Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114433	05/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Surepoint Emergency Center Samuell Farm	1745 N Beltline Road, Mesquite, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's procedures, review of patient test records from May 6, 2022 to May 12, 2022, and staff interview, it was revealed the laboratory failed to have documentation for following its procedure for flagged Complete Blood Count (CBC) results. The findings include: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer under the section titled "WBC Differential Abnormalities" revealed the manufacturer identified the following flags and action to perform to resolve the flags: BD Blood sample too

	old or pathological sample. Follow laboratory's protocol for verification of results. NM Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. OM Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. TM Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 2. A review of the laboratory's procedure for the Medonic M-series hematology analyzer under the section titled "C. Abnormal Results" revealed: "Flagged Results Specimen results with instrument error flags that cannot be resolved are sent to the reference lab for testing." 3. A review of patient test records from May 6, 2022 to May 12, 2022 identified the following 5 patient reports with flagged CBC results which were reported to the provider and not sent to the reference lab as required by the procedure: a) May 6, 2022 ID: 1050622334 1st run: Flag OM 2nd run: Flag BD b) May 7, 2022 ID: 1050722340 Flag: BD c) May 9, 2022 ID: 1050922356 Flag: BD d) May 11, 2022 ID: 1051122366 Flag: OM e) May 12, 2022 ID: 1051222369 1st run: OM 2nd run: OM 4. The laboratory was asked to provide documentation of sending the sample to the reference lab as required by its procedure. No documentation was provided. 5. An interview with the technical consultant on 05/18/2022 at 1400 hours in the laboratory - after her review of the records- confirmed the 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 the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing semiannual competency assessments within the first year of employment for 4 of 7 testing personnel requiring them. The findings include: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of semiannual competency assessments being performed within the first year of employment for 4 of 7 testing personnel who required them. They were (as listed on Form CMS 209): Testing personnel number 16 employed: 04/2021 to 04/2022 Testing personnel number 17 employed: 03/2021 to current Testing personnel number 21 employed: 01/2021 to current Testing personnel number 23 employed: 04/2021 to current 2. The laboratory was asked to provide documentation of competency assessment being performed semiannually within the first year of employment. No documentation was provided. 3. An interview with the technical consultant on 05/18 /2022 at 1300 hours in the nurse's station - after her review of the records- confirmed the findings.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments in 2021 for 16 of 19 testing personnel requiring them. The findings include: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of annual competency assessments being performed on 16 of 19 personnel who required them in 2021. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 7 Testing personnel number 12 Testing personnel number 13 Testing personnel number 15 Testing personnel number 19 Testing personnel number 22 Testing personnel number 27 Testing personnel number 28 Testing personnel number 29 Testing personnel number 31 Testing personnel number 32 Testing personnel number 33 Testing personnel number 34 Testing personnel number 35 Testing personnel number 36 2. The laboratory was asked to provide documentation of competency assessment being performed in 2021 for the identified personnel. No documentation was provided. 3. An interview with the technical consultant on 05/18 /2022 at 1300 hours in the nurse's station - after her review of the records- confirmed the 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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to ensure testing personnel had the required education and training to perform moderate complexity testing (refer to D6065 and D6066).
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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 8 of 36 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed

	the laboratory identified 38 personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation to qualify 8 of 36 testing personnel had the required education to perform testing. They were (as listed on Form CMS 209): Testing personnel number 14 Testing personnel number 22 Testing personnel number 24 Testing personnel number 28 Testing personnel number 30 Testing personnel number 31 Testing personnel number 37 Testing personnel number 38 3. The laboratory was asked to provide documentation of education to qualify the identified personnel. No documentation was provided. 4. An interview with the technical consultant on 05/18 /2022 at 1300 hours in the nurse's station - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 22 of 36 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 38 personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of training for 22 of 36 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 2 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 5 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 12 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 13 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 14 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer Testing personnel number 18 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 21 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 22 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 23 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel (training documented as being performed 4 months prior to instrument installation) Testing personnel number 25 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 27 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 28 - missing training for the Medonic M-series hematology analyzer - missing

	training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 29 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 31 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 32 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 33 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 34 - missing training for the Medonic M-series hematology analyzer - missing training for the Alere Triage analyzer - missing training for the Piccolo Express analyzer - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 35 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel Testing personnel number 36 - missing training for the BioFire GI assay - missing training for the BioFire Respiratory 2.1 panel 3. The laboratory was asked to provide documentation of training for the identified personnel. No documentation was provided. 4. An interview with the technical consultant on 05/18/2022 at 1300 hours in the nurse's station - after her review of the records- confirmed the findings. Testing personnel number 14 Testing personnel number 22 Testing personnel number 24 Testing personnel number 28 Testing personnel number 30 Testing personnel number 31 Testing personnel number 37 Testing personnel number 38 3. The laboratory was asked to provide documentation of education to qualify the identified personnel. No documentation was provided. 4. An interview with the technical consultant on 05/18/2022 at 1300 hours in the nurse's station - after her review of the records- confirmed the findings.