

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1098706	(X3) Date Survey Completed 02/08/2018
Name of Provider or Supplier Prostate Diagnostics, Llc	Street Address, City, State 16601 N 40th St Ste 222, Phoenix, AZ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2016 and 2017. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 950. 2. No documentation was presented for review to indicate the laboratory verified the accuracy of Epidermal Nerve Fiber Density Testing (ENFD) slide interpretation at least twice annually during 2016 and 2017 as indicated in the laboratory's policy. 3. The facility personnel confirmed that the laboratory did not provide the documentation indicated above during the survey.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p>

This STANDARD is not met as evidenced by:
 Based on lack of documented evidence of each of the criteria listed under the regulation for establishment of performance verification and interview with the facility personnel, the laboratory failed to provide evidence of the verification of performance criteria for a Dermatophyte molecular testing methodology by polymerase chain reaction (PCR) that has not received FDA clearance in the United States. Findings include: 1. The laboratory started performing the Dermatophyte PCR test described above in February 2016. 2. The facility personnel indicated that the Dermatophyte PCR test was validated by performing four separate analysis prior to patient testing. 3. No written documentation of acceptable performance criteria for each of the analysis was presented for review nor was there evidence of approval of a performance verification by the director prior to the start of patient testing. 4. The approximate annual test volume for the PCR testing under the sub-specialty of Mycology is sixty.

D5433

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
 Based on review of laboratory maintenance policies for (A) the microscope, microscope maintenance stickers placed on the microscope by the preventative maintenance company, (B) manufacturer's instructions for calibration of the electronic pipettes and interview with the facility personnel, the laboratory failed to perform and document the annual microscope maintenance for 2017 and perform calibrations for the electronic pipettes since initially utilized in February 2016 . Findings include: (A) 1. The laboratory's established policy states that the the preventative maintenance schedule for the microscope used in patient testing under the sub-specialty of Histopathology is indicated on the sticker placed on the microscope. 2. No documentation was presented for review to indicate the laboratory performed the annual preventative maintenance in November 2017 as displayed as the next service date. The microscope was previously inspected in November 2016. 3. The facility personnel confirmed that the laboratory failed to perform the annual maintenance on the microscope in 2017. (B) 1. The manufacturer's instructions for the electronic pipettes used in Dematophyte polymerase chain reaction (PCR) testing under the sub-specialty of Mycology indicated a quick calibration procedure for the electronic pipettes. 2. There was no indication that the electronic pipettes had been calibrated since first utilized in February 2016 until the day of the survey. 3. At the time of the survey it was not clear in the manufacturer's instructions how often the manufacturer required the pipettes be calibrated. 4. The facility personnel acknowledged that the electronic pipettes had not been calibrated since first utilized.

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 lack of control slides for the Congo Red stain used in patient testing under the specialty of Histopathology and interview with the facility personnel, the laboratory failed to provide a control slide for each patient or group of patients tested during 2017. Findings include: 1. No control slides for Congo Red stain were presented for review for patients tested during 2017. 2. The laboratory personnel indicated that there were control slides for the Congo Red staining performed in 2016 but could not find any control slides for 2017 during the survey. 3. It could not be determined at the time of the survey how many patients or groups of patients were missing Congo Red control slides. 4. The total annual test volume under the sub-specialty of Histopathology is 950.