratory failed to have the correct name of the laboratory where histopathology testing was performed from May 2017 to the date of the survey. The findings include: 1) The laboratory name on the Clinical Laboratory Improvement Act certificate was Shore Health Center. 2) The laboratory name on the FR was Howard N. Guss, D.O. 3) The OM confirmed on 2/15/18 at 10:00 am the name of the laboratory in the FR was incorrect.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from May 2017 to the date of the survey. The OM confirmed on 2/15/18 at 10:30 am that a CA procedure with the required elements was not established.