Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1100175	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wmg Urgent Care Cherokee Health Park	1120 Wellstar Way, Suite 105, Holly Springs, 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	On November 09, 2021 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, staff and laboratory coordinator interviews, the laboratory failed to assess, monitor, and when indicated, correct problems identified in the laboratory in 2020 and 2021. Th findings include: 1. Review of QA records revealed the laboratory director and Technical Consultant(TC) did not take necessary steps to identify and correct problems with Proficiency Testing (PT) and CBC testing on Beckman Coulter AcT DiFF II Hematology Analyzer in 2020 and 2021. 2. Corrective actions and QA activities were not documented properly in the laboratory to reflect all phases (Pre-Analytic, analytic and Post Analytic) of the QA policy in 2020 and 2021. 2. Interviews with staff and the laboratory coordinator on 09/21/ 2021 at approximately 12:20 PM in the review room confirmed that the laboratory was not monitoring QA activites appropriately in 2020 and 2021.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Hematology maintenance, Quality Control (QC) documents review and staff interviews, it was determined that the laboratory did not have a policy in place to monitor Quality Control (QC) on the Beckman Coulter AcT DiFF II Hematology analyzer in 2020 and 2021. Findings include: 1. Hematology QC review revealed there were NO Levey Jennings graphs or EQC data to monitor Quality Control runs in 2020 and 2021. 2. Staff, Technical Consultant (TC) and laboratory coordinator's interviews on 09/21/2021 at approximately 12:40 PM in the review room confirmed the laboratory did not have Levey Jennings graphs nor EQC to monitor hematology controls in 2020 and 2021.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on personnel documents review, interviews with the laboratory coordinator and office manager, the Technical Consultant (TC) performed in-complete competencies in 2020 and 2021. Findings include: 1. Annual competency assessment documents review revealed, annual competencies for Testing Personnel (TP): TP #5 (CMS 209) in 2020, TP # 11 (CMS 209) in 2021 and TP # 12 (CMS 209) in 2021 were incomplete but signed by the TC. 2. The documents were shown to the laboratory coordinator and office manager on 09/21/2021 at approximately 12:45 PM in the review room who confirmed the findings.