Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0999981	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Cancer Institute, Pc	1267 Highway 54 West, Suite 4200, Fayetteville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 13, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of profiency test (PT) records and staff interview, the laboratory testing personnel and lab director failed to retain the attestation form stating the PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the College of American Pathologists (CAP) PT records of 2021 events 1, 2, 3 and 2022 events 1 and 2 reveals the lab failed to retain the signed attestation form for 2021 Event 3. 2. Interview with staff # 3 (CMS 209) on 7/13/22 at 1:34 PM in the facility's breakroom confirmed the lab failed to retain the signed attestation form for 2021 Event 3.

D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of profiency test (PT) records and staff interview, the laboratory failed to retain the results obtained on proficiency testing performed. Findings include: 1. Review of the College of American Pathologists (CAP) PT records of 2021 events 1, 2, 3 and 2022 events 1 and 2 reveals the lab failed to retain the results returned by the PT provider for 2021 Event 1, therfore, no documented review of the results. 2. Interview with staff # 3 (CMS 209) on 7/13/22 at 1:34 PM in the facility's breakroom confirmed the lab failed to retain the results returned by the PT provider for 2021 Event 1, therfore, no documented review of the results.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the standard operations procedure manual (SOP), the Horiba ABX Pentra 60 C+ user manual, and observation during the lab tour, the laboratory director failed to ensure testing personnel (TP) were performing the test method as written in the aforementioned manuals. Findings include: 1. Review of the SOP and Horiba ABX Pentra 60 C+ user manual, reveals patient samples were to be placed on a rocker or inverted 15 - 20 times to ensure proper mixing of the blood with the anticoagulant prior to processing via the Horiba ABX Pentra 60 C+. 2. Observation on 7/13/22 of TP #1 (CMS 209) in the lab during the lab tour at 10:15 AM reveals TP vortexing the patient samples prior to processing via the Horiba ABX Pentra 60 C+. 3. Interview with staff #3 (CMS 209) on 7/13/22 at 1:40 PM in the facility's breakroom confirmed TP vortexing the patient samples prior to processing via the Horiba ABX Pentra 60 C+.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the standard operations procedure manual (SOP), the Horiba ABX Pentra 60 C+ user manual, and observation during the lab tour, testing personnel (TP)

	were not performing the test method as written in the aforementioned manuals. Findings include: 1. Review of the SOP and Horiba ABX Pentra 60 C+ user manual, reveals patient samples were to be placed on a rocker or inverted 15 - 20 times to ensure proper mixing of the blood with the anticoagulant prior to processing via the Horiba ABX Pentra 60 C+. 2. Observation on 7/13/22 of TP #1 (CMS 209) in the lab during the lab tour at 10:15 AM reveals TP vortexing the patient samples prior to processing via the Horiba ABX Pentra 60 C+. 3. Interview with staff #3 (CMS 209) on 7/13/22 at 1:40 PM in the facility's breakroom confirmed TP vortexing the patient samples prior to processing via the Horiba ABX Pentra 60 C+.