

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2130736	(X3) Date Survey Completed 07/21/2022
Name of Provider or Supplier Surepoint Emergency Center Grand Prairie	Street Address, City, State 901 W Jeferson Street, Grand Prairie, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. 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.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the instrument operator's manual, laboratory policy, verification records, laboratory records, and patient final reports, and confirmed in interview, the laboratory failed to ensure the reference ranges for the Metlac 12 panel on the Abaxis</p>

Piccolo Xpress analyzer were verified by the laboratory's studies before performing patient testing on 235 of 235 panels from August 2020 to July 2022. The findings include: 1. Review of the Abaxis Piccolo Xpress chemistry analyzer operator's manual revealed, "Samples from approximately 90 - 140 adult males and females were analyzed on the Piccolo Xpress chemistry analyzer to determine the reference intervals ...These intervals are provided as a guideline only. It is recommended that your office or institution establish normal ranges for your particular patient population." 2. Review of the laboratory policy titled "Laboratory Procedure Reference Range Verification" revealed, "The laboratory will have the responsibility to ensure the reference ranges for non-waived test systems are properly verified as required under CLIA ...For practical purposes, the Medical Laboratory Director may determine the number of selected, healthy individuals to include in the reference range study. Generally, somewhere around 5-10 samples can be utilized for testing and verifying the manufacturer's published reference ranges." 3. Review of verification records revealed a page titled "Verification of Reference Range Study" signed by the laboratory director on 04/30/2021 stating, "Manufacturer's suggested ranges used as Provisional Ranges until approved as established ranges." 4. Review the laboratory policy titled, "Laboratory Policy Patient Reference Range Values" (effective 03/01/2021), the Piccolo Xpress chemistry analyzer operator's manual, and patient final reports from 07/20/2022 revealed the following Metlac 12 reference ranges: Albumin: 3.3-5.5 g/dL Glucose: 73-118 mg/dL BUN: 7-22 mg/dL Creatinine: 0.6-1.2 mg/dL Sodium: 128-145 mmol/L Potassium: 3.6-5.1 mmol/L Chloride: 98-108 mmol/L CO2: 18-33 mmol/L Calcium: 8.0-10.3 mg/dL Magnesium: 1.6-2.3 mg/dL Lactate: 4.8-18.9 mg/dL; 0.53-2.10 mmol/L The laboratory's reference ranges were the manufacturer's reference ranges. The laboratory was asked to provide documentation used to verify the reference ranges. None was provided. 5. Review of laboratory records revealed the Metlac 12 panel was added in 08/2020 and 235 Metlac 12 panels were run since implementation. 6. An interview with the Technical Consultant on 07/21/2022 at 12:01 p.m. 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 manufacturer's instructions, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the Respiratory Panel 2.1 on the Biofire Filmarray microbiology analyzer. Findings: 1. Review of the Biofire Filmarray's Respiratory Panel 2.1 instructions for use revealed: "QUALITY CONTROL ... External Controls Good laboratory practice recommends running external positive and negative controls regularly. Transport media can be used as an external negative control. Previously characterized positive 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 manufacturer's instructions and appropriate accrediting organization requirements, as applicable." 2. Review of the laboratory's Biofire Filmarray IQCP (Individualized Quality Control Plan) for the respiratory panel revealed: "BIOFIRE FILMARRAY SYSTEM A. QC SAMPLES Analyze two levels of QC samples that were not in the same shipment as the reagents on receipt of new reagents, when a new lot number is opened and every 30 days. Ensure QC sample acceptance criteria are appropriate for the clinical setting. Analyze two levels of QC samples before newly trained testing personnel start to run patient samples." 3. Further review of the IQCP revealed the laboratory only tested quality control material for a period of 19 consecutive days from September 20, 2021 to October 9, 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 October 2021 through July 2022 revealed the laboratory performed quality control on the following dates on the Biofire Filmarray analyzer for the Respiratory Panel 2.1: Positive and negative QC level lot #H21APR22, expiration date 05/31/2023 positive and negative QC were performed on 10/21/21, 11/16/21, 12/17/21, 01/09/22, 02/08/2022, 03/10/2022, 04/11/2022, 05/10/2022, 06/07/2022, 07/06/2022 5. Review of patient records revealed the laboratory failed to perform QC every day of patient testing. Refer to D5449. 6. During an interview on 07/21/2022 at 10:10 am, the Technical Consultant confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the Respiratory Panel 2.1 on the Biofire Filmarray 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 manufacturer's instructions, laboratory policies, quality control (QC) records, patient 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 Respiratory Panel 2.1 on the Biofire Filmarray analyzer for 4 of 4 days in 2022 (02/2022-07/2022). Findings included: 1. Review of the Biofire Filmarray's Respiratory Panel 2.1 instructions for use revealed: "QUALITY CONTROL ... External Controls Good laboratory practice recommends running external positive and negative controls regularly. Transport media can be used as an external negative control. Previously characterized positive 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 manufacturer's instructions and appropriate accrediting organization requirements, as applicable." 2. Review of the laboratory's "BIOFIRE FILMARRAY 2.0 RESPIRATORY PANEL 2.1 (RP2.1)" policy revealed the laboratory developed an Individualized Quality Control Plan (IQCP). Review of the IQCP revealed: "BIOFIRE FILMARRAY SYSTEM A. QC SAMPLES Analyze two levels of QC samples that were not in the

same shipment as the reagents on receipt of new reagents, when a new lot number is opened and every 30 days. Ensure QC sample acceptance criteria are appropriate for the clinical setting. Analyze two levels of QC samples before newly trained testing personnel start to run patient samples." 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 analyzer. Refer to D5445. 3. A review of QC records and patient records from February 2022 through July 2022, revealed the following dates QC was not performed and patients were tested and reported for the Respiratory Panel 2.1 on the Biofire Filmarray analyzer: 02/28/2022 Patient ID# 1022822372 03/07/2022 Patient ID# 1030722471 03/09/2022 Patient ID# 1030922492 QC was last performed on 02/8/2022 03/30/2022 Patient ID# 1033022722 04/07/2022 Patient ID# 55087263 QC was last performed on 03/10/2022 05/09/2022 Patient ID# 1050922190 QC was last performed on 04/11/2022 06/29/2022 Patient ID#s 01121970DF, 10629222783 07/03/2022 Patient ID# 1070322815 07/04/2022 Patient ID#s 1070422817, 1070422816 QC was last performed on 06/07/2022 The laboratory did not include a positive and negative control each day of patient testing for the Respiratory Panel 2.1 on the Biofire Filmarray analyzer. 4. During an interview on 07/21/2021 at 10:10 am, the Technical Consultant confirmed the confirmed the above findings.