Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2122137	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Precise Diagnostics, Llc	2695 Villa Creek Dr Ste B255, Farmers Branch, TX	

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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Revisit 09/06/2018 New condition. Based on review of the laboratory's policy, patient test requisitions, and patient test reports, the laboratory failed to meet the requirements of the preanalytical systems, as evidenced by: 1. The laboratory failed to ensure the test requisitions solicited the tests to be performed for 5 of 13 patients in 07/2018. Refer to D5305. 2. The laboratory's policies were not consistent for preservation of specimen type received and processed. Refer to D5311. 3. The written policy provided to clients for specimen handling did not include all required components. Refer to D5317.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Revisit 09/06/2018 New deficiency. Based on review of the laboratory's policy and client services manual, the laboratory's policy were not consistent for preservation of specimen type received and processed. Findings included: 1. Review of the laboratory's "Specimen Receiving" stated, "PROCEDURE: 1. Each specimen has been placed inside a biopsy bottle that is label with patient name, date of birth, name of specimen site that contains 10% formalin fixative, the top replaced tightly and the bottle place inside a biohazard specimen bag with the universal symbol for biohazard on it with the requisition by Lab." 2. Review of the "REQUIREMENT FOR SPECIMEN COLLECTION" provided to clients stated, "2. Place patient biopsy inside specimen-envelopes or specimen-bottles (with no fixative enclosed) and write the patient's name, date, and anatomic site the clipping was taken from." The policies were not consistent with one another for toenail specimen preservation for fixative versus no fixative. 3. A total of 13 patient toenail specimens were processed in 07 /2018, the disposition of the specimens was unknown. Note: The laboratory had not not recieved specimens at the time of the revisit. The last date of service for receiving and processing specimens from outside clients was 07/07/2018, 07/09/2018 and 07/10 /2018.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Revisit 09/06/2018 New deficiency. Based on direct observation, review of the laboratory's policy, temperature charts, and quality assessment (QA) records, the laboratory failed to have a QA program that included a review of the effectiveness of corrective action taken to resolve problems, revision of procedures necessary to prevent recurrence of problems in analytic systems in 08/2018. Findings included: 1. During a tour of the laboratory on 09/06/2018 at 10:30 am, the following reagents were observed to be stored in the refrigerator: Gold Chloride Solution (2 bottles) 125 mL, Lot #47869, expiration date 11-2019, received 07/07/18. Bottle stated, "Store 2-8C." This solution was for making stains. Methenamine Solution (3 bottles) 500 mL, Lot #47968, expiration date 11-2019, received 07/07/18. Bottle stated, "Store 2-8C." This solution was for the GMS stain. 2. Review of the laboratory's "QUALITY CONTROL - EQUIPMENT" policy, stated, "Check and record the temperature of the refrigerator daily. Daily evaluation and function maintenance including temperature of the refrigerator in which reagents or patients' specimens are kept. Measurements taken to show the refrigerator is within an acceptable range is kept in the 'Pathology Quality Control Logs.'" 3. Review of refrigerator temperature charts for 08/2018 revealed 6 of 24 documented days were not within the defined range 2-8C, as follows: 08/10/2018: 11C 08/13/2018: 1C 08/18/2018: 1.5C 08/22/2018: 1.3C 08/24/2018: 1.9C 08/30 /2018: 0.8C There was no documented corrective action taken on those days. At the bottom of the temperature chart stated, "10-when temp is out it must be recheck: not currently running patients." 4. Review of the laboratory's "PATHOLOGY MONTHLY QUALITY ASSURANCE CHECKLIST" for 08/2018 stated, "No

	documentation of temperature recheck when fridge temp was out. This must be rechecked in the same day." This was signed by Testing Person -2 and the laboratory director on 09/05/2018. The laboratory did not document corrective action taken for the solutions observed to be stored in the refrigerator (received 07/07/2018). The solutions had required storage temperatures of 2-8C. The laboratory's QA program did not include a review of the effectiveness of corrective action taken to resolve problems, revision of procedures necessary to prevent recurrence of problems in analytic systems. 5. Review of refrigerator temperature charts for 07/2018 revealed temperatures were not documented to ensure storage conditions were appropriate for solutions. A monthly QA for 07/2018 was not performed and documented. Refer to D5413.
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: Revisit 09/06/2018 New Deficiency. Based on review of the CMS 209 form and personnel records, the laboratory director failed to specify, in writing, the responsibilities and duties of each testing person engaged in the performance of all 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 review is required to reporting patient test results for 3 of 3 Testing Persons (TP-2, TP-3, TP-4). Findings included: 1. Review of the CMS 209 form revealed TP-2, TP-3, and TP-4 listed as performing high complexity testing for histopathology. Testing included grossing by the mentioned above Testing Persons. The laboratory director was also listed as the technical supervisor and testing person. Note: The laboratory director/technical supervisor was not onsite on a daily basis. 2. Review of TP-2 and TP-3 written "JOB RESPONSIBILITIES" revealed testing persons responsibilities and duties signed by the testing persons (TP-2 signed 04/27/2018; TP-3 signed 04/28/2016) but not the laboratory director. Written job responsibilities and duties were not available for TP-4 (TP-4 began employment 07/2018). The laboratory director did not specify, in writing, the responsibilities and duties of each testing person engaged in the performance of all 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 review is required to reporting patient test results for the TP-2, TP-3, and TP-4.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: Revisit 09/06/2018 New Condition. Based on review of laboratory policies and personnel records, the technical supervisor failed to provide technical supervision, as evidenced by: 1. The technical supervisor failed to ensure written policies were followed. Refer to D6112. 2. The technical supervisor failed to establish a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process. Refer to D6117. 3. The technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually for 1 of 3 Testing Persons (TP-2). Refer to D6128.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Revisit 09/06/2018 New Deficiency. Based on review of the CMS 209 form and personnel records, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually for 1 of 3 Testing Persons (TP-2). Findings included: 1. Review of the CMS 209 form revealed TP-2 listed as performing high complexity testing in histopathology, which included grossing. The laboratory director was also listed as the technical supervisor. 2. Review of personnel records revealed TP-2 "JOB RESPONSIBILITIES" and duties was signed 04/28/2016. TP-2 recent annual competency dated 08/29/2018 included evaluation and performance ("PERFORMANCE STANDARD EVALUATION (CLINICAL) HISTOPATHOLOGY TECHNOLOGIST/TECHNICIAN") signed by TP-4, the "Assessor." 3. Review of the laboratory director's "Job Description" included "ROLE AND RESPONSIBILITIES" and stated, "2. Approve competency testing of testing personnel." The annual competency for TP-2 was not signed by the technical supervisor, as required. (Note: TP-4 did not qualify as a general supervisor or as a technical supervisor)