Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1011121	12/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Public Health Laboratory Of East Texas	11949 Us Highway 271 N, Tyler, 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	An onsite survey conducted 12/05/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, client services manual, patient test reports, and confirmed in interview, the laboratory failed to ensure temperature of specimens were within manufacturer's requirements for 10 of 10 influenza patients in May 2022. Findings included: 1. During a tour of the facility the surveyor observed 2 Applied Biosystems 7500 Fast Dx Real-Time PCR (Polymerase Chain Reaction) Instruments (Serial Numbers: Right:275010713; Left: 275030105) currently in use performing influenza and COVID testing. 2. Review of manufacturer's instructions for use, "CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay" (Effective Date: 08/05/2021), revealed the following: "Specimen Collection, Handling, and Stability Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended due to the importance of specimen quality. ..Respiratory specimens should be collected and placed into appropriate transport media, such as VTM (viral transport media). Transporting specimens: Store specimens at 2-8 C and ship overnight on ice pack. If a specimen in frozen at less than or equal to -70 C, ship overnight on dry ice." 3. Review of manufacturer's instructions

for the VTM, used to transport patient COVID specimens, "MicroTest M4RT Multi-Microbe Media" (Lot Number: 474777; Expiration: 04/04/2024) revealed the following: "Specimen collection, storage and transport Specimens should be collected and handled following recommended guidelines. To maintain optimum vitality, transport specimens to laboratory as soon as possible. Although M4RT can maintain even fragile organisms for relatively long periods of time at room temperature, specimens should be refrigerated at 2-8 C or kept on wet ice (or equivalent) following collection and while in transit." 4. Review of laboratory client services manual, "Submission Information and Instructions 2018/2019 updates" (Reviewed by Laboratory Director on 08/01/2022) revealed the following: "Seasonal Influenza typing, Real Time PCR (RT) Collect samples in transport media and refrigerate immediately. Transport to lab within 72 hours of collection on cold packs or freeze at -70 C and ship on dry ice." 5. Review of patient test reports revealed the following 10 of 10 randomly reviewed patients reported in May 2022 in which the laboratory did not document specimen temperature upon arrival: a. Specimen Identification (ID): 22PH-143M0022; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 b. ID: 22PH-143M0023; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 c. ID: 22PH-143M0024; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/18/22 d. ID: 22PH-143M0025; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 e. ID: 22PH-143M0026; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 f. ID: 22PH-143M0027; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 g. ID: 22PH-143M0028; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 h. ID: 22PH-143M0029; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 i. ID: 22PH-143M0030; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 j. ID: 22PH-143M0031; Test Ordered: Influenza A by RT-PCR, Influenza B by RT-PCR Collected: 05/19/22 The laboratory failed to ensure temperature of specimens were within manufacturer's requirements for 10 of 10 influenza patients in May 2022. 6. During an interview on 12/05/2022 at 04:15 p.m. in the facility conference room, the laboratory manager confirmed the above findings. II. Based on direct observation, review of manufacturer's instructions, client services manual, patient test reports, and confirmed in interview, the laboratory failed to ensure temperature of specimens were within manufacturer's requirements for 10 of 10 COVID patients in May 2022. Findings included: 1. During a tour of the facility the surveyor observed 2 Applied Biosystems 7500 Fast Dx Real-Time PCR (Polymerase Chain Reaction) Instruments (Serial Numbers: Right:275010713; Left:275030105) currently in use performing influenza and COVID testing. 2. Review of manufacturer's instructions for use, "CDC SARS CoV2 (COVD-19) Real Time PCR" (Effective Date: 07/21/2021), revealed the following: "Specimen Collection, Handling, and Stability Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended due to the importance of specimen quality. ..Respiratory specimens should be collected and placed into appropriate transport media, such as VTM (viral transport media). Transporting specimens: Store specimens at 2-8 C and ship overnight on ice pack. If a specimen in frozen at less than or equal to -70 C, ship overnight on dry ice." 3. Review of manufacturer's instructions for the VTM, used to transport patient influenza specimens, "MicroTest M4RT Multi-Microbe Media" (Lot Number: 474777; Expiration: 04/04/2024) revealed the following: "Specimen collection, storage and transport Specimens should be collected and handled following recommended guidelines. To maintain optimum vitality, transport specimens to laboratory as soon as possible. Although M4RT can maintain even fragile organisms for relatively long

	periods of time at room temperature, specimens should be refrigerated at 2-8 C or kept on wet ice (or equivalent) following collection and while in transit." 4. Review of laboratory client services manual, "Submission Information and Instructions 2018 /2019 updates" (Reviewed by Laboratory Director on 08/01/2022) revealed the laboratory did not provide transport conditions of COVID specimens to offsite collection facilities using VTM. 5. Review of patient test reports revealed the following 10 of 10 randomly reviewed patients reported in May 2022 in which the laboratory did not document specimen temperature upon arrival: a. Specimen Identification (ID): 22PH-143M0022; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 b. ID: 22PH-143M0023; Test Ordered: Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 c. ID: 22PH-143M0024; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/18/22 d. ID: 22PH-143M0025; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 e. ID: 22PH-143M0026; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 f. ID: 22PH-143M0027; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 g. ID: 22PH-143M0028; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 h. ID: 22PH-143M0029; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 i. ID: 22PH-143M0030; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 j. ID: 22PH-143M0031; Test Ordered: SARS CoV2 (COVD-19) by RT-PCR Collected: 05/19/22 The laboratory failed to ensure temperature of specimens were within manufacturer's requirements for 10 of 10 patients in May 2022. 6. During an interview on 12/05/2022 at 04:15 p.m. in the facility conference room, the laboratory manager confirmed the above findings.
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 observation, review of laboratory documents, review of the CMS form 116, and confirmed in an interview, the laboratory failed to have a system in place for the twice-annual comparison of test results for two of two ABI 7500 PCR instruments used for testing in 2021. The findings include: 1. In a tour of the laboratory on 12/5/2022 at 10:05 hours, the surveyor noted two ABI 7500 PCR instruments with the identifiers 275030105 and 275010713 used for testing. 2. Review of the laboratory test list included the following 19 PCR tests performed on both ABI 7500 PCR instruments: Flu A/B Screen Flu A subtype Flu B Genotype Flu H5 Flu H7 FluSC2 (ABC) InBios SARS-2 CDC SARS-2 nCoV B. anthracis Brucella Burkholderia Coxiella F. tularensis Non-Variola Orthopox Rickettsia Trioplex VZV Y. pestis 3. Surveyor queried the technical supervisor (TS) 2, on 12/5/2022 at 14:30 in the conference room, for the laboratory policy and supporting documentation for the twice-annual test comparison in 2021 between the two ABI 7500 PCR Instruments and none was provided. 4. In an interview on 12/5/2022 at 14:45 hours, in the conference room, TS2 confirmed that the laboratory did not have a system in place for the twice-annual test comparison for the two ABI 7500 PCR instruments in use.