Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0180295	11/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Hospital	401 E Murphy Ave Floor #1, Connellsville, 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 recertification survey was conducted by the Pennsylvania State Agency at Highlands Hospital on 11/18/2025 and 11/19/2025. The laboratory was found out of compliance with the following conditions: 493.801 Condition: Enrollment and testing of samples. 493.1230 Condition: General Laboratory Systems.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) reports, lack of documentation, and interview with general supervisor (GS) #3, the laboratory failed to enroll in an HHS approved PT program for 2 of 2 non-waived regulated analytes listed in Subpart I from 01/01/2025 to 11/18/2025. Findings include: 1. On the date of the survey, 11/18/2025 at 10:30 am, the laboratory failed to provide documentation for the enrollment in an HHS approved PT Program for the following 2 of 2 non-waived regulated analytes listed in Subpart I from 01/01/2025 to 11/18/2025: - Gram Stain (Bacteriology) - Blood Gases: pH, pCO2, pO2 (Routine Chemistry) 2. GS #3 confirmed the findings above on 11/18/2025 at 03:30 pm.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with General Supervisor (GS) #3 , the Laboratory Director (LD)/designee failed to sign 7 of 162 CAP PT attestation statements for hematology, chemistry and microbiology testing performed from 11/15/2023 to 11/18/2025. 1. The CAP PT attestation forms stated, "The laboratory director and the testing personnel must sign this form." 2. On the day of the survey, 11/18/2025 at 10:30 am, the laboratory failed to provide attestation statements signed by the LD/designee for the following 7 of 162 CAP PT events performed from 11/15/2023 to 11/18/2025: - Urine Drug Testing: Screening (UDS-A 2024) - Clostridoides (Clostridium) dificile Detection Survey (CDF-B 2024) - Coagulation-Limited Survey (CGL-C 2023) - Rapid Group A Strep Antigen Detection Survey (D6-B 2024) - General Chemistry and Therapeutic Drugs Survey (C-B 2024) - Reticulocyte Survey (RT3-A 2024) - Rapid Group A Strep Antigen Detection Survey (D6-A 2025) 3. GS #3 confirmed the findings above on 11/18/2025 at 03:30 pm.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with General Supervisor (GS) #3, the laboratory failed to monitor and document temperature and humidity to ensure operating conditions were met when 1 of 1 chemistry test (Whole Blood Glucose) was performed using the Accu-Chek Inform II glucose meter from 11 /15/2023 to 11/19/2025. Findings include: 1. On the day of the survey, 11/19/2025 at 10:00 am, review of the manufacturer's instruction for use stated, " Use the test strips at temperatures between 16 to 35 degrees Celcius. Use the test strips between 10 - 80% relative humidity." 2. The laboratory failed to provide documentation for temperature and humidity readings taken to ensure operating conditions were met for 1 of 1 chemistry test (Whole Blood Glucose) performed using the Accu-Chek Inform II glucose meter from 11/15/2023 to 11/19/2025. 3. GS #3 confirmed the findings above on 11/19/2025 at 10:30 am.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on lack of documentation, record review, and interview with General Supervisor (GS) #3, the laboratory failed to meet applicable general laboratory systems requirements in 493.1235 for 23 of 23 months from 11/15/2023 to date of survey. Refer to D5209
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, record review, and interview with General Supervisor (GS) #3, the laboratory failed to follow established procedures to assess the competency of 2 of 5 General Supervisors for their supervisory responsibilities performed in the laboratory from 11/15/2023 to the date of the survey. Findings Include: 1. The laboratory's Competency Assessment Policy stated, "A Competency Assessment is required for all Testing Personnel, Technical Consultants, Technical Supervisors and General Supervisors of the Penn Highlands Connellsville Laboratory. Frequency: All Testing Personnel will have a competency assessment performed semiannually during the first year the individual test patient specimens and then annually thereafter. The Laboratory Director or Technical Supervisor will assess the competency of the General Supervisor annually, in writing". 2. On the day of survey, 11/18/2025 at 9:24 am, the laboratory failed to provide competency assessment records for 2 of 5 GS (CMS 209 GS #2 and #3, dated 11/13/2025), for their supervisory responsibilities performed in the laboratory from 11/15/2023 to 11/19 /2025. 3. GS#3 confirmed the above findings on 11/19/2025 at 10:30 am. Repeat Deficiency **
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 record review, lack of documentation, and interview with General Supervisor (GS) #3, the laboratory failed to verify the required performance specifications for Chemistry testing performed on 1 of 1 ALCOR MiniSED, SN 02573 before reporting patient results from 3/26/2024 to 11/18/2025. Findings Include: 1. On the day of survey, 11/18/2025 at 11:30 am, the laboratory could not provide documentation for the verification of the following performance

	specifications perfromed for 1 of 1 ALCOR MiniSED, SN 02573 before reporting patient results from 3/26/2024 to 11/18/2025: - Reportable range - Reference intervals /normal values 2. GS #3 confirmed the above findings on 11/18/2025, at 11:45 am.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with General Supervisor (GS) #3, the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for platelet count (PLT) examinations performed on 1 of 1 Beckman Coulter DxH 600 hematology analyzer using sodium citrate anticoagulant from 11/15/2023 to 11/18/2025. Findings include: 1. Review of the Beckman Coulter DxH 600 manufacturer's instructions for use stated, "Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended." 2. On the day of the survey, 11/18/2025 at 1:45 pm, the laboratory failed to provide documentation for the performance specifications established when performing PLT counts using sodium citrate anticoagulant (blue top tube) on 1 of 1 Beckman Coulter DxH 600 hematology analyzer using sodium citrate anticoagulant from 11/15/2023 to 11/18/2025. 3. GS #3 confirmed the findings above on 11/18/2025 at 2:00 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on lack of maintenance records, and interview with General Supervisor (GS) #3, the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 15 of 15 traceable thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory from 11/15/2023 to 11/19/2025. Findings include: 1. During observation in the laboratory on 11/19/2025 at 10:15 am, the following thermometers were observed in use in the laboratory for storage of reagents, supplies, calibrators, and quality control: 2 room temperature/humidty thermometers S/Ns: 209022 and 32838 11 refrigerator thermometers, S/Ns: 4689, 218613, 24715, 196982, 197009, 20632, 43860, 91533,

	24707, 9895, and 27960 2 freezer thermometers, S/Ns: 20337 and 21758 2. The laboratory failed to provide documentation of maintenance and function checks as defined by the manufacturer for 15 of 15 traceable thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory from 11/15 /2023 to 11/19/2025. 3. GS #3 confirmed the above findings on 11/19/25 at 10:30 am. B. Based on review of procedures, maintenance records, and interview with General Supervisor (GS) #3, the laboratory failed to perform and document 1 of 4 quarterly maintenance check as defined by the manufacturer for the Beckman Coulter iChem Velocity used for urinalysis examinations from 11/15/2023 to 11/18/2025. Findings include: 1. On the day of survey, 11/19/2025 at 9:30 am, review of the laboratory's maintenance records revealed The laboratory failed to perform and document the quarterly manufacturer recommended maintenance check in October 2025 for the Beckman Coulter iChem Velocity used for urinalysis examinations from 11/15/2023 to 11/18/2025. 2. GS #3 confirmed the findings above on 11/19/2025 at 2:00 pm.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor (GS) #3, the laboratory failed to establish and maintain a policy that ensured compliance with testing and distribution records for emergency release of blood (606.160(b)(3)(v)) for 2 of 4 emergency transfusion requests from 11/15/2023 through 11/19/2025. Findings include: 1. The laboratory's Emergency Release of Blood Procedure stated, "10. Immediately have the physician sign the emergency Transfusion Request form. If the physician is not able to sign, have the RN in charge of the patient sign and date the Emergency Transfusion Request form. (If the patient is being given type-specific units, then immediately have the physician or RN sign the Patient/Donor Compatibility Verification Form PRBC also). These forms MUST BE SIGNED by the physician or RN in charge of the patient BEFORE the units are released." 2. On the day of the survey, 11/18/2025 at 2:53 pm, review of the laboratory's Emergency Release Blood Procedure revealed the laboratory failed to establish and maintain a policy that ensured compliance with blood and blood product distribution for emergency release, including signature of requesting physician obtained before or after release (606.160(b)(3)(v)) from 11/15/2023 to 11/18/2025. 3. Further review of the laboratory's Emergency Transfusion Request forms revealed the laboratory failed to ensure the following 2 of 4 emergency transfusion requests were signed by the requesting physician from 11/15/2023 to 11/19/2025: - Emergency Transfusion Request, Unit #: W18272518096900H, signed by Registered Nurse (RN) on 6/17 /2025. - Emergency Transfusion Request, Unit #: W1822407826800U, signed by RN on 7/21/2024. 4. GS#3 confirmed the above findings on 11/19/2025 at 10:30 am..
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test

	results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with General Supervisor (GS) #3, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies for 2 of 2 comparison studies performed for hematology methodologies used from 11/14/2023 to 11/18/2025. Findings include: 1. On the day of the survey, 11/18/2025 at 1:30 pm, the laboratory failed to provide documentation for the evaluation performed twice a year (2 of 2 comparison studies) to monitor and evaluate the relationship between the following methodologies used for hematology examinations performed from 9/28/2023 to 9/17 /2025: - EDTA vs Sodium Citrate tubes for Platelets 2. GS # 3 confirmed the findings above on 11/18/2025 at 2:30 pm.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview with General Supervisor (GS) #3, the laboratory director (LD) failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics before reporting patient results for hematology examinations for erythrocyte sedimentation rates (ESR) performed on 1 of 1 ALCOR MiniSED analyzer from 3/26/2024 to 5/3/2024. 1. On the date of the survey, 11/18/2025 at 12: 35 pm, review of instrument logs and verification and performance specification reports revealed that testing on the ALCOR MiniSED began on 3/26/2024. and the LD reviewed and approved the method for patient testing on 5/3/2024. 2. Further review of the verification of performance specifications revealed the LD reviewed and approved the verification of performance specifications for 1 of 1 Alcor MiniSED analyzer on 05/03/2024. 3. During interview, 11/18/2025 at 02:30 pm, GS #3 confirmed the findings above and stated, "the laboratory performed 74 ESR examinations from 3/26/2024 to 5/3/2024 prior to the review and approval of the verification procedures by the LD."
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation, record review, and interview with the General Supervisor (GS) #3, the Technical Supervisor failed to follow established procedures to assess the competency of 1 of 8 Testing Personnel (TP) that performed

	immunohematology, chemistry, hematology and urinalysis examinations in the laboratory from 11/15/2023 to the date of the survey. Findings Include: 1. The laboratory's Competency Assessment Policy stated, "A Competency Assessment is required for all Testing Personnel, Technical Consultants, Technical Supervisors and General Supervisors of the Penn Highlands Connellsville Laboratory. Frequency: All Testing Personnel will have a competency assessment performed semiannually during the first year the individual test patient specimens and then annually thereafter. The assessment will be completed by the Technical Supervisor". 2. On the day of survey, 11/18/2025 at 9:24 am, the laboratory failed to provide competency assessment records for 1 of 8 TP (CMS 209 TP #1, dated 11/13/2025), that performed immunohematology, chemistry, hematology and urinalysis examinations in the laboratory from 11/15/2023 to 11/19/2025. 3. GS#3 confirmed the above findings on 11/19/2025 at 10:30 am.