Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0660522	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Corpus Christi Nueces County Public Health Lab	Street Address, City, State 1702 Horne Road, Corpus Christi, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on laboratory policy and confirmed in interview of facility personnel, the laboratory failed to provide its clients written instructions to include policies and procedures that addressed specimen labeling, specimen storage and preservation, conditions for transportation, and specimen acceptability and rejection. The findings were: 1. Review of laboratory policy revealed no documentation outlining procedures for: a) Patient preparation. b) Specimen collection. c) Specimen labeling (name or unique patient identifier) and when appropriate specimen source. d) Specimen storage and preservation. e) Condition for specimen transport. f) Specimen processing. g) Specimen acceptability and rejection 2. The findings were confirmed during an

	interview with the General Supervisor on November 14, 2019 at 11:00 hours in the break room. When asked if the laboratory provides a copy of the policy to its outside clients, she stated, "No."
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on surveyor observations, review of manufacturer's instructions, laboratory policy, patient records and confirmed in interview of facility personnel, it was revealed the laboratory failed to follow manufacturer instructions for using a tube rocker when mixing reagents in preparation for patient testing using Aptima Combo 2 Assay on the Panther. The findings were: 1. Surveyor observation made in the Reagent Preparation Room on November 14, 2019 at 09:15 hours found Testing Personnel #3 (as listed on Form CMS-209) preparing reagents for a patient run on the Panther. She loaded Aptima Combo 2 amplification, enzyme, and probe reagents onto a laboratory developed Styrofoam tube holder. During the mixing process, she had to periodically place her hands-on top of the reagent vials to keep them steady. Amplification Reagent Lot 259118 exp. 2021-01-15 Amplification Reconstitution Solution Lot 252416 exp. 2020-11-15 Enzyme Reagent Lot 259129 exp. 2021-01-15 Enzyme Reconstitution Solution Lot 253413 exp. 2021-01-15 Probe Reagent Lot 258256 exp. 2021-01-15 Probe Reconstitution Solution Lot 259182 exp. 2021-01-15 2. A review of manufacturer instructions for the Aptima Combo 2 analyzer (Panther system) under "Panther System Test Procedures" it stated, "Option: additional mixing of the Amplification, Enzyme, and Probe Reagents using a tube rocker is allowed..." 3. A review of laboratory policy (Document # SER-SOP- 13-015, Revision 05/2019 #3) approved by the laboratory director 05/2019, stated "The reagents may be mixed by placing the recapped plastic bottle on a tube rocker set at 20 rpm (or equivalent) for a minimum of 5 minutes." 4. A review of patient records resulted on November 14, 2019 13:23 hours, revealed the following 21 patients were tested when the laboratory failed to follow the manufacturer's instructions when using a tube rocker. Sample ID CT result GC result C19004854-01-001 CT neg GC neg C19004856-01-001 CT neg GC neg C19004858-01-001 CT neg GC neg C19004860-01-001 CT neg GC neg C19004862-01-001 CT neg GC neg C19004865-01-001 CT neg GC neg C19004868-01-001 CT neg GC neg C19004870-01-001 CT neg GC neg C19004872-01-001 CT neg GC neg C19004874-01-001 CT neg GC neg C19004876-01-001 CT neg GC neg C19004881-01-001 CT neg GC neg C19004883-01-001 CT neg GC neg C19004884-01-001 CT pos GC pos C19004886-01-001 CT neg GC neg C19004888-01-001 CT pos GC neg C19004889-01-001 CT neg GC neg C19004864-01-001 CT neg GC neg C19004866-01-001 CT neg GC neg C19004877-01-001 CT neg GC neg C19004878-01-001 CT neg GC neg C19004879-01-001 CT neg GC neg C19004880-01-001 CT neg GC neg 5. Review of the submitted Form CMS-116, the laboratory documented a microbiology annual test volume of 6,701. 6. Interview with testing person #3 (as listed on Form CMS-209) on November 15, 2019 at 09:15 hours in the laboratory confirmed the findings. B. Based on surveyor observations, review of manufacturer's instructions, laboratory policy, patient records and confirmed in interview of facility personnel, it was revealed the laboratory failed to follow manufacturer instructions for

	mixing time and speed when preparing Aptima Combo 2 Assay reagents for use on the Panther. 1. Surveyor observation made in the Reagent Preparation Room on November 14, 2019 at 09:15 hours found Testing Personnel #3 (as listed on Form CMS-209) preparing reagents for a patient run on the Panther. After loading the reagents on the mixer, she set the time and speed for 1 minute at 4 rpm (revolutions per minute). 2. A review of laboratory policy (Document # SER-SOP- 13-015, Revision 05/2019 #3) approved by the laboratory director 05/2019, stated " 3. Review of manufacturer instructions for the Aptima Combo 2 analyzer (Panther system) under "Panther System Test Procedures" it stated, " Option: additional mixing of the Amplification, Enzyme, and Probe Reagents using a tube rocker is allowed. The reagents may be mixed by replacing the recapped plastic bottle on a tube rocker set 20 RPM (or equivalent) for a minimum of 5 minutes. Warning: Avoid creating foam when reconstituting reagents. Foam compromises the level sensing in the Panther System. Adequate mixing of the reagent is necessary to achieve expected assay results." 4. The laboratory failed to follow the manufacturer's instructions for mixing time and speed when preparing Aptima Combo 2 Assay reagents. 5. A review of patient records resulted on November 14, 2019 13:23 hours, revealed the following 21 patients were tested when the laboratory failed to follow the manufacturer's instructions for mixing time and speed when mixing reagents on a tube rocker. Sample ID CT result GC result C19004854-01-001 CT neg GC neg C19004856-01-001 CT neg GC neg C19004858-01-001 CT neg GC neg C19004860-01-001 CT neg GC neg C19004862-01-001 CT neg GC neg C19004865-01-001 CT neg GC neg C19004868-01-001 CT neg GC neg C19004870-01-001 CT neg GC neg C19004872-01-001 CT neg GC neg C19004874-01-001 CT neg GC neg C19004876-01-001 CT neg GC neg C19004881-01-001 CT neg GC neg C19004883-01-001 CT neg GC neg C19004884-01-001 CT pos GC pos C19004886-01-001 CT neg GC neg C19004888-01-001 CT pos GC neg C19004889-01-001 CT neg GC neg C19004864-01-001 CT neg GC neg C19004866-01-001 CT neg GC neg C19004877-01-001 CT neg GC neg C19004878-01-001 CT neg GC neg C19004879-01-001 CT neg GC neg C19004880-01-001 CT neg GC neg 6. Review of the submitted Form CMS-116, the laboratory documented a microbiology annual test volume of 6,701. 7. Interview with testing person #3 (as listed on Form CMS-209) on November 15, 2019 at 09:15 hours in the laboratory confirmed the findings. Key: exp. - expiration CT - Chlamydia trachomatis neg - Negative GC - Neisseria gonnorhoeae pos - Positive
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, manufacturer instructions, environmental records, and confirmed in interview, the laboratory failed to define an acceptable room temperature for storage of CO_2 gas generating sachets The findings were: 1. Surveyor observation on November 14, 2019 at 09:20 hours during tour of facility, revealed BD GasPak EZ Gas Generating Container System sachets in the laboratory at room temperature

	located in an overhead cabinet. 2. Review of manufacturer's instructions for the BD GasPak EZ Gas Generating Container Systems (8010412 (04) 2018-08) under "Storage Instructions" it stated " On receipt, store sachets at 2-25 Celsius in a dry environment." 3. Review of environmental records from January 2018 to September 2019 revealed the laboratory had established its acceptable room temperature range as 20-30 Celsius. 4. An interview with the general supervisor on November 14, 2019 at 14:58 hours in her office, confirmed the findings. Key: CO2 - Carbon dioxide BD - Becton Dickinson
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions for the ASI RPR Card Test for Syphilis, laboratory policy and staff interview, it was revealed the laboratory failed to failed to perform needle drop function checks as defined by the manufacturer. The findings were: 1. Surveyor observation on November 14, 2019 at 13:10 hours in the laboratory revealed testing personnel #2 (as listed on Form CMS-209) performing a needle drop function check for a patient test run of RPRs. To perform the needle drop function check, the testing person delivered 2 drops of antigen suspension to the test card. 2. A review of the manufacturer's instructions for the ASI RPR Card Test for Syphilis (6004-900, 11/16) under the section titled "Handling and Procedural Notes" it stated "The needle should deliver 60 +/- 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." The laboratory failed to perform the needle drop function check as required by the manufacturer. 3. A review of the laboratory policy RPR Test Card SOP (document # SER-SOP-13-017) and (signed by the Laboratory Director October 04, 2017) under "Handling and Procedural Notes" stated "The needle should deliver 60+/- drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." 5. Review of laboratory's submitted CMS form-116 for revealed an annual test the volume of 1,936 for syphilis tests. 6. Review of final patient results for the patient test run on November 14, 2019 revealed the following: Specimen # Result 4869 NR 4871 R 4873 NR 4875 NR 4882 R 4885 NR 4887 R 7. An interview with testing personnel number 2 (as listed on Form CMS 209) on November 14, 2019 at 1305 hours in the laboratory. After performance of the needle drop function check she revealed that she was nervous and meant to count to 60. Key: RPR - Rapid Plasma Reagin ASI - Arlington Scientific, Inc. CMS - Centers for Medicare and Medicaid Services NR - Non-reactive R - Reactive ml - milliliter