

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1038043	(X3) Date Survey Completed 07/24/2026
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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey completed on 07/24/2026 and recertification is recommended. Standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the proficiency testing records from 2025 to 2026, a list of testing personnel with areas of competency, CMS 209 form, and confirmed in an interview, the laboratory failed to ensure 9 of 9 routine chemistry and hematology proficiency testing events were analyzed by personnel who routinely perform testing in the laboratory. The findings were: 1. Review of the laboratory's policy titled "Proficiency Testing Program-Laboratory Services", approved by the laboratory director on 02/18/2019, under "PROFICIENCY TESTING PROCEDURES" revealed "2. b. ...test samples in the same manner as patient samples." 2. Review of CMS 209 form, Laboratory Personnel Report (CLIA), and a list of testing personnel with areas of competency completed by the laboratory on 07/10/2026 revealed there were 9 testing personnel to perform moderate routine chemistry testing and 8 testing personnel to perform moderate hematology testing. 3. Review of the API proficiency testing records from 2025 to 2026 revealed testing personnel#1 (as indicated on the CMS 209 form) attested to the analyzing 9 of 9 proficiency testing events for routine chemistry and hematology testing. 2025 Chemistry Core 1st Event Samples: IB-01 to IB-05 Testing personnel signed: TP#1 2025 Chemistry Core 2nd Event Samples: BLX-06 to BLX-10 and IB-06 to IB-10

Testing personnel signed: TP#1 2025 Chemistry Core 3rd Event Samples: BLX-11 to BLX-15 and IB-11 to IB-15 Testing personnel signed: TP#1 2025 Hematology /Coagulation 1st Event Samples: IAC-01 and IAC-02 Testing personnel signed: TP#1 2025 Hematology/Coagulation 2nd Event Samples: IAC-03 and IAC-04 Testing personnel signed: TP#1 2025 Hematology/Coagulation 3rd Event Samples: IAC-05 and IAC-06 Testing personnel signed: TP#1 2026 Chemistry Core 1st Event Samples: BLX-01 to BLX-05 and IB-01 to IB-05 Testing personnel signed: TP#1 2026 Chemistry Core 2nd Event Samples: BLX-06 to BLX-10 and IB-06 to IB-10 Testing personnel signed: TP#1 2026 Hematology/Coagulation 1st Event Samples: IAC-01 and IAC-02 Testing personnel signed: TP#1 4. In an interview on 07/23/2026 at 11:40 am in a room, the technical consultant confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services API=American Proficiency Institute TP=Testing personnel