Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0709679	05/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Central Pennsylvania Blood Bank	8167 Adams Drive, Hummelstown, 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	An onsite validation survey was conducted on May 28, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documented quality assessment (QA) activities and interview with general supervisor (GS) #4, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor and assess general laboratory systems requirements specified at 493.1231 through 493.1236 for 2 of 2 years (May 2024 to May 2026). Findings: 1. Review of laboratory procedure, Root Cause Analysis of Nonconformances and Development of Corrective Actions Plan, provided a process for investigation and corrective action of identified nonconformances. 2. The above procedure did not address ongoing QA processes for the laboratory's general systems and overall system effectiveness as required by 493. 1231 through 493.1236. 3. The laboratory failed to provide documentation of periodic QA activities performed for 2 years (May 2024 to May 2026). 4. In an interview on May 28, 2026 at 2:00 pm, GS#4 confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documented quality assessment activities and interview with general supervisor (GS) #4, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, preanalytic systems requirements specified at 493.1241 through 493.1242 for 2 of 2 years (May 2024 to May 2026). Findings: 1. Review of laboratory procedure, Root Cause Analysis of Nonconformances and Development of Corrective Actions Plan, provided a process for investigation and corrective action of identified nonconformances. 2. The establish procedure failed to assess ongoing quality assessment process for the laboratory's preanalytic systems and overall system effectiveness as required by 493.1241 through 493.1242. 3. The laboratory failed to provide documentation of periodic QA activities performed for 2 years (May 2024 to May 2026). 4. In an interview on May 28, 2026 at 2:00 pm, GS#4 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's temperature tracking system, manufacters humidity requirements, and interview with general supervisor (GS) #4, the laboratory failed to follow manufacters humidity requirements for 2 out of 3 testing analyzers currently in use. Findings: 1. During a tour of the laboratory on May 28, 2026 at 10:50 am, the following analyzers were observed in use for donor testing: a. 1 - Immucor WERFREN NEO Iris. b. 1 - Sysmex XN-1000. c. 1 - STREK Sickledex. 2. Review of the following manufacters documents revealed: a. The NEO-Iris Operator Manual stated, under environmental conditions, "Limitation: Environmental conditions: Relative humidity range : 20% to 80% (non-condensing)." b. The Sysmex XN-1000 Operator Manual stated, under technical information, "operating environment (relative humidity) 20-85%." 3. Review of the laboratory temp track system revealed the laboratory's humidity ranges were set at 12 to 75%. 4. In an interview on May 28, 2026, at 2:00 pm, GS#4 confirmed established humidity ranges were not following manufacturers requirements.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documented quality assessment activities and interview with general supervisor (GS) #4, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, analytic systems specified in 493.1251 through 493.1283 for 2 of 2 years (May 2024 to May 2026).. Findings: 1. Review of laboratory procedure, Root Cause Analysis of Nonconformances and Development of Corrective Actions Plan, provided a process for investigation and corrective action of identified nonconformances. 2. The establish procedure failed to assess ongoing quality assessment process for analytic systems specified in 493.1251 through 493.1283. 3. The laboratory failed to provide documentation of periodic QA activities performed for 2 years (May 2024 to May 2026).. 4. In an interview on May 28, 2026 at 2:00 pm, GS#4 confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documented quality assessment activities and interview with general supervisor (GS) #4, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, postanalytic systems requirements specified in 493.1291 for 2 of 2 years (May 2024 to May 2026). Findings: 1. Review of laboratory procedure, Root Cause Analysis of Nonconformances and Development of Corrective Actions Plan, provided a process for investigation and corrective action of identified nonconformances. 2. The establish procedure failed to assess ongoing quality assessment process for the laboratory's postanalytic systems requirements specified in 493.1291. 3. The laboratory failed to provide documentation of periodic QA activities performed in 2 years (May 2024 to May 2026). 4. In an interview on May 28, 2026 at 2:00 pm, GS#4 confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 review laboratory procedure, lack of documented quality assessment acitivies and interview with general supervisor (GS) #4, the laboratory director (LD) failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided for 2 of 2 years (May 2024 to May 2026). Refer to D5291, D5391, D5791 and D5891.