

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2018360	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier Precision Diagnostics Llc	Street Address, City, State 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 at Precision Diagnostics,LLC, CLIA ID 19D2018360 on January 29, 2020. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: *** Repeat deficiency from previous survey February 7, 2018 *** Based on record review and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Employee Competency and Annual Performance Evaluation" policy revealed "Employee competency may be monitored by blind sample testing, direct observation and/or written assessments." 2. Further review of the laboratory's "Employee Competency and Annual Performance Evaluation" policy and "Employee Performance Evaluation" form revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing 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</p>

of problem solving skills. 3. In interview on January 29, 2020 at 10:17 am, the General Supervisor confirmed the laboratory's policy and evaluation form did not include the identified six (6) procedures.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples. Findings: 1. Review of the laboratory's "Client Procedures" for Group B Streptococcus (GBS), BD MAX Vaginal Panel, and BD MAX CT/GC/TV assay revealed the laboratory did not include sample stability limitations in their rejection criteria. 2. Review of the BD Max "CLSI Laboratory Procedures" revealed the following specimen stability requirements: a) BD Max Vaginal Panel: "Specimens in BD MAX UVE Sample Buffer Tubes can be stored for a maximum of 8 days at 2-30 degrees C or for a maximum of 14 days at 2-8 degrees C before testing." b) BD MAX CT/GC/TV: "Sample Stability in BD MAX UVE Sample Buffer Tube prior to Pre-Warm 5 days at 2-30 degrees Celsius or 30 days at -20 degrees Celsius. 3. In interview on January 29, 2020 at 10:17 am, the General Supervisor confirmed the laboratory did not include sample stability limitations in their written client procedures.

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 observation, record review, and interview with personnel, the laboratory failed to follow their method verification procedure for precision studies for the BD MAX instrument. Findings: 1. Observation by surveyor during the laboratory tour on January 29, 2020 revealed the laboratory utilizes the BD MAX for testing of the following: Group B Streptococcus (GBS), Chlamydia/Gonorrhea, and Trichomonas (CT/GC/TV), and Bacterial Vaginosis (BV) panel. 2. In interview on January 29, 2020 at 9:07 am, the General Supervisor stated the laboratory started patient testing on the BD MAX on December 30, 2019. 3. Review of the laboratory's Verification (Validation) procedure for Precision revealed the following: "Most sources agree that a minimum of 2 negative samples and 2 positive samples run in triplicate for 5 days will provide data or within run and between-run components to estimate precision." 4. Review of the laboratory's Precision studies revealed the laboratory did not test samples in triplicate for five (5) days per their policy. 5. In interview on January 29, 2020 at 11:01 am, the General Supervisor confirmed the laboratory did not test samples for precision studies as stated in their policy.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to perform and document visual inspections, sterility checks, and ability to support growth for each batch/shipment of BBL Lim Broth. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory failed to include quality control procedures for Microbiology media testing, that includes the following: a) Visual inspection b) Ability to support growth, select or inhibit specific organisms or produce biochemical response c) Sterility checks 2. Review of the "BBL Lim Broth" package insert revealed a "Performance Test Procedure" and "Additional Quality Control" procedures. 3. In interview on January 29, 2020 at 9:07 am, the General Supervisor stated the laboratory began patient testing on the BD Max for Group B streptococci on December 30, 2019. 4. In further interview on January 29, 2020 at 11:03 am, the General Supervisor stated the laboratory does not perform any type of testing on the Lim Broth prior to use. 5. Review of the laboratory's test menu revealed the laboratory performs seventy five (75) Group B Streptococci tests annually.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 2. The laboratory failed to follow their method verification procedure for precision studies for the BD MAX instrument. Refer to D5401.

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 record review and interview with personnel, the Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D5477.

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:

Based on record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's "Employee Competency and Annual Performance Evaluation" policy revealed "It is the Director's responsibility to determine if and when an employee is competent to perform patient sample testing." 2. In interview on January 29, 2020 at 9:40 am, the General Supervisor stated Testing Personnel 1 was hired in October 2018. 3. Review of the BD Max initial training documents for Testing Personnel 1 revealed no documentation of the Laboratory Director's approval/signature for patient testing. 4. In interview on January 29, 2020 at 11:23 am, the General Supervisor stated the Laboratory Director did not sign off on Testing Personnel 1's initial training.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) 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 record review and interview with personnel, the Laboratory Director failed

to ensure complete policies and procedures were established for assessing personnel competency. Refer to D5209.

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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.