

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2259613	<b>(X3) Date Survey Completed</b>  09/20/2022
<b>Name of Provider or Supplier</b>  Surepoint Emergency Center Woodlands	<b>Street Address, City, State</b>  10815 Kuykendahl Road, The Woodlands, 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>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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: A. Based on review of the laboratory's establishment studies for the Piccolo Meltac 12 test panel, review of patient testing documents and staff interview, it was determined the laboratory failed to document verification of normal ranges prior to patient testing, 1 of 4 required test performance verification components. Findings included: 1. Review of the laboratory's establishment studies for the Piccolo Meltac 12 test panel</p>

(completed 06/23/2022) revealed there was no documentation of normal range verification for this test panel. 2. Review of patient testing documents from June to August 2022 revealed the following patients were tested using the Metlac 12 test panel: Date: 07/17/2022 Patient: E77649 3. In an interview on 09/20/2022 at 1130 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings. B. Based on review of the laboratory's establishment studies for the Triage D-Dimer test, review of patient test reports and staff interview it was determined the laboratory failed to document verification of normal ranges prior to patient testing, 1 of 4 required test performance verification components. Findings included: 1. Review of the laboratory's establishment studies for the Triage D-Dimer test (completed 07/02/2022) revealed there was no documentation of normal range verification for this test. 2. Review of patient test reports for the Triage D-Dimer test form June to August 2022 revealed the following patients were tested: Date: 08/01/2022 Patient: E79059 Date: 08/15/2022 Patient: E80245 Date: 09/02/2022 Patient: E81703 3. In an interview on 09/20/2022 at 1130 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings.