

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2067303	<b>(X3) Date Survey Completed</b>  05/17/2022
<b>Name of Provider or Supplier</b>  Surepoint Emergency Center Mesquite	<b>Street Address, City, State</b>  3400 Gus Thomasson Road, Mesquite, 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>The laboratory was found to be out of compliance based on the following  <b>CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition:</b>                      Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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 Dallas Regional Office (RO) 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.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b>                      CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:                      Based on review of the laboratory's procedure for addressing flags on the Medonic S-series hematology analyzer, review of patient test records from May 5, 2022 to May 16, 2020, review of patient electronic medical records, and staff interview, it was revealed the laboratory failed to follow its policy for resolving flags on CBC (complete blood count) samples. The findings include: 1. A review of the laboratory's procedure for addressing flags on the Medonic S-series hematology analyzer revealed the following flags and corrective actions to perform: Flag: BD Action: 1) Re-mix then re-run the sample, 2) If error again, re-draw the sample from the patient before</p>

	<p>running again, 3) If error again, alert the MD to determine if the sample needs to be sent to THH for manual diff., 4) Document in Incident Log 2. A review of patient test records from May 5, 2022 to May 16, 2022 identified the following patient whose results were flagged with a BD flag: a) sample: 1050522658 sequence: 2812 Lymph% Mid% Gran% Lym Mid Gran sequence: 2813 Lymph% Mid% Gra% Lym Mid Gran 3. A review of the patient electronic medical record revealed the results from sequence 2812 were reported to the provider including the flagged results. 4. The laboratory was asked to provide documentation of following its corrective actions as listed in its procedure. No documentation was provided. 5. An interview with the technical consultant on 05/17/2022 at 1300 hours in the laboratory - after her review of the results- confirmed the findings.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the CDS Boule-Con Diff controls, review of the laboratory's quality control records from December 2021, review of patient test records from December 2021, and staff interview, revealed the laboratory failed to ensure quality control material was not expired prior to use. The findings include: 1. A review of the manufacturer's instructions for the CDS Boule-Con Diff control (Lot 22107) revealed the lot expired on 12/13/2021. 2. A review of the laboratory's quality control records from December 2021 revealed the laboratory performed daily quality control testing utilizing the expired control material on December 14, 2021 and December 15, 2021. 3. A review of patient test records identified the following patients tested on days when expired quality control was tested: a) December 2014 112142116 112421169 112421162 4. The laboratory was asked to provide documentation of performing quality control testing on the identified days utilizing in-date quality control material. No documentation was provided. 5. An interview with the technical consultant on 05/17/2022 at 1400 hours in the break room - after her review of the records- confirmed the findings.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 8 testing personnel (refer to D6065).</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p>

(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 laboratory's submitted Form CMS 209, review of personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 8 testing personnel. The findings include:

1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 8 testing personnel.
2. A review of the laboratory's personnel records revealed the facility did not have documentation of education to qualify testing personnel number 7 (as listed on Form CMS 209) to perform moderate complexity testing.
3. The laboratory was asked to provide documentation of education to quality testing personnel number 7. No documentation was provided.
4. An interview with the technical consultant on 05/17/2022 at 10:00 am in the break room - after her review of the records - confirmed the findings.