Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2018360	05/20/2022
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 Recertification survey was performed on May 18, 2022 through May 20, 2022 at Precision Diagnostics, LLC, CLIA ID # 19D2018360. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient test requisitions, patient final reports, and interview with personnel, the laboratory failed to have a written request for Trichomonas vaginalis test performed for two (2) of two (2) patients reviewed. Findings: 1. Review of random selection of patient test requisitions and patient test final reports revealed the laboratory reported Trichomonas vaginalis results without a written request for the following two (2) patients: Patient PD2021-030606.1 Patient PD2021-029325 2. In interview on May 19, 2022 at 2:54 pm , the Technical Consultant confirmed the laboratory reported the identified two (2) patient's test results for a test that did not have a written requisition/order. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written policies and procedures that included the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria b) Twice a year instrument comparison of test results for the same tests performed on multiple instruments 2. In interview on May 20, 2022 at 9:06 am, the Technical Consultant confirmed the laboratory did not have a written policy for the identified items.
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 the laboratory's policies and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures to include corrective actions to take when results fail to meet the laboratory's acceptability criteria. 2. In interview on in May 20, 2022 at 9:15 am, the Technical Consultant confirmed the laboratory did not include the identified procedure.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's validation records, patient test requisition, and interview with personnel, the laboratory failed to perform performance verification studies for urine samples utilized for Microbiology testing on the BD Max instrument. Findings: 1. Observation by surveyors during the laboratory tour on May 18, 2022 at 10:57 am, revealed the laboratory utilizes the BD Max for testing of Chlamydia trachomatis, Neisseria and Trichomonas (CT/GC/TV Panel). 2. Review of the laboratory's test requisitions revealed under the "STI" section for the "CT/GC/ TV Panel" urine is listed as a sample type. 3. Review of the laboratory's "Specimen Requirements" policy dated December 12, 2021 revealed instructions for collection and transport of urine samples. 4. Review of the laboratory's performance verification studies for the BD Max revealed the laboratory did not perform studies that include accuracy, precision, reference range, and reportable range, for urine samples. 5. In interview on May 19, 2022 at 8:49 am, the Technical Consultant stated the laboratory did not perform validation (verification) studies on the BD Max for urine samples. II. Based on observation by surveyors, review of the laboratory's validation records, and interview with personnel, the laboratory failed to verify the accuracy of the BioFire instrument following the addition of six (6) drawers. Findings: 1. Observation by surveyors during the laboratory tour on May 18, 2022 at 10:57 am, revealed the laboratory utilizes the the BioFire Torch instrument for Gastrointestinal (GI) Panel testing. 2. Review of the laboratory's validation records revealed the laboratory verified the accuracy of the BioFire Torch in July 2021 when the laboratory had the original drawers. Further review of manufacturer records revealed the laboratory added an additional 6 drawers to the BioFire Torch in August 2021. 3. Review of verification of performance specifications as well as quality control records revealed the laboratory performed no method of verification of the additional 6 drawers prior to patient testing. 4. In interview of May 19, 2021 at 3:15pm, the Technical Consultant stated she was unaware expanding the test platform required additional verification of the system.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of the laboratory's Individualized Quality Control Plan (IQCP), and interview with personnel, the laboratory failed to review the quality control plan annually per laboratory policy for 2020 and 2021. Findings: 1. Observation by surveyors during the laboratory tour on May 18, 2022 at 10:57 am, revealed the laboratory utilizes the BD Max for testing of Group B Streptococcus

	(GBS), Chlamydia trachomatis, Neisseria, Trichomonas, Bacterial vaginosis, Candida, and Trichomonas. 2. Review of the laboratory's IQCP plans for the BD Max analytes revealed the following "QCP (quality control plan) will be reapproved by Medical Laboratory Director once a year." 3. Further review of the laboratory's IQCP records revealed the laboratory did not have documentation of an annual review of the quality control plan for 2020 or 2021. The laboratory's last documented review was December 23, 2019; the effective date of the IQCP. 4. In interview on May 19, 2022 at 2:54 pm, the Technical Consultant stated she thought the review of the general policies covered the review of the IQCP. The Technical Consultant confirmed the Laboratory Director did not review the IQCP annually per laboratory policy. II. Based on observation by surveyor, review of the laboratory's policies, control records, patient logs, and interview with personnel, the laboratory failed to perform quality control (QC) for the BioFire Film Array GI Panel every thirty (30) days per policy in 2021. Findings: 1. Observation by surveyors during the laboratory tour on May 18, 2022 at 10:18 am revealed the laboratory utilizes the BioFire for Gastrointestinal (GI) and Respiratory panel testing. 2. In interview on May 18, 2022 at 11:22 am, the Technical Consultant stated the laboratory performs controls every thirty (30) days. 3. Review of the laboratory's "Quality Assessment Policy" under the "Monthly QC Review" secetion revealed "Once a month, all QC data (including any prallel testing) are to be cimbimned into a cumulative submission (preferable, utilizing Levy-Jennings charts with plotted points/values). Assessment of the charted data will be made by the laboratory manager and documented on the Monthly Review of Quality Control Form which will be submitted with the QC data to the laboratory director for review." 4. Review of the laboratory's quality control records revealed the laboratory did not perform QC for November 2021. The laboratory previously performed controls October 28, 2021 and later December 20, 2021. 5. Review of patient logs for the GI Panel tests revealed sixteen (16) patient test results were reported from November 29, 2022 through December 17, 2022 without QC performed. 6. In interview on May 19, 2022 at 2:45pm, the Technical Consultant confirned the laboratory did not perform QC for every thrity (30) days per laboratory policy.
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 observation by surveyor, review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. Observation by surveyors during laboratory tour on May 18, 2022 at 10:57 am and review of the laboratory's test menu revealed the laboratory utilizes the following test kits/systems for SARS COV-2: a) Accula (2000 tests performed annually) b) TaqPath COVID-19 Combo Kit utilizing the Quant Studio 5 (50,000 tests performed annually) 2. Review

	of the manufacturers' instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories." 3. Review of the following random patient final test report for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on the patient final reports: Accula: Patient PD2022-018196 TaqPath: Patient PD2022-018337 4. In interview on May 19, 2022 at 8:49 am, the Technical Consultant confirmed the laboratory's patient final reports for the Accula and TaqPath COVID-19 Combo tests for SARS COV-2 did not include the identified statement.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Findings: 1. Observation by surveyors during laboratory tour on May 18, 2022 at 10:57 am and review of the laboratory's test menu revealed the laboratory utilizes the following test kits/systems for SARS COV-2: a) Accula (2000 tests performed annually) b) TaqPath COVID-19 Combo Kit utilizing the Quant Studio 5 (50,000 tests performed annually) 2. Review of the manufacturer's instructions revealed "Authorized laboratories * using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on May 18, 2022 at 3:56 pm, the Technical Consultant stated fact sheets are not provided to patients that are collected at curbside.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, patient test requisitions, patient final test reports, and interview with personnel, the laboratory failed to issue corrected reports for Trichomonas vaginalis test results issued for two (2) patients reviewed. Findings: 1. Review of the following two (2) patient test requisitions revealed the Trichomas

	vaginalis test performed on the Panther instrument was not ordered: Patient PD2021-029325 Patient PD2021-030606.1 2. Review of the identified patient final test reports revealed the laboratory reported test results for Trichomonas vaginalis. A note was included for Patient PD2021-030606.1 "Trichnomonas vaginalis ordered in error; no charge;" however, the result was visible. The final report for Patient PD2021-039325, the laboratory did not include a note. The laboratory did not issue a corrected lab report. 3. Review of the laboratory's "Corrected Laboratory Report Policy" revealed " Appropriate documentation and follow-up action should be taken were {sic} indicated to decrease and or eliminate future occurrences a Corrected Lab Report Form (LB-QA-11) shall be generated and forwarded to the Laboratory Clinical Director for review of appropriateness of actions taken. The form will then be reviewed and signed by the Medical Director." 4. In interview on May 19, 2022, the Technical Consultant confirmed the laboratory did not issue corrected reports for the Trichomonas vaginalis tests performed in error.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421 I and D5421 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to review the quality control plan annually per laboratory policy for 2020 and 2021. Refer to D5445 I. 2. The laboratory failed to perform quality control (QC) for the BioFire Film Array GI Panel every thirty (30) days per policy in 2021. Refer to D5445 II.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: ***Repeat deficiency from survey conducted on January 29, 2020** Based on review of the laboratory's policies, personnel training records, and interview with personnel, the Laboratory Director failed to ensure two (2) of five (5) Testing Personnel reviewed had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's "Quality Assessment Policy," approved on December 12, 2021, under "Personnel Assessment" section revealed "The laboratory director, to ensure all laboratory personnel are qualified and competent, will perform random personnel assessment checks." 2. Review of the laboratory's BD Max training documents for the Technical Consultant, who also serves as Testing Personnel, and Testing Personnel 3 revealed no documentation of the Laboratory Director's approval /signature for patient testing. 3. In interview on May 19, 2022 at 3:57 pm, the Technical Consultant confirmed the Laboratory Director did not sign off on the identified Testing Personnel's training for the BD Max.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by:

	Based on review of patient records and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5301.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of records, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required information. Findings: 1. The laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Refer to D5805. 2. The laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Refer to D5809. 3. The laboratory failed to issue corrected reports for Trichomonas vaginalis test results for two (2) patients reviewed. Refer to D5821.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, personnel training records, and interview with personnel, the Laboratory Director failed to ensure four (4) of five (5) Testing Personnel reviewed had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's "Quality Assessment Policy," approved on December 12, 2021, under "Personnel Assessment" section revealed "The laboratory director, to ensure all laboratory personnel are qualified and competent, will perform random personnel assessment checks." 2. Review of the laboratory's TaqPath COVID-19 Combo kit training documents for the Technical Consultant, who also serves as Testing Personnel, Testing Personnel 1, Testing Personnel 2, and Testing Personnel 3 revealed no documentation of the Laboratory Director's approval/signature for patient testing. 3. In interview on May 19, 2022 at 3: 57 pm, the Technical Consultant confirmed the Laboratory Director did not sign off on the identified Testing Personnel's training for the SARS COV-2 testing utilizing the TaqPath COVID-19 Combo kit. II. Based on review of the laboratory's policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure one (1) of ten (10) Testing Personnel met the education requirement. Findings: 1. Review of the laboratory's personnel records revealed the laboratory did not have documentation of education for Testing Personnel 10. Testing Personnel 10 was previously employed April 1, 2021 through May 12, 2021. 2. Review of the laboratory's "Quality Assessment Policy" under "Personnel Assessment" section revealed "documentation of education and competence {sic} must also be present." 3.

	In interview on May 15, 2022 at 12:42 pm, the Technical Consultant stated Testing Personnel 10 did not make it out of training. The Technical Consultant confirmed the laboratory did not have documentation of education for Testing Personnel 10.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403.