Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2073229	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Contra Costa Pathology Associates	399 Taylor Blvd Ste 200, Pleasant Hill, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2019 - 2021 laboratory proficiency testing records, the lack of signed Attestation Statement documents, and interview with laboratory personnel, it was determined that the Laboratory Director and testing persons failed to attest to including proficiency testing samples in routine workloads with patients specimen. Findings included: 1. The laboratory chose to participate in the College of American Pathologists proficiency testing programs for Human Papilloma Virus, Chlamydia and Gonnorhoea, Mycoplasma genitalium, Herpes Simplex Virus 1/2, the Molecular Vaginal Panel (for Bacterial Vaginosis, Candida, and Trichomonas), and IHC Estrogen Receptor, Progesterone Receptor, and HER2 for a total of 41 testing events from 2019 - 2021. 2. The laboratory failed to provide for review 41 out of 41 documents of signed Attestation Statements for all events in 2019 - 2021. 3. The Laboratory Director and Technical Supervisor (Testing Person) affirmed (9/21/21 at 2pm) the failure to retain the Attestation Statement documents with the laboratory proficiency testing records. 4. Without the documents, the reliability and quality of proficiency testing results and scores could not be assured for 41 out of 41 aforementioned events in 2019 - 2021. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the Hologic Panther test system (serial number 01113), review of laboratory documents verifying test performance characteristics when testing Female Urine, Throat swabs, and Rectal swabs for Chlamydia trachomatis and Neisseria gonnorhoea, the lack of laboratory documents, and interview with the Technical Supervisor (Testing Person), it was determined that the laboratory failed to demonstrate and verify the reproducibility (precision) of test results for these types of specimen. Findings included: 1. The laboratory document titled "Contra Costa Pathology Associates; Aptima Combo 2: Verification of Female Urine Samples" (10/05/18) failed to include re-testing within an assay and on different dates to determine the reproducibility of results when testing female urines. 2. Clinical specimen representing Throat swabs and Rectal swabs were provided to the laboratory by Hologic in October 2019. There was no re-testing of these specimen to determine the reproducibility of results inter-assay and intra-assay. 3. The Technical Supervisor affirmed (9/21/21 at 4pm) the aforementioned failure to verify the reproducibility of results when testing these types of specimen. 4. The ability of the laboratory to provide reliably reproducible results when testing Female Urine, Throat swabs, and Rectal swabs for Chlamydia and Gonnorheoa could not be assured since 2018 and 2019, respectively. The laboratory affirmed (10/19/21 at 11:25AM) annual test volumes through September 2021, as follows: Female Throat Rectal Urine swabs swabs ---------- 2018 0 NA NA 2019 26 0 0 2020 7 1 0 2021 25 3 3 .
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the deficiency cited (D2009), it was determined the Laboratory Director failed to ensure proficiency testing was performed as required. Findings included: 1. The laboratory failed to provide for review Attestation Statements, documents of signed statements from the Laboratory Director and Testing Persons, attesting to testing proficiency testing samples in the same manner as patients specimen. .
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 review of laboratory testing records and personnel training records, the lack of laboratory documents, and interview with the Laboratory Director and Technical Supervisor, it was determined that the Laboratory Director was deficient in the practice of providing overall administration to ensure that upon completion of training and prior to testing patients' specimen, all personnel demonstrated their ability to assist in testing to obtain reliable and accurate results. Findings included: 1. The laboratory provided training records for personnel assisting with the Hologic Panther test system for HPV, Chlamydia/Gonnorhoeae, and Trichomonas, but failed to provide records of each person actually demonstrating what they learned. a. Laboratory test records (assay worksheets) documented four persons assisted with the Chlamydia/Gonnorhoeae assays but only two of the four had records of performing hands-on demonstrations prior to testing patients specimen. 2. Assay worksheets documented one person in particular (assistant 3) assisted with six assays, but failed to first demonstrate their abilities with HPV Genotyping, HSV, BV, and CV-TV. 3. The Laboratory Director and Technical Supervisor affirmed (9/21/21 at 5pm) that there was no policy or practice of requiring trainees to perform hands-on demonstrations of each assay at the conclusion of their training to provide the basis for their initial test performance evaluation for competency. 4. And thus the reliability, accuracy, and quality of results reported from the Hologic Panther test system could not be assured when assistance was provided by personnel who didn't first provide hands-on demonstrations of acceptable work for each assay.