

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2132022	<b>(X3) Date Survey Completed</b> 04/12/2022
<b>Name of Provider or Supplier</b> Surepoint Emergency Center Padre Island	<b>Street Address, City, State</b> 14433 S Padre Island Drive, Corpus Christi, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed on April 12, 2022 and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of instrument print outs, patient final reports from December 2021 to March 2022, and confirmed in interview of laboratory personnel, the laboratory failed to ensure 4 of 4 patient final reports accurately reflected patient results using the BioFire FilmArray for GI (gastrointestinal) Panel. The findings included: 1. Review of patient printouts retrieved from the BioFire instrument (instrument number 2FA07289) found the following patient test records that stated the patient result for E. coli O157 was resulted as "N/A" by the instrument: Sample ID: 1121421346 Date Performed: 12-14-2021 E. coli I157 Result: N/A Sample ID: 1121421347 Date Performed: 12-14-2021 E. coli I157 Result: N/A Sample ID: 101022583 Date Performed: 01-01-2022 E. coli O157 Result: N/A Sample ID: 1032622609 Date Performed: 03-26-2022 E. coli O157 Result: N/A 2. Review of patient final reports found the following 4 of 4 records did not accurately reflect the result specified by the analyzer: Sample ID: 1121421346 Date Performed: 12-14-2021 E. coli O157 Final</p>

Result: Not Detected Sample ID: 1121421347 Date Performed: 12-14-2021 E. coli O157 Final Result: Not Detected Sample ID: 101022583 Date Performed: 01-01-2022 E. coli O157 Result: N/A (flagged as abnormal) Sample ID: 1032622609 Date Performed: 03-26-2022 E. coli O157 Result: result is blank (marked as abnormal) 3. The laboratory was asked to provide documentation that the patient final report accurately reflected results specified by the analyzer. No documentation was provided. 4. Interview with the technical consultant and testing personnel #14 (as listed on Form CMS 209) on April 12, 2022 at 11:30 hours in the breakroom confirmed the findings. Key: N/A - not applicable CMS - Centers for Medicare and Medicaid Services