Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0322676	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Annville Medical Clinic	**Street Address, City, State** 78 Highway 3444, Annville, KY	
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 recertification survey was conducted on 07/29/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
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: Based on a review of patient test reports and confirmed in staff interview, the laboratory failed to verify 1 of 1 reference intervals for Urine testing for their patient population. Findings include: 1. Review of 5 patient test reports titled "Lab Test" for years 2023, 2024, and 2025 revealed 1 unisex reference interval for Urine testing: Clarity: Clear Specific Gravity 1.005-1.030 PH 5.0-7.5 Albumin/Protein Negative-Trace Glucose Negative Ketones Negative Bilirubin Negative Blood Negative Nitrates Negative Urobilinogen 0.2-1.0 Leukocytes Negative WBC 0-5 RBC 0-2 Epithelial Cells 0-10 Bacteria None-Few 2. During an interview on 07/29/2025 at 10:45 a.m. in the administrative office, the Rural Health Coordinator was asked to provide documentation of verification of the reference intervals in use for their patient population. No documentation was provided. This confirmed the findings. Word Key: PH = Potential of Hydrogen WBC= White Blood Cell Count RBC = Red Blood Cells