Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2018360	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Precision Diagnostics Llc	1304 Bertrand Dr, Suite E8, Lafayette, LA	

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
D0000	A Certification Survey was performed on February 7, 2018 at Precision Diagnostics LLC - CLIA #19D2018360 and was found in compliance with 42 CFR 493, Requirements for Laboratories. However, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the proficiency attestation statements for three (3) of twelve (12) proficiency testing (PT) results. Findings: 1. Review of College of American Pathologist (CAP) proficiency testing records for 2016 through 2017 revealed the following three (3) attestation statements did not include the signature of the Laboratory Director: 2017 Human Papillomavirus (CHPV) - 2nd Event. 2017 Human Papillomavirus (CHPV) - 3rd Event. 2107 Trichomonas vaginalis (TVAG) - 2nd Event. 2. Interviews with Personnel 1 and 2 on February 7, 2017 confirmed the Laboratory Director failed to sign the attestation statements.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with the Laboratory Director on February 7, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with the Laboratory Director on February 7, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing

	samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with the Laboratory Director on February 7, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 review of Laboratory's Policy and Procedures and interview with personnel, the laboratory failed to maintain a complete policy and procedure manual. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have detailed policies and procedures for the following: a) Policies and Procedures addressing Proficiency Testing (PT) or twice a year verification, to include but not limited to enrollment, record retention, handling of samples, corrective actions, acceptability criteria and who is responsible for each step. b) Performance Specifications to include: * Instructions for testing personnel of what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. * How to handle when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. c) Establishment of written policies and procedures for Quality Control (QC) which include: * What QC testing will be performed, when it will be performed, and how often it will be performed. * Establishment of mean and ranges for QC materials to include but not limited to: How to establish ranges for QC materials and/or verification of QC material *What corrective action to take when calibration and/or control results fail to meet laboratory's criteria for acceptability 2. Interview with the Laboratory Director on February 7, 2018 confirmed the laboratory policy and procedure manual was incomplete.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure Proficiency Testing Records are evaluated to identify problems that require corrective action for four (4) of twelve (12) events. Findings: 1. Review of College of American Pathologist (CAP) Proficiency Testing (PT) Reports from 2016 through 2017 revealed the following four (4) events were given a code of (26) for results and failed to have documentation the laboratory evaluated the PT Reports to determine if the laboratory failed and needed corrective action: NOTE: Code 26 = Educational Challenge and was not scored by CAP, leaving the laboratory to evaluate against the summary report to determine if the laboratory need corrective action. 1st Event for Trichomonas vaginalis (TVAG): All Samples (TVAG-04, TVAG-05 and TVAG-06) were given a Code 26 and there was no documentation that the laboratory evaluated themselves to determine if corrective action was needed. 1st Event for Human Papillomavirus (CHPV) HR HPV Genotyping: All Samples (CHPVM - 1, CHPVM-2, CHPVM-3, CHPVM-4 and CHPVM 5) were given a Code 26 and there was no documentation that the laboratory evaluated themselves to determine if corrective action was needed. 2nd Event for Human Papillomavirus (CHPV) HR HPV Genotyping: All Samples (CHPVM - 11, CHPVM-12, CHPVM-13, CHPVM-14 and CHPVM 15) were given a Code 26 and there was no documentation that the laboratory evaluated themselves to determine if corrective action was needed. 3rd Event for Human Papillomavirus (CHPV) HR HPV Genotyping: All Samples (CHPVM - 6, CHPVM-7, CHPVM-8, CHPVM-9 and CHPVM 10) were given a Code 26 and there was no documentation that the laboratory evaluated themselves to determine if corrective action was needed. 2. Interviews with Personnel 1 and 2 on February 7, 2018 confirmed the laboratory failed to document evaluation of the events noted above to determine if corrective action was needed. an unacceptable result of 50% for the 3rd Event Immunohematology-Direct Antiglobulin Testing (DAT). 2. Further review of the 3rd Event Immunohematology-DAT records revealed documentation of the DAT sample with the notation "Clerical error noted." Additionally a "Performance Review and Corrective Action Documentation" form signed and undated by Personnel 2 was found; however, the form failed to have the Lab Director's signature. 3. In interview on February 16, 2017, Personnel 2 revealed she was unaware the corrective action form was incomplete.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to establish a quality assessment (QA) program to assure the quality of laboratory testing provided. Findings: 1. A review of Laboratory's Policy and Procedure Manual revealed the Laboratory Director failed to establish written policies and procedures that address quality assessment of laboratory services

	provided to include but not limited to the preanalytic, analytic and post analytic phases of testing. 2. Interviews with Personnel 1 and 2 on February 7, 2018 confirmed there were no established quality assessment policies and procedures.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to specify in writing the duties and responsibilities of personnel involved in all phases of high complexity testing. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory failed to include written duties and responsibilities for personnel involved in all phases of testing to include: a) Laboratory Director, b) Clinical Consultant, c) Technical Supervisor, d) General Supervisor, Note: Personnel records also failed to have written delegation of duties from the Laboratory Director for the General Supervisor. 2. Interview with Personnel 1 and 2 on February 7, 2018 confirmed the laboratory failed to have detailed written job duties and responsibilities for all positions in the laboratory involved in all phases of testing.