

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0902822	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Kindred Hospital - Philadelphia	Street Address, City, State 6129 Palmetto Street, Philadelphia, PA	
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 conducted by the Pennsylvania State Agency on 08/27/2025 found the Kindred Hospital Philadelphia laboratory to be out of compliance with the following condition: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to ensure 2 of 4 General Supervisors (GS) (PA State personnel #4 and #5) met the minimum state educational requirements (5.23(a)(1)(2)(3)) and were on the laboratory premises during all hours in which tests were performed from 08/27/2023 to 08/27/2025 as required per PA regulations. Findings include: 1. The PA State regulation 5.23 states: "(a) No person shall be a supervisor in a clinical laboratory unless he conforms with one of the following requirements: (b) (1) A general supervisor who meets all the requirements of paragraphs (1), (2), or (3) of subsection (a) of this section and is on the laboratory premises during all normal scheduled working hours in which tests are being performed. The director may also qualify as a general supervisor." 2. On the day of survey, 08/27/2025 at 9:55 am, review of the Laboratory Personnel Report (PA State) form (dated 08/27/2025) and personnel records revealed the laboratory failed to ensure 2 of 4 General Supervisors (GS) (PA State personnel #4 and #5) met the minimum state educational requirements (5.23(a)(1)(2)(3)) and were on the laboratory premises during all hours in which tests were performed from 08/27/2023 to 08/27/2025 as required per PA regulations. 3. Further review of personnel credentials revealed GS #3 has an Associate's degree in Respiratory Therapy and GS #4 has an Associate's degree in Respiratory Care. 4. The</p>

hours of laboratory testing are Sunday through Saturday 12:00 am to 11:59 pm. (24/7) (CMS 116, dated 08/22/2025). 5. The LM confirmed the above findings on 08/27/25 at 1:00 pm.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to establish a competency assessment procedure to assess 2 of 2 Technical Consultants (TC) for their supervisory responsibilities performed in 2024 and 2025. Findings Include: 1. On the day of survey, 08/27/2025 at 9:55 am, the laboratory failed to provide a competency assessment procedure to assess the competency of TC #1 and TC #2 (CMS 209 personnel #2 and #3, dated 03/10/2025) for their supervisory responsibilities performed in the laboratory in 2024 and 2025. 2. The laboratory failed to provide competency assessment documentation for the supervisory responsibilities of TC #1 and TC #2 when overseeing chemistry testing performed in 2024 and 2025. 3. The LM confirmed the findings above on 08/27/2025 at 1:00 pm.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Laboratory Manager (LM), the laboratory failed to verify the required performance specifications for testing performed on 1 of 2 Nova Stat Profile Prime Blood Gas analyzers prior to reporting patient test results from 06/30/2025 to the date of the survey. Findings Include: 1. The laboratory's Instrument, Test & Method Validation policy states, "Due to the extreme difficulty of obtaining arterial samples from normal individuals, laboratory medical director may use alternate methods to determine reference ranges. Methods include accepting manufacturers previously published ranges, reviewing literature to determine ranges or accepting ranges currently in use at the laboratory if there is no significant methodology differences." 2. On the day of the survey, 08/27/2025 at 11:30 am, review of the laboratory's verification of performance specification records for the 1 of 2 Nova Stat Profile Prime Blood Gas analyzers (s/n P07A220470C) performed on 06/30/2025, revealed the laboratory failed to perform a reference range /normal value study appropriate for the laboratory's patient population for the

following chemistry analytes prior to reporting patient test results from 06/30/2025 to 08/27/2025: - pH - pCO2 - pO2 - Lactate 3. The laboratory reported 6 patient test results from 06/30/2025 to 08/27/2025 using the 1 of 2 Nova Stat Profile Prime Blood Gas analyzers (s/n P07A220470C). 4. The LM confirmed the findings above on 08/27/2025 at 1:00 pm.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure an established Quality Assessment (QA) program was maintained to assure the quality of laboratory services provided when chemistry testing was performed for 4 of 24 months from 08/27/2023 to the date of the survey. Findings include: 1. The laboratory's Laboratory Quality Assessment /Improvement Plan policy states "The Medical Director of the Laboratory has the ultimate authority and responsibility for overseeing all Quality Assessment /Improvement activities performed in the Laboratory. The Medical Director will periodically review Quality Assurance findings, recommendations, actions and follow-up review to ensure that the objective of the Laboratory Quality Assessment /Improvement Plan has been met". 2. On the day of survey 08/27/2025, the laboratory could not provide documentation of LD/designee review of QA activities to assess the laboratory's pre-analytical, analytical and post-analytical processes for 4 of 24 months (September 2024 - December 2024) when chemistry testing was performed from 08/27/2023 to 08/27/2025. 3. The LM confirmed the above findings on 08/27/2025 at 1:00 pm.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:
Based on review of competency assessment records, personnel credentials, and interview with the Laboratory Manager (LM), the laboratory failed to ensure 1 of 1 testing personnel (TP) (CMS 209, TP #2, dated 03/10/2025) that performed the duties of a technical consultant met the minimum education requirements listed under 493.1411 to provide technical oversight for moderate complexity blood gas analysis in 2024 and 2025. Refer to D6035

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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on review of competency assessment (CA) records, personnel credentials, and interview with the Laboratory Manager (LM), the laboratory failed to ensure 1 of 1 testing personnel (TP) (CMS 209, TP #2, dated 03/10/2025) that performed the duties of a technical consultant met the minimum education requirements listed under 493.1411 to provide technical oversight for moderate complexity blood gas analysis in 2024 and 2025. Findings include: 1. On the day of the survey, 08/27/2025 at 9:55 am, review of CA records revealed that TP #2 performed the competency assessments for TP #3 through TP #17(CMS 209, dated 03/10/2025) for blood gas testing performed in 2024 and 2025. 2. Interview with the LM on 08/27/2025 at 10:39 am and review of personnel credentials revealed TP #2 has an Associate's degree in Respiratory Care. 3. The LM confirmed the findings above on 08/27/2025 at 1:10 pm.