Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2100272	07/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Surepoint Emergency Center Arlington	4747 Little Road, Arlington, 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 entrance conference was held with laboratory representatives. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 07/22/2022, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1421 Testing Personnel (moderate complexity) An exit conference was held with laboratory representatives. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. The process for submitting the corrections was explained. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) testing records, laboratory's CMS (Centers for Medicare & Medicaid Services) 209 form, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing

	in the laboratory for 1 of 1 events in 2020 (Event 3), 3 of 3 events in 2021 (Event 1, 2, 3), and 2 of 2 events in 2022 (Event 1, 2). Findings included: 1. Review of the laboratory's proficiency testing policy revealed: "POLICY ... Proficiency testing samples must be tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory using routine methods of the laboratory (the individual performing testing on the samples must attest to this policy by signing the Attestation Statement accompanying each testing event)." 2. Review of the API testing records revealed the laboratory participated in the following events: 2020: Chemistry; Event 3 Hematology; Event 3 2021: Chemistry; Event 1, 2, 3 Hematology; Event 1, 2, 3 Microbiology; Event 3 2022: Chemistry; Event 1, 2 Hematology; Event 1 Microbiology; Event 1, 2 Further review of the PT records revealed Testing Persons 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 13 and 14 participated in the above PT events. 3. Review of the laboratory's CMS 209 form revealed 14 Testing Persons (TP) were listed as performing moderate complexity testing (chemistry, hematology, and microbiology). Testing Person-6 (TP-6) Hire date: 08/04/2020 TP-6 participated in testing patient specimens and did NOT participate in any of the above listed PT events for 2020, 2021 and 2022. 4. During an interview on 07/22/2022 at 11: 45 am, the Technical Consultant confirmed the above findings. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and confirmed in interview, the laboratory failed to retain records of the raw data used to implement the laboratory's Individualized Quality Control Plan (IQCP) for the Cardiac Panel on the Quidel Triage analyzer. The findings include: 1. Review of the laboratory's records revealed no documentation of the raw data used to support reduction in QC frequency to every 30 days for the Cardiac Panel on the Quidel Triage analyzer. 2. During an interview of 07/22/2022 at 3:35 p.m, the Technical Consultant confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's Individualized

	Quality Control Plan (IQCP), quality control (QC) records, patient test records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the GI Panel v2.1 pouch on the Biofire Filmarray microbiology analyzer. The findings include: 1. Review of the Biofire Filmarray's GI Panel instructions for use revealed, "QUALITY CONTROL ... External Controls External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Cary Blair can be used as an external negative control. Previously characterized positive stool samples or negative samples spiked with well characterized organisms can be used as external positive controls. Commercial external control materials may be available from other manufacturers; these should be used in accordance with the manufacturers' instructions and appropriate accrediting organization requirements, as applicable." 2. Review of the laboratory's Biofire Filmarray IQCP revealed: "CAUTION: No patient samples may be tested if External QC is unacceptable. All unacceptable External QC results must be resolved, and any corrective actions must be documented prior to patient testing ... A. External QC Frequency The external controls should be run: with every new kit lot opened, with every new shipment of test kits, when training new personnel on test kit use, at least every 30 days." 3. Further review of the IQCP revealed the laboratory only tested quality control material for a period of 28 consecutive days from September 19, 2021 to October 17, 2021. Quality control had not been tested each day for 30 consecutive days to support the laboratory's reduction in frequency as stated in their IQCP. 4. Review of QC records from November 2021 through June 2022 revealed the laboratory performed quality control on the following dates on the Biofire Filmarray microbiology analyzer for the GI panel v2.1 pouch: Level 1 and Level 2 QC were performed on 11/18/2021, 12/18/2021, 01/17/2022, 02 /16/2022, 03/18/2022, 04/17/2022, 05/17/2022, 06/16/2022, and 06/29/2022 5. Review of patient test records revealed the laboratory failed to perform QC every day of patient testing. Refer to D5449. 6. During an interview of 07/22/2022 at 3:35 p.m., the Technical Consultant confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the GI Panel v2.1 pouch on the Biofire Filmarray microbiology analyzer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policy, quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for the GI panel v2.1 pouch on the Biofire Filmarray microbiology analyzer for 1 of 1 days in 2022 (01/2022 through 06/2022). The findings include: 1. Review of the Biofire Filmarray's GI Panel instructions for use revealed, "QUALITY CONTROL ... External Controls External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Cary Blair can be used as an external negative control. Previously characterized positive stool samples or negative samples spiked with well

	characterized organisms can be used as external positive controls. Commercial external control materials may be available from other manufacturers; these should be used in accordance with the manufacturers' instructions and appropriate accrediting organization requirements, as applicable." 2. Review of the laboratory's policy titled "Laboratory Procedure Biofire Filmarray 2.0 Gastrointestinal Panel" revealed the laboratory developed an IQCP. Review of the IQCP revealed: "CAUTION: No patient samples may be tested if External QC is unacceptable. All unacceptable External QC results must be resolved, and any corrective actions must be documented prior to patient testing ... A. External QC Frequency The external controls should be run: with every new kit lot opened, with every new shipment of test kits, when training new personnel on test kit use, at least every 30 days." Further review of the IQCP revealed the laboratory failed to support its reduction in frequency to every 30 days for the respiratory panel on the Biofire Filmarray microbiology analyzer. Refer to D5445. 3. Review of QC and patient test records from January 2022 through June 2022 revealed the laboratory failed to document negative and positive controls each day of patient testing on the following day: 05/16/2022; Patient ID: 1051622660 QC was last performed on 04/17/2022 4. During an interview of 07/22/2022 at 3:35 p.m., the Technical Consultant confirmed the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties 6 of 14 Testing Persons (TP-9, TP-10, TP-11, TP-12, TP-13, TP-14) performing moderate complexity testing. Findings included: 1. Review of the CMS 209 form listed TP-9, TP-10, TP-11, TP-12, TP-13, TP-14 as testing persons performing moderate complexity procedures in the specialties of: hematology, chemistry, and microbiology. The laboratory director did NOT specify, in writing, which procedures TP-9, TP-10, TP-11, TP-12, TP-13, TP-14 were authorized to perform. 2. During the exit interview on 07/22/2022 at 3:35 pm, the Technical Consultant confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS (Center for Medicare & Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Consultant failed to evaluate and document performance for 1 of 14 Testing Persons (TP-11) responsible for moderate complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the laboratory's policy titled "COMPETENCY AND SKILLS CHECKS FOR TECHNICAL PERSONNEL" revealed: "POLICY... COMPETENCY AND SKILLS CHECKS ... 2. PROCEDURE ... d. The Technical Consultant will document competency of Testing Personnel on the Skills Competency Forms, noting the skill level of the employee and the verification methods used." 2. Review of the submitted CMS 209 form revealed Testing Person-11 (TP-11) was listed to perform moderate complexity testing. 3. Review of personnel records from 2022 revealed the following: TP-11 Training documentation for Biofire Filmarray 2.0 microbiology analyzer: training date 03/30/2022 Review of the "SKILLS VERIFICATION AND COMPETENCY BIOFIRE SYSTEM" "6-month Eval" was performed on 03/30/2022 Evaluator/Supervisor Signature: Signed by Testing Person-1 who was NOT listed on the CMS-209 as the Technical Consultant The Technical Consultant failed to evaluate and document performance at least semiannually during the first year of patient testing. 4. During an interview on 07/22/2022 at 12:44 pm, the Technical Consultant confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to have documentation that 1 of 14 testing persons (TP-14) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to have documentation that 1 of 14 testing persons (TP-14) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Findings included: 1. Review of the CMS-209 form included TP-1 through TP-14 listed to perform moderate complexity testing. 2. A random review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: TP-14; No education documents provided 3. During an interview on 07/22/2022 at 12:44 pm, the Technical Consultant confirmed there was no educational documentation for TP-14.