Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2134965	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wellstar Vining's Health Park Urgent Care	4441 Atlanta Road Se, Suite 107, Smyrna, 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 August 30, 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:
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 Quality Control (QC) data review and staff interview, the laboratoryfailed to document corrective actions taken when QC failed to meet the laboratory's established criteria for acceptability. Findings include: 1. Hematology QC documents review for the Coulter AcTDiff II analyzer revealed Levels (L and N) were out of range on 7/10 /2022 and WBCs failed on 07/11/2022. No corrective actions were documented as of how the problem was resolved. 2. An interview with the Technical Consultant (TC) and staff on 08/30/2022 in the conference room at approximately 1:00 PM confirmed that QC values were out of range with no documented corrective action on the aformentioned dates.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Quality Control (QC) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QC guidelines are followed including regular review of instrument Quality Control (QC) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Quality Control (QC) documents review revealed the laboratory director(LD) did not review daily (QC) instrument data and implement a QC monitor program identify and correct problems for the specialty of Hematology as required in 2022. 2. An interview with staff and Technical Consultant (TC) (TP#5, pg 3 CMS 209) in the coference room on 08/30/2022, at approximately 12:55 PM confirmed the LD did not monitor and review the aformentioned (QC) data in 2022.