Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1084950	05/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cpn, Inc Dba Atrium Health Primary Care	3970 West Hwy 27, Lincolnton, NC	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 Coulter AcT diff hematology quality control and maintenance records, review of 2021, 2022, and 2023 quality assessment records, and interview with the TC (technical consultant) 5/3/23, the laboratory failed to discard hematology quality control material that exceeded the expiration date. Review of 2021, 2022, and 2023 hematology quality control records revealed the laboratory used Coulter 4C-ES quality control material lot #068900 low/078900 normal/088900 high with expiration date 1/31/22 from 2/1/22 to 2/28/22. Review of the February 2022 Coulter maintenance log revealed the following notation dated 5/5 /22 and signed by the TC: "Expired QC all month but in range. Reviewed w/ (the laboratory director) & left pt. summary with him to review." Review of quality assessment records revealed the TC instructed the laboratory to have the laboratory director review all patient results for tests completed during the use of expired controls, but there was no documentation that a patient review was performed. During interview at approximately 1:15 p.m., the TC confirmed that the patient review had not been completed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022, and 2023 Coulter AcT diff hematology calibration records and review of 2020, 2021, 2022, and 2023 quality assessment records 5/3/23, the laboratory failed to perform and document calibration at least once every six months. Findings: Review of 2020, 2021, 2022, and 2023 Coulter AcT diff hematology calibration records revealed the laboratory performed calibration on the following dates: 2/19/20, 9/30/20, 2/15/21, 10/14/21, 10/22/21, 5/12/22, 11/11/22, and 3/2/23. Calibrations performed 10/14/21, 10/22/21, 5/12/22, and 11/11/22 were not successful. Review of 2020, 2021, 2022, and 2023 quality assessment records revealed: 1. The calibration factors were not saved for the calibration performed 5/12/22. The "List of Issues" from the 8/10/22 TC visit stated "Cal Coulter and get this updated as soon as possible." There was no documentation that service was contacted. 2. The calibration performed 11/11/22 failed and was not repeated. There was no documentation that service was contacted. The "List of Issues" from the 11/28/22 TC visit stated "Do not use the machine until Calibration is repeated." The "List of Issues" from the 2/28/23 TC visit stated "Calibrate ASAP and document corrective actions here." A handwritten note stated the calibration was performed 3/2/23.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022, and 2023 Coulter AcT diff hematology quality control and patient test records, 2020, 2021, 2022, and 2023 quality assessment records, and interview with the TC 5/3/23, the laboratory failed to ensure all patient results were evaluated when quality control results were unacceptable on 3/22/21. Findings: Review of hematology quality control records revealed the RBC (red blood cell count) quality control results were outside acceptable limits for the normal and high levels of control on 3/22/21. The controls were not re-tested. Review of patient test records revealed 4 patients (#1386314, #1374614, #13740838, #2890347) were tested on 3/22/21. Review of quality assessment records ("List of Issues") from the 7/15/21 TC visit revealed 2 of the 4 patients (#1374614, #2890347) had another CBC (complete blood count) since 3/22/21. During interview at approximately 1:50 p.m.,

	the TC verified there was no documentation available to indicate that results for 2 of the 4 patients (#1386314, #13740838) were evaluated by the laboratory director to determine whether follow-up was needed.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2020, 2021, 2022, and 2023 quality assessment activities 5/3/23, the laboratory failed to follow their quality assessment plan to identify and correct problems and prevent their recurrence. Findings: Review of the laboratory's quality assessment plan revealed "Annual Quality Assessment Requirements ... a big part of Quality Assessment is the ability to recognize and correct problems. ... Document all errors, miscommunications, complaints, etc. and remember that you must follow-up to see that your corrective action was effective. If it was not effective, you must find a different solution! ... You have been provided with a written QA policy and QA monitors, but you should document your investigations when you trouble-shoot specific problems in your labs. ..." Review of 2020, 2021, 2022, and 2023 quality assessment activities and "List of Issues" reports revealed the laboratory failed to follow their quality assessment plan and instructions from the TC after problems were identified in the following areas: 1. Reagents and supplies - see D5417 2. Calibration - see D5437 3. Quality control / Corrective action - see D5783.