

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1038043	(X3) Date Survey Completed 08/22/2022
Name of Provider or Supplier St Lukes Diagnostic Cath Lab Lp	Street Address, City, State 6620 Main Street Suite 1520, Houston, 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	A recertification survey was performed on 8/22/22. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to ensure the laboratory personnel had documentation of training on the Abbott i-STAT analyzer and the AVOXimeter 1000E prior to performing patient testing (refer to D6066).</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

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 submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical consultant failed to perform a competency assessment in 2021 on one of eleven testing personnel performing moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 8/17/22), revealed the laboratory identified 11 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed no documentation of the technical consultant performing a competency assessment in 2021 for testing person #8. 3. An interview with the technical consultant on 8/22/22 at 11:50 a.m. in the break room, after review of the records, confirmed the above 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 personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to determine the qualifications of two of eleven testing personnel to perform moderate complexity testing (refer to D6065).

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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of education for two of eleven testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS

209 form (signed by the laboratory director on 8/17/22) revealed 11 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for testing person #8 and testing person #11. 3. An interview with the technical consultant on 8/22/22 at 12:40 p.m. in the break room, after review of the records, confirmed the above 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 CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that, prior to performing patient testing, the laboratory failed to have documentation of training for the following: a) One of eleven testing personnel for the Abbott i-STAT Chem 8 cartridge b) One of eleven testing personnel for the AVOXimeter 1000E. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 8/17/22) revealed the laboratory identified 11 testing personnel who performed moderate complexity testing on the Abbott i-STAT analyzer and the AVOXimeter 1000E analyzer. 2. A review of the laboratory's personnel records revealed the following personnel failed to have documentation of training prior to performing patient testing on the following moderate complexity analyzers: a) Testing person #10 failed to have training for testing on the Chem 8 cartridge using the Abbott i-STAT analyzer b) Testing person #11 failed to have training for testing on the AVOXimeter 1000E. 3. Further review of the laboratory's personnel records revealed the following hire dates for the above listed testing personnel: a) Testing person #10 hired 2/15/22 b) Testing person #11 hired 7/25/18 4. An interview with the technical consultant on 8/22/22 at 12:40 p.m. in break room, after review of the records, confirmed the above findings.