Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0659062	11/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Department Of Health	630 Hart Lane, Nashville, TN	

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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on surveyor record review of Manufacturer Package Insert /Standard Operating Procedure (SOP) and interview with General Supervisor, the laboratory failed to have a supplement that lists specific laboratory testing requirements not included in the manufacturer package insert. . The findings include: 1. The review of the SOP for Virology, Influenza A/B (ABI 7500) and Immunoserology, Aptima Combo 2 Assay for Chlamydia trachomatis and Neisseria gonorrhoeae (Panther System) found the laboratory was using the manufacturer package insert as their SOP. The manufacturer package insert is used by all laboratories who purchase the test kit. 2. The laboratory failed to have a supplement for the Tennessee Department of Health, Division of Laboratory Services (TDH) listing specific procedures or requirements for testing personnel to perform not included in manufacturer package insert. 3. The Aptima Comb 2 Assay states on page 16 that " Each laboratory should implement appropriate control procedures to satisfy the requirements of CLIA regulations". 4. The laboratory made a change to the specimen collection device in June 20, 2019, that was documented in the laboratory test submission manual. 5. The laboratory Influenza A /B Typing Kit, PI provides guidance for laboratories to refer specimens to CDC. 6. Interview with the General Supervisor on 11/7/2019 in the Virology and Immunoserology section at 3:00 PM confirmed the laboratory did not have a TDH supplement.
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 procedure manual, laboratory test records and interview with laboratory staff, the procedure manual for the Enterics section of the laboratory was not current for procedures performed in the Enterics section. Findings: 1. Review of the Campylobacter I.D. procedure in the Enterics SOP manual revealed the following: a. The Enterics SOP manual contained a title page which included a SOP under tab 8 for Campylobacter I.D. b. The Campylobacter I.D. procedure under tab 8 included a procedure for multiplex TaqMan PCR assay to differentiate between Campylobacter jejuni and Campylobacter coli. The procedure was not noted as discontinued for patient testing. c. Review of patient test records for 2019 revealed the laboratory identified Campylobacter by MALDI-TOF and biochemical reactions, but no records of multiplex TaqMan PCR assay were found. d. During interview the morning of November 7, 2019, Technical Supervisor 1 (TS #1) and Technical Supervisor 2 (TS #2) stated the laboratory discontinued performing the multiplex TaqMan PCR assay to differentiate Campylobacter species in 2017. When asked the specific date the PCR was discontinued, neither Technical Supervisor could provide a date. TS #1 stated the laboratory continued to perform quality control testing for the multiplex TaqMan PCR assay. The Laboratory Test and Equipment List form provided to the survey team indicated an annual test volume of 4 for the multiplex TaqMan PCR assay. e. The Enterics SOP manual was reviewed and signed by TS #1 on June 27, 2019 and by TS #2 on June 24, 2019. The Laboratory Director approved the Enterics SOP by signature on August 7, 2019. 2. Review of the Bioplex for Salmonella procedure in the Enterics SOP manual revealed the following: a. The Enterics SOP manual contained a title page which included a SOP under tab 15 for Bioplex for Salmonella. b. The Bioplex for Salmonella procedure was not noted as discontinued for patient testing. c. The Laboratory Test and Equipment List form provided to the survey team indicated for Salmonella serotyping testing "As of 8/1/2019, using Bionumeric exclusively". d. During interview the morning of November 7, 2019, TS #1 stated Salmonella serotyping is currently performed by MALDI-TOF and the Bioplex assay is no longer in use. e. The Enterics SOP manual was reviewed and signed by TS #1 on June 27, 2019 and by TS #2 on June 24, 2019. The Laboratory Director approved the Enterics SOP by signature on August 7, 2019.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with general supervisor, the laboratory failed to perform comparison studies for the same instrument in 2018 and once in 2019. The findings include: 1. The laboratory survey revealed the laboratory failed to

	perform comparison studies for Hologic Panther (Immunoserology) and ABI 7500 (Virology) twice in 2018 and once in 2019. 2. The laboratory provided a copy of comparison testing completed September 9, 2019 for ABI 7500 and October 2, 2019 for Panther system. 3. The laboratory worksheet for "Instrument Comparison Studies" states "comparison studies must be performed twice per year". 4. The laboratory failed to include the comparison studies worksheet in the laboratory SOP or the Quality Assessment manual. 5. Interview with the general supervisor on 11/7/2019 in the Virology and Immunoserology section at 3:00 PM confirmed the comparison studies were not performed twice per year in 2018 and once in 2019.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Manual, review of proficiency testing records and interview with laboratory staff, the laboratory failed to follow their Quality Assurance policy for external assessments. Findings: 1. Routine Testing Methods a. Review of the laboratory's quality assurance manual, TDH Division of Laboratory Services Quality Assurance Manual, revealed a policy for performing External Quality Assessments/Proficiency Testing on page 27 under "8.3 Quality Assessments". Under "1. Processing the Specimens" (c), the policy states "Use your laboratory's routine testing methods." The TDH Division of Laboratory Services The Quality Assurance Manual was reviewed and signed by the laboratory director on June 21, 2019. b. Review of the Enterics SOP for Campylobacter Identification and Workup states stool cultures, positive EIA broths, and isolates are cultured for isolation and purity. Suspicious colonies have an oxidase test performed and oxidase positive organisms are identified by MALDI-TOF assay. If MALDI-TOF assay does not provide an acceptable identification, the procedure indicates additional biochemical workup of the isolate. c. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records for Campylobacter Survey (CAMP) for 2018 and 2019 indicate the laboratory performed identification of Campylobacter by Biofire assay in addition to MALDI-TOF assay. d. During interview on the afternoon of November 7, 2019, the surveyor asked TS #1 if the laboratory performed Biofire assay on patient samples ordered for isolation/identification of Campylobacter. TS #1 stated the laboratory performs the Biofire assay on proficiency testing samples but not on patient samples unless the patient order is for an enteric pathogens screen. 2. Proficiency Testing Records a. Review of the laboratory's quality assurance manual, TDH Division of Laboratory Services Quality Assurance Manual, revealed a policy for performing External Quality Assessments/Proficiency Testing on page 27 under "8.3 Quality Assessments". On page 28 under "2. Reporting the Test Results" (b), the policy states "File a copy of this report and all records used in performing PT tests in your section." b. On November 6, 2019, the surveyor requested TS #1 to provide records needed for review to include all proficiency testing records for 2018 and 2019. c. Review of proficiency testing records on the morning of November 7, 2019, revealed the proficiency testing files did not include documentation of biochemical workup and all molecular analysis performed by the laboratory to support the results sent to the proficiency testing organizations. For example, CAP

	Campylobacter Survey PT files included records of Biofire analysis but no records of performance of oxidase or MALDI-TOF and Wisconsin State Laboratory of Hygiene proficiency testing records for Shiga Toxin included Biofire assay printouts which identify Shiga Toxin 1/2, but no records of the laboratory testing used to differentiate Shiga Toxin 1 from Shiga Toxin 2. d. TS #1 attempted to print out the needed PT testing records on the afternoon of November 7, 2019, however the surveyor did not have sufficient time to review. As a result, the surveyor was unable to determine if the Enterics section of the laboratory was in compliance with proficiency testing requirements.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance manual, TDH Division of Laboratory Services Quality Assurance Manual, and interview with Information Technology (IT) personnel the laboratory failed to establish a written policy and procedure to monitor and evaluate the accuracy of the laboratory's test reports supplied to clients. The findings include: 1. The laboratory's quality assurance manual did not include a procedure to verify that test reports received by the client are transmitted with accurate information. 2. On 11/6/19 at 2PM, the IT personnel stated the laboratory had not performed any evaluations of test reports after being sent to clients.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on review of validation records, laboratory records and interview with laboratory staff, the laboratory director failed to review and approve test performance specifications for a laboratory developed test prior to patient testing. Findings: 1. Review of the Enteric Laboratory Validation records for Validation for the Detection of the Stx2f Variant by PCR revealed the performance specifications study was reviewed and signed by TS #1 and TS #2 on August 20, 2018. 2. Review of the Laboratory Test and Equipment List form provided to the survey team revealed the annual test volume for Detection of the Stx2f Variant by PCR testing was 300. 3. During interview on the afternoon of November 7, 2019, TS #2 acknowledged the laboratory director failed to review and approve the validation study for the Detection of the Stx2f Variant by PCR prior to patient testing. 4. Review of the Enteric Laboratory Validation records for Validation for the Detection of the Stx2f Variant by PCR revealed the performance specifications study was reviewed and signed by Laboratory Director on November 7, 2019, during the onsite recertification survey.