Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657005	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Allegheny County Health Department	3901 Penn Avenue, Pittsburgh, PA	

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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Premier EHEC quality control (QC) records, and interview the technical supervisor (TS) #3, the laboratory failed to document QC procedures each day of patient testing in 2020 and 2021. Findings Include: 1. The Premier EHEC package insert states, "The positive and negative controls must be used with each assay run". 2. On the day of survey, 05/10/2022 at 11:45 am, review of the Premier EHEC quality QC records revealed, the laboratory did not document QC each day of patient testing from 05/10/2020 to 05/10/2022. 3. The TS #3 confirmed the findings above on 05/10/2022 around 12:00 PM.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on lack of documentation and interview with the Technical Supervisor (TS)#4, the laboratory failed to evaluate and document the relationship between the 2 of 2 Biofire FilmArray analyzers at least twice in 2020 and 2021. Findings Include: 1. On the day of survey, 05/10/2022, the laboratory could not provide documentation for the comparison of test results between 2 of 2 Biofire FilmArray analyzers for the gastrointestinal panel twice annually from 05/10/2020 to 05/10/2022. 2. The TP#4 confirmed the finding above on 05/10/222 around 12:00 pm.