

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D1010783	<b>(X3) Date Survey Completed</b>  10/22/2020
<b>Name of Provider or Supplier</b>  Tukhs - South Kansas City Medical Pavilion	<b>Street Address, City, State</b>  1000 E 101st Terr, Kansas City, 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>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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: Based on lack of established verification of performance specifications for the Abbott i-Stat and interview with technical supervisor (TS), the laboratory failed to establish performance characteristics to ensure accuracy, precision, reportable range and verify the manufacturer's reference intervals are appropriate for the laboratory's patient population for nine of nine analytes before reporting patient test results. Finding: 1. Lack of documentation for verification of performance specifications showed the laboratory failed to establish characteristics for the following analytes: Ionized calcium, glucose, creatinine, blood urea nitrogen, sodium, potassium, chloride, total carbon dioxide and brain natriuretic peptide for the Abbott i-Stat. 2. Interview with TS on October 21, 2020 at 11:00 AM confirmed the laboratory failed to have verification specifications for the Abbott i-Stat before reporting patient test results.</p>
<b>D6033</b>	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on review of personnel records and interview with the technical consultant, the laboratory did not have academic credentials required to qualify one of four technical consultants that provides technical oversight for moderate complexity testing (refer to tag #6035).

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with the technical consultants, the laboratory failed to have documentation of academic credentials to qualify one of four technical consultants that provide technical oversight for moderate complexity testing. Findings: 1. Review of the personnel records for technical consultant #2 that provides technical oversight for moderate complexity testing revealed the laboratory failed to have academic credentials to qualify the technical consultant. 2. Interview with the

technical consultants #1 and #2 on October 21, 2020 at 11:30 AM confirmed, the laboratory failed to have the required documentation to qualify one technical consultant that provided technical oversight for moderate complexity testing.

**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 and interview with the technical consultants, the laboratory did not have academic credentials required to qualify eleven of twenty six 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 consultants, the laboratory failed to have documentation of academic credentials to qualify eleven of twenty six testing personnel for moderate complexity testing. Findings: 1. Review of the personnel records for testing personnel #1, #2, #3, #5, #13, #14, #16, #17, #18, #19 and #21 for the speciality of chemistry revealed the laboratory failed to have academic credentials to qualify the testing personnel. 2. Interview with the technical consultants #1 and #2 on October 21, 2020 at 11:30 AM confirmed, the laboratory failed to have the required documentation to qualify eleven testing personnel of moderate complexity chemistry testing.