

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0896925	(X3) Date Survey Completed 05/09/2025
Name of Provider or Supplier St Vincent Infirmiry Medical Center	Street Address, City, State 2 St Vincent Circle, Little Rock, AR	
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 validation survey was conducted on 5/8/25 to 5/9/25 for St. Vincent Infirmiry Medical Center CLIA # 04D0896925. The facility was found to be not in compliance with condition 493.1421, testing personnel.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of facility policy number POC03.1005 "Clinical Laboratory: Authorized Designees", personnel competency records for fifteen randomly selected personnel, and interview, the laboratory failed to assess the competency of two of fifteen personnel for duties for which they were designated. Findings follow: A) Review of the laboratory policy, POC03.1005 (Clinical Laboratory: Authorized Designees) revealed that the laboratory staff member (#1 on the separate personnel worksheet) is listed as authorized to perform competency assessments, quality control (QC) review, quality assurance (QA) review, review of equipment records, review of procedures, and review of proficiency testing. B) Review of the competency assessment for laboratory staff member (#1 on the separate personnel worksheet) for calendar year 2023, 2024 and 2025 to date, revealed that competency for the duties authorized for this staff member in POC01.1005 were not documented. C) Review of the competency assessment for the personnel (# 4 on the separate personnel worksheet) revealed that competencies were provided for June 2022 and September 2022 but no competencies were provided for 2023 or 2024. D) Upon request, the laboratory could not provide competency assessments for the authorized duties for the personnel (#1 on the separate personnel worksheet) or competencies for 2023 and 2024 for the personnel (#4 on the separate personnel worksheet). E) In an interview</p>

on 5/8/25 at 1100, laboratory staff member (#4 on the form CMS 209) confirmed the competency assessments identified above were not available.

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 upon a review of personnel files for sixteen randomly selected laboratory testing personnel listed on the point of care (POC) testing Personnel Identification Worksheet, review of unofficial transcripts, a review of certificates of course completion, a lack of documentation, and interviews with staff, the laboratory failed to ensure one of sixteen testing personnel met the qualifications in 493.1423 (b)(6)(i)(ii) to perform moderately complex 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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based upon a review of laboratory personnel records for sixteen randomly selected testing personnel, review of "primary source verification" for testing personnel (# 8 as listed on the Personnel Identification Worksheet), review of unofficial transcript, review of certificate of course completion, lack of documentation, and interviews with laboratory staff, the laboratory failed to document that laboratory employee one of sixteen testing personnel (#8 as listed on the Personnel Identification Worksheet) met educational requirements to perform moderate complexity testing. Survey findings follow: A) In an interview, at 2:07 p.m. on 5/8/25, employee #3 (as listed on the form CMS 209) confirmed employee #8 performed testing using the moderate complexity I-Stat test system. B) Review of the primary source verification submitted for POC testing personnel (# 8 as listed on the Personnel Identification Worksheet) revealed that educational qualifications could not be verified by the agency on 5/20/21 @ 11:13 a.m. C) Review of the unofficial transcript from Baptist Health Schools Little Rock revealed 36 credits including Fundamental Nursing I, II, II, and IV, Adult Nursing I and Adult Nursing II. D) Review of a certificate from Baptist Health School of

Nursing revealed that testing personnel (#8 as listed on the Personnel Identification Worklist) had "successfully completed the prescribed course of study and has met certain standards and qualifications of the school of nursing" but did not include the awarding of an associate degree. E) In an interview on 5/8/25 at 02:30 p.m., the laboratory staff member (# 3 on the form CMS 209) was asked to provide a diploma of an associate degree in nursing or a high school diploma for testing personnel (# 8 on the Personnel Identification Worklist) and neither was provided.