Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0685582	06/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Public Health-Dayton & Montgomery	117 South Main Street, Dayton, OH	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Laboratory Director (LD), the laboratory failed to ensure reagents utilized for the processing of moderate complexity Gram stains were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect 207 out of 207 Gram stain test procedures performed in the subspecialty of Bacteriology between 04/17/2024 through 07/10/2024. Findings Include: 1. Review of the laboratory's policy and procedure "MEDICAL AND HAZARDOUS WASTE DISPOSAL" approved by the Laboratory Director via signature and date on 01/02/2024 and provided on the date of inspection did not find any instructions to not utilize reagents when they had exceeded their expiration dates. 2. Direct observation of the laboratory's flammable cabinet found three StatLab brand, 1-gallon plastic containers of acetone with the expiration date of 01/31/2024. 3. The LD confirmed the above listed reagents were expired and continued to be utilized for patient Gram stain tests when they had exceeded their expiration dates. The interview occurred on 06/25/2024 at 12:15 p.m.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to check and document the positive and negative reactivity of control organisms using gram stains each week of use. This deficient practice had the potential to affect 207 out of 207 Gram stain test procedures performed in the subspecialty of Bacteriology between 04/17/2024 through 07/10/2024. Findings: 1. Review of the policy and procedure "GRAM STAIN" approved by the LD via signature and date on 01/02/2024 did not find any mention of checking and documenting the positive and negative reactivity of control organisms using gram stains each week of use. 2. Review of the "STAT LAB EXTERNAL CONTROL QC LOG-REIBOLD, GRAM STAIN TEST" Gram stain QC log sheet from 04/17/2024 through 06/10/2024 found the following quality control information: "Date QC Code 04/17/2024 New Lot 06/10/2024 Invalid Patient Test" 3. Review of the "Lab Results Analysis Report" log for Gram stains from 04/17/2024 through 07/10/2024 found 207 patients tested. 4. The inspector requested documentation of the positive and negative reactivity of control organisms using gram stains for each week of testing from the LD. The LD confirmed the laboratory failed to check and document the positive and negative reactivity of control organisms using gram stains each week of use and could not provide the requested information. The interview occurred on 06/25/2024 at 11:45 a.m.