

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2041253	<b>(X3) Date Survey Completed</b>  02/02/2018
<b>Name of Provider or Supplier</b>  Palladium Primary Care, Inc	<b>Street Address, City, State</b>  2510 Gate City Boulevard, Greensboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 12/8/17 and review of 2017 American Proficiency Institute (API) proficiency testing results 2/2/18 during the onsite recertification survey, the laboratory failed to achieve satisfactory performance for the subspecialty of bacteriology in two of three consecutive testing events, resulting in unsuccessful participation. See the deficiency cited at D2028.</p>
<b>D2028</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</p>

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 12/8/17 and review of 2017 American Proficiency Institute (API) proficiency testing results and interview with staff 2/2/18 during the onsite recertification survey, the laboratory failed to achieve satisfactory performance for the subspecialty of Bacteriology in two of three consecutive testing events, resulting in unsuccessful participation. Findings: 1. Desk review of CMS Casper reports 153D and 155D 12/8/17 revealed the laboratory received a score of 0% for the subspecialty of bacteriology on the 2017 Microbiology 1st event, and a score of 20% on the 2017 Microbiology 3rd event. 2. Review of 2017 API proficiency testing results 2/2/18 during the onsite recertification survey revealed: a. The laboratory failed to participate and received an overall score of 0% on the 2017 Microbiology 1st event. b. The laboratory received a score of 20% for Gardnerella vaginalis, a score of 60% for Trichomonas vaginalis, and a score of 80% for Candida species, resulting in an overall score of 20% on the 2017 Microbiology 3rd event. During interview at approximately 9:30 a.m., the office manager stated that one of the former testing personnel observed TP #2 during the process of testing the samples. She stated the former testing personnel did not notice any problems, so it was not clear what happened.

**D5407**

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's IQCP (Individualized Quality Control Plan) and review of 2016 and 2017 quality assessment records 2/2/18, the laboratory director failed to review and approve the IQCP before use. Review of the laboratory's IQCP revealed it was originally established sometime in March 2016. A notation by the TC (technical consultant) 10/27/16 states "After reviewing 22 patients that have been done since January until September and QC was performed each day of testing - QC can now be done each time an Affirm kit is opened." There was no documentation that the laboratory director reviewed and approved the update prior to implementation. The "Laboratory Quality Assessment Review" completed 4/10/17 by the TC states in a notation at the bottom of the form "... talked with (the office manager) about getting IQCP review signed ...". On May 22, 2017, the "Laboratory Quality Assessment Review" noted "QC/Calibration Review: Lab director needs to sign QA annual review of IQCP for Affirm..."

**D5449**

CONTROL PROCEDURES  
CFR(s): 493.1256(d)(3)(ii)(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--

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and review of 2016 and 2017 quality control and patient test logs 2/2/17, the laboratory failed to perform and document quality control with each new Affirm VPIII kit as specified by their IQCP (Individualized Quality Control Plan) for the Affirm VPIII Microbial Identification Test. The laboratory's IQCP (effective 10/27/16) states "... Manufacturer's suggested External Quality Control frequency will continue and two levels of external controls - positive and negative for Gardnerella, Candida, and Trichomonas - will be performed with each new kit opened. All will be documented accordingly. Compliance will be monitored by the technical consultant. ... Patient test logs will also be reviewed monthly to assure correct interpretation of patient and quality control results. The TC will monitor for compliance. ..." An untitled 1-page document located in the notebook with the Affirm VPIII logs states "When doing AFFIRM testing make sure of the following items: ... 2. External QC is done each time a kit it opened and acceptable results achieved before patients can be reported out. ..." Review of 2016 and 2017 quality control and patient test logs revealed: 1. The laboratory tested positive and negative external controls for Affirm VPIII lot #6138725 on 11/3/16. Results of the positive control were recorded on the log as "neg" (negative), and results of the negative control were recorded as "pos" (positive) for Trichomonas, Gardnerella, and Candida. 14 patients were tested from 11/14/16 to 1/27/17. 2. The laboratory started using Affirm VPIII lot #7019600 for patient testing 4/28/17. There was no documentation that external positive and negative controls were tested until 6/24/17. 15 patients were tested from 4/28/17 to 6/23/17. 3. The laboratory started using Affirm VPIII lot #7018754 for patient testing 7/28/17. There was no documentation that external positive and negative controls were tested until 8/1/17. 3 patients were tested on 7/28/17.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of 2016 and 2017 quality control and patient test logs, and review of 2016 and 2017 quality assessment records, the laboratory failed to document corrective action for 32 patients tested 11/3/16 - 7/28/17 when quality control results were not acceptable or quality control testing was not performed as specified by the laboratory's IQCP (Individualized Quality Control Plan) for the Affirm VPIII Microbial Identification Test. The laboratory's IQCP (effective 10/27/16) states "... Manufacturer's suggested External Quality Control frequency will continue and two levels of external controls - positive

and negative for Gardnerella, Candida, and Trichomonas - will be performed with each new kit opened. All will be documented accordingly. Compliance will be monitored by the technical consultant. ... Patient test logs will also be reviewed monthly to assure correct interpretation of patient and quality control results. The TC will monitor for compliance. ..." An untitled 1-page document located in the notebook with the Affirm VPIII logs states "When doing AFFIRM testing make sure of the following items: ... 2. External QC is done each time a kit it opened and acceptable results achieved before patients can be reported out. ..." Review of 2016 and 2017 quality control and patient test logs and quality assessment records revealed: 1. The laboratory tested positive and negative external controls for Affirm VPIII lot #6138725 on 11/3/16. Results of the positive control were recorded on the log as "neg" (negative), and results of the negative control were recorded as "pos" (positive) for Trichomonas, Gardnerella, and Candida. 14 patients were tested from 11/14/16 to 1/27/17 with no corrective action noted. The log was reviewed by the TC (technical consultant) 11/18/16, 12/19/16, and 1/30/17. 2. The laboratory started using Affirm VPIII lot #7019600 for patient testing 4/28/17. There was no documentation that external positive and negative controls were tested until 6/24/17. 15 patients were tested from 4/28/17 to 6/23/17 with no corrective action noted. The log was reviewed by the TC 5/22/17 and 6/26/17. The "Laboratory Quality Assessment Review" completed 5/22/17 by the TC states "QC/Calibration Review: ... Affirm box currently in use - No QC has been done ...". The "Laboratory Quality Assessment Review" completed by the TC 6/26/16 states "QC/Calibration Review: QC on Affirm kit lot #7019600 still not done even after discussing this with (testing personnel) last visit. - did QC w/ two new girls - initial training. ..." 3. The laboratory started using Affirm VPIII lot #7018754 for patient testing 7/28/17. There was no documentation that external positive and negative controls were tested until 8/1/17. 3 patients were tested on 7/28/17 with no corrective action documented. The log was reviewed by the TC 7/31/17, 8/28/17, and 9/29/17. The "Laboratory Quality Assessment Review" completed 7/31/17 by the TC states "QC/Calibration Review: Talked to (testing personnel) about Affirms - doing QC and recording results. ... Reviewed Affirm - Box in fridge needs to be QC - (testing personnel) to do today - ..."

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on review of 5 random patient Affirm VP III test reports (#1, #2, #3, #4, #5), review of 2016 and 2017 quality assessment records, and interview with the office manager 2/2/18, 5 of 5 test reports did not include the reference range. Review of 5 random patient Affirm VPIII test reports revealed the Affirm VPIII test results were documented in the patients' electronic medical records, but the reference range (normal value) was not included for Candida, Gardnerella, or Trichomonas for 5 of 5 test reports reviewed. Review of 2016 and 2017 quality assessment records revealed the 5/22/17 "Laboratory Quality Assessment Review" noted "...Did chart audit from Nov 2016 to April 2017 several issues...". Documentation of a chart audit performed by the TC (technical consultant) was not dated, but it included 12 patients tested 11/28/16 - 4/28/17. A notation by the TC at the bottom of the page states "Talked w/ (the office manager) about getting reference ranges in. ..." During interview at

approximately 12:20 p.m., the office manager confirmed that the test reports did not include reference ranges.

**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 and procedures, review of 2016 and 2017 quality assessment records, review of 2016 and 2017 Affirm VPIII patient logs, and review of 5 random patient (#1, #2, #3, #4, #5) Affirm VPIII test reports 2/2/18, the laboratory failed to issue corrected reports when incorrect test results were identified for 2 of 5 patients (#1, #2). The laboratory's "CORRECTED REPORT POLICY" states "A. Corrected In-House Reports: If a mistake or error has been made, a corrected report must be generated and sent to appropriate individuals. A text comment must be added to the corrected report that states 'Corrected report, physician notified of result, and the date and time and your initials.' The physician or his nurse must be notified either in person or by phone. ..." Review of 2016 and 2017 quality assessment records revealed the 5/22/17 "Laboratory Quality Assessment Review" noted "... Did chart audit from Nov 2016 to April 2017 several issues...".

Documentation of a chart audit performed by the TC (technical consultant) was not dated, but it included 12 patients tested 11/28/16 - 4/28/17. Test records for patient #1 and patient #2 were included in the audit. "Results wrong" was noted beside the review for patient #1 and the review for patient #2. Review of 2016 and 2017 Affirm VPIII patient logs revealed patient #1 was tested 12/12/16 with a positive result for Trichomonas and negative results for Gardnerella and Candida. Review of patient #1's test report printed from the EMR (electronic medical records system) revealed a negative result for Trichomonas, a positive result for Gardnerella, and a negative result for Candida. There was no corrected report available in the EMR, and there was no documentation that the physician had been notified of the incorrect result. Review of 2016 and 2017 Affirm VPIII patient logs revealed patient #2 was tested 4/11/17 with a negative result for Trichomonas and positive results for Gardnerella and Candida. Review of patient #2's test report printed from the EMR also revealed a negative result for Trichomonas and positive results for Gardnerella and Candida. There was no documentation to indicate that the report was corrected after the chart audit identified the incorrect result(s).