Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2164924	08/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ideal Pathology Associates, Llc	35 Green Pond Road, Rockaway, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from November 2018 to the date of survey. The LD confirmed on 8 /20/19 at 10:50 am that a BA procedure was not established.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD) the laboratory failed to establish a procedure for ordering special stains for Histopathology tests from November 2018 to the date of the survey. The LD confirmed on 8/20/19 at 10:50 am that the laboratory did not have a procedure to request special stains. b. Based on surveyor review of the patient manifest received with slides and interview with the LD, the laboratory failed to establish a procedure to ensure tracking of patient specimens from time of collection

	to receipt by the laboratory from the processing laboratories from November 2018 to the date of the survey. The LD confirmed on 8/20/19 at 11:25 am that the laboratory did not establish the above procedure.
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 and interview with the Laboratory Director (LD), the LD failed to document the Immunohistochemical Stain (IS) reactions from November 2018 to the date of the survey. The LD confirmed on 8 /20/19 at 11:15 am that the IS reactions were not documented.
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 Patient Manifest (PM) included with Histopathology slides, lack of a PM and interview with the Laboratory Director (LD), the laboratory failed to maintain an accurate information system for Histopathology slides from November 2018 to the date of the survey. The findings include: 1. Review of a PM received from a laboratory revealed the number of slides on the PM did not match the number received. 2. The laboratory did not receive a PM from all reference laboratories sending slides for testing. 3. The LD confirmed on 8/20/19 at 11:25 am that the laboratory did not maintain an accurate information system.
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 Test Report (TR) and interview with the Laboratory Director (LD), the laboratory failed to include the name and address of the laboratory where the Technical Component (TC) for Histopathology tests were performed from November 2018 to the date of survey. The LD confirmed on 8/20/19 at 10:50 am that the TC laboratory name and address was not on the TR.