

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2006397	<b>(X3) Date Survey Completed</b>  01/08/2018
<b>Name of Provider or Supplier</b>  Affiliated Pathologists	<b>Street Address, City, State</b>  20001 S Rancho Way, Rancho Dominguez, CA	
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>D5453</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g)</p> <p>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 test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Hologic Aptima manufacturer's instructions for HPV High Risk, HPV16 Genotype, 18/45 Genotype Assays, Bacterial Vaginosis, Trichomonas, Candida, and Chlamydia / Gonorrhea (Ct/Gc) assays, and patients test results; and interview with the testing person (Technical Supervisor), the laboratory failed to include two control materials in each batch of Extractions, of which one is capable of detecting errors in the extraction process. Findings include: a. Review of patients test reports revealed results were reported as "Negative" or "Positive". b. The manufacturer provided statements and instructions for quality controls as follows: 1) The Internal Control monitors the target capture, amplification, and detection steps only; and thus, does not monitor the process of Extracting nucleic acid from the organisms. 2) External quality control materials are not included in the test kit and should be tested in conformance with local, state, and/or federal regulations; and that laboratories must establish the criteria for acceptability of the external quality control samples. c. The Technical Supervisor affirmed (11/15/17) the aforementioned manufacturer's instructions, that the Internal QC doesn't detect errors in extraction, and the failure to include external QC material in the extraction process with each day's patients specimen to detect errors leading to false negative results. d. The reliability and quality of Negative results reported without an Extraction control could not be assured. Based on the stated estimated annual test volume, the laboratory</p>

reported results each month from 2016 to present, as follows: Monthly volume HPV 435 Bacterial vaginosis 1 Candia 1 Trichomonas 2 Chlamydia / Gonorrhea 36 e. A few examples of results reported as Negative are as follows: Date Accession # Test ----- 10/15/16 GY16-09469 HPV 11/23/16 P16-01224 " 12/23/16 P16-01328 " 11/22/17 P17-02890 " 11/22/17 P17-02895 HPV 10/06/16 P1600848 HPV, Ct/Gc 12/13/16 P16-01168 Ct/Gc 5/25/17 P17-00562 Bacterial vaginosis, Ct/Gc, Candida, Trichomonas 6/23/17 P17-00720 HPV, Ct/Gc, Trichomonas 6/30/17 P17-00764 Bacterial vaginosis, Candida, Trichomonas

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
 Based on survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring that the quality control program established for molecular based assays identify failures in nucleic acid extractions as they occur. See D5453.

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing 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 from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:  
 Based on the findings and deficiency cited, the Technical Supervisor is herein cited for deficient practice in establishing a quality control program appropriate for molecular based assays requiring nucleic acid extractions of the specimen. See D5453.