Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2152027	05/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Avance Care West Cary	7750 Mccrimmon Parkway, Suite 100, Cary, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's policies and procedures, review of performance verification records for the TOSOH G8 analyzer, lack of documentation and interview with compliance advisor 05/13/26, the laboratory failed to ensure the verification of precision for the Hemoglobin (Hgb)A1c testing performed on the TOSOH G8 analyzer included day to day testing variances since testing began in 02/25/26, approximately 1846 patients were tested. The performance verification records for the TOSOH G8 analyzer also failed to include the method used for the establishment of normal values for HgbA1c testing. Findings: 1. The laboratory failed to ensure the verification of precision for the HgbA1c testing performed on the TOSOH G8 analyzer included day to day testing variances. Findings: Review of the laboratory's "Verification of Performance Specification Policy" stated "... Procedure ... Precision: ... The QC material will be run 5 times for 2 consecutive days, for each analyte being tested. ... ". Review of performance verification records revealed all testing to verify percison was performed on one day, 02/23/26. Interview with compliance advisor at approximately 11:20 a.m. confirmed precision testing was performed on one day, 02/23/26, and failed to include day to day variances. They also confirmed approximately 1846 patients were tested since testing began 02/25/26. 2. The performance verification records for the TOSOH G8 analyzer failed to include

	the method used for the establishment of normal values for HgbA1c testing. Findings: Review of performance verification records revealed no documentation of the method used to establish the normal values for HgbA1c testing. Interview with compliance advisor at approximately 11:20 a.m. confirmed the performance verification records failed to include the method used for the establishment of normal values for the HgbA1c testing. They stated they utilized the manufacturer's normal ranges. B. Based on review of the laboratory's policies and procedures, review of performance verification records for the Cepheid Gene Xpert analyzer, and interview with compliance advisor 05/13/26, the laboratory failed to ensure the verification of precision for the CT (chlamydia trachomatis) and NG (Neisseria gonnorhoeae) testing performed. Approximately 28 patients were tested since testing began on 03/20/26. Findings: Review of the laboratory's "Verification of Performance Specification Policy" stated "... Procedure ... Precision: ... The QC material will be run 5 times for 2 consecutive days, for each analyte being tested. ... " Review of performance verification records for the Cepheid Gene Xpert revealed all precision testing for CT /NG was performed on the same day (11/25/25) by one testing personnel. Interview with compliance advisor at approximately 12:35 p.m. confirmed all precision testing was performed on one day, 11/25/25. The compliance advisor also confirmed approximately 28 patients were tested since testing began on 03/20/26.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on deficiency cited at D5421, absence of documentation and interview with compliance advisor 05/13/26, the laboratory director (LD) failed to document review and approval of the performance verifications for the TOSOH G8 ands Gene Xpert analyzers prior to beginning patient testing to ensure the precision verification included day to day variances, and to ensure TOSOH G8 normal range verification included the method used to establish the normal ranges of the HgbA1c testing. Findings: 1. TOSOH G8 The LD failed to ensure precision verification included day to day variances and failed to include the method used to establish normal ranges of the HgbA1c testing performed on the TOSOH G8 analyzer. See D5421. Review of performance verification records for the HgbA1c testing revealed no documentation the LD had reviewed and approved the performance verifications prior to beginning patient testing in February of 2026. Interview with compliance advisor at approximately 11:20 a.m. confirmed the performance verification records for the HgbA1c testing failed to include the review and approval of the LD. 2. Cepheid Gene Xpert Review of performance verification records for the Cepheid Gene Xpert revealed all testing for verification of precision was performed on the same day (11/25 /25) by one testing personnel. See D5421. Interview with compliance advisor at approximately 12:35 p.m. confirmed the LD failed to review and approve the performance verification records for the Cepheid Gene Xpert for CT/NG testing prior to the start of patient testing on 03/20/26.