

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0445646	<b>(X3) Date Survey Completed</b>  09/25/2019
<b>Name of Provider or Supplier</b>  Freeman Health System East Campus	<b>Street Address, City, State</b>  932 East 34th St, Joplin, MO	
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>D5401</b>	<p>PROCEDURE MANUAL 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 procedures, i-Stat calibration verification and interview with the technical consultant the laboratory failed to follow "i-Stat QC policy". Findings: 1. Review of "i-Stat QC policy" states "calibrant solution and calibration", "At least every 6 months". 2. Review of i-Stat calibration verification showed no documentation for 2018. 3. Interview with the technical consultant on September 25, 2019 at 11:30AM showed the laboratory failed to follow i-Stat procedure and perform calibration verification every six months in 2018.</p>
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of 2018, 2019 instrument comparison documentation and interview with the technical consultant on September 25, 2019 at 11:30 AM, the laboratory failed to perform instrument comparisons for four i-Stat blood gases two times a year.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel competencies and interview with the technical consultant, the technical consultant failed to evaluate the competency for two of fourteen testing personnel in 2018. Findings: 1. Review of competencies showed no technical consultant documentation of competency for testing personnel #10 and #11. 2. Interview with the technical consultant on September 25, 2019 at 11:00 AM confirmed the technical consultant failed to evaluate two testing personnel competencies in 2018.

**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 personnel records revealed and interview with the technical consultant confirmed, the laboratory failed to have academic credentials required to qualify one of thirteen testing personnel for the speciality of chemistry for moderate complexity testing (refer to tag #6065).

**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 personnel records and interview with the technical consultant, the

laboratory failed to have documentation of academic credentials to qualify one of thirteen testing personnel for moderate complexity testing. Findings: 1. Review of the personnel records for testing personnel # 3 for the speciality of chemistry revealed the laboratory failed to have academic credentials to qualify this individual. 2. Interview with the technical consultant on September 25, 2019 at 1:00 PM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as testing personnel #3 of moderate complexity chemistry testing.