

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0945905	(X3) Date Survey Completed 09/23/2026
Name of Provider or Supplier Medstar Laboratory Inc	Street Address, City, State 4531 W Harrison St, Hillside, IL	
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: A) Based on review of laboratory policies and procedures, review of laboratory records, and interview with the laboratory director; the laboratory failed to biannually verify method accuracy of Lipoprotein A testing in the subspecialty of routine chemistry by running unknown, blind patient samples in duplicate for four of four alternate proficiency testing (APT)/split testing events reviewed in 2025 through the date of survey, 09/23/2026. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing (PT) Policy", which stated, under "Alternate Performance Assessment", "a. For tests for which CMS does not require proficiency testing (PT), the laboratory at least semiannually exercises an alternative performance assessment system for determining the reliability of analytic testing. "b. Semiannual alternate performance assessment must be performed on tests for which external PT is not available. "c. The laboratory will use split sample analysis with an established in-house method or Split-sample analysis with reference, or other laboratories." 2. Review of laboratory APT/split testing records revealed the laboratory failed to verify the accuracy, but rather the precision, of Lipoprotein A testing in the subspecialty of routine chemistry by running samples in duplicate between testing personnel (TP) utilizing the same methodology of testing, the Beckman Coulter AU5800. APT Event 1 - 2025 Performed by TP #1 on 01/10/2025 on the AU5800. Performed by TP #2 on 01/10/2025 on the AU5800. APT Event 2 - 2025 Performed by TP #6 on 07/15/2025 on the AU5800. Performed by TP #7 on 07/15/2025 on the AU5800. APT Event 1 - 2026 Performed by TP #1 on 01/20/2026 on the AU5800. Performed by TP #2 on 01/21/2026 on the AU5800. APT Event 2 - 2026 Performed by TP #6 on 08/06/2026 on the AU5800. Performed by TP #7 on 08/07

/2026 on the AU5800. 3. Interview with the laboratory director on 09/22/2026, at 4:17 pm, confirmed the laboratory failed to biannually verify method accuracy of Lipoprotein A testing in the subspecialty of routine chemistry by running unknown, blind patient samples in duplicate for four of four APT/split testing events reviewed in 2025 through the date of survey, 09/23/2026. B) Based on review of laboratory policies and procedures, review of laboratory records, and interview with the laboratory director; the laboratory failed to biannually verify method accuracy of systemic lupus erythematosus (SLE)/anti-deoxyribonucleoprotein (anti-DNP) testing in the subspecialty of general immunology by running unknown, blind patient samples in duplicate for four of four alternate proficiency testing (APT)/split testing events reviewed in 2025 through the date of survey, 09/23/2026. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing (PT) Policy", which stated, under "Alternate Performance Assessment", "a. For tests for which CMS does not require proficiency testing (PT), the laboratory at least semiannually exercises an alternative performance assessment system for determining the reliability of analytic testing. "b. Semiannual alternate performance assessment must be performed on tests for which external PT is not available. "c. The laboratory will use split sample analysis with an established in-house method or Split-sample analysis with reference, or other laboratories." 2. Review of laboratory APT/split testing records revealed the laboratory failed to verify the accuracy, but rather the precision, of SLE/anti-DNP testing in the subspecialty of general immunology by running samples in duplicate between testing personnel (TP) utilizing the same methodology of testing, Arlington Scientific SLE Slide Test. APT Event 1 - 2025 Performed by TP #6 on 01/09/2025 utilizing SLE Slide Test. Performed by TP #2 on 01/10/2025 utilizing SLE Slide Test. APT Event 2 - 2025 Performed by TP #7 on 07/17/2025 utilizing SLE Slide Test. Performed by TP #9 on 07/17/2025 utilizing SLE Slide Test. APT Event 1 - 2026 Performed by TP #2 on 01/16/2026 utilizing SLE Slide Test. Performed by TP #1 on 01/17/2026 utilizing SLE Slide Test. APT Event 2 - 2026 Performed by TP #9 on 08/05/2026 utilizing SLE Slide Test. Performed by TP #7 on 08/06/2026 utilizing SLE Slide Test. 3. Interview with the laboratory director on 09/22/2026, at 4:17 pm, confirmed the laboratory failed to biannually verify method accuracy of SLE/anti-DNP testing in the subspecialty of general immunology by running unknown, blind patient samples in duplicate for four of four APT/split testing events reviewed in 2025 through the date of survey, 09/23/2026.