Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2006397	02/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Affiliated Pathologists	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on observation of the Hologic Panther molecular analyzer, review of laboratory policy, records, and patients test reports for the laboratory-developed tests titled, "Gyn Molecular Report: Vaginitis Panel"; the lack of laboratory records, and interview with Testing Person-7, it was determined that the laboratory failed to at least twice annually verify the accuracy of testing for Bacterial Vaginosis, Candida Vaginitis, Candida Species, Candia Glabrata, and Trichomonas Vaginalis. Findings included: a. The laboratory utilized the automated Hologic Panther analyzer to test for the following: Bacterial Vaginosis Candida Vaginitis Candida Species Candia Glabrata Trichomonas Vaginalis b. A laboratory policy stated that previously tested patients specimen would be blinded and re-tested to meet the requirement to verify accuracy of testing at least twice annually. c. Laboratory records documented such testing was performed as follows in 2019: Analyte Date ---------- Bacterial Vaginosis ..... 12/19/19 Candida ..... 11/15/19 Trichomonas ..... 4/12/19....11/07/19 d. The laboratory was unable to provide documents for a second testing in 2019 that verifed accuracy for Bacterial vaginosis and Candida for 12 out of 13 patients reports: Date Accession # ---------- 1/10/19 ....P19-00055 2/28/19 ....P19-01242 3/12/19 ....P19-01669 4/23/19 ....P19-03982 5/30/19 ....P19-06322 6/13/19 ....P19-07189 7/11/19 ....P19-08658 7/31/19 ....P19-09531 8/09/19 ....P19-10599 9/12/19 ....P19-12812 10/17/19.....P19-14867 11/19/19 ....P19-16970 e. Testing Person-7 affirmed (1/29/20 @ 12:30pm) the aforementioned lack of documents; and thus, the failure to at least twice annually verify the accuracy of testing. f. The reliability and quality of results reported in 2019 could not be assured when the laboratory failed to

	at least twice annually verify accuracy of testing. Based on laboratory information (1 /29/20), the laboratory reported 380 Bacterial vaginosis and 317 Candida results in 2019. .
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) 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. This STANDARD is not met as evidenced by: Based on observaton of the Hologic Panther analyzer, review of patients reports and laboratory documents for developing and validating molecular testing for bacterial vaginosis and candidiasis, the lack of laboratory documents, and interview with Testing Person-7, it was determined that the laboratory failed to validate the use of ThinPrep transport tubes. Findings included: a. Patients reports recorded Specimen Type as "Liquid based PAP". b. Validation reports stated the use of Aptima transport tubes and ThinPrep transport tubes for specimen collection The Aptima transport medium was FDA-approved for use in HPV tests. The ThinPrep transport medium was FDA-approved for HPV, Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas. c. The laboratory obtained organisms (Gardnerella vaginalis, Lactobacillus crispatus, Candida albicans, Candida glabrata) from Hologic which were then serially diluted and spiked into Aptima transport media to establish test performance characteristics. d. The laboratory was unable to provide records of spiking ThinPrep transport media with the known organisms to establish test performance characteristics. e. Testing Person-7 affirmed (1/29/20 @ 2pm) the aforementioned findings; and thus, the laboratory failed to validate the use of ThinPrep transport tubes for bacterial vaginosis and candidiasis assays. f. The reliabililty and quality of results reported for bacterial vaginosis and candidiasis could not be assured when the laboratory failed to establish test performance characteristics of the ThinPrep transport medium in these laboratory-developed, non-FDA approved tests. Based on laboratory information (1/29/20), 380 bacterial vaginosis and 317 candidiasis results were reported annually.