Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657005	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Allegheny County Health Department	**Street Address, City, State** 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interviews with technical supervisors (TS) #2 and (TS) #3, the laboratory failed to establish and follow written policies to continually monitor, assess, and correct problems identified in the analytic systems when immunology and virology testing was performed from 05/10/2022 to the day of survey. Findings include: 1. On the day of survey, 03/06/2024, review of the laboratory's Sure-Vue Rapid plasma reagin (RPR) card test records and the Panther 2 Lab Room Temp and Humidity records revealed the laboratory failed to document the following when Immunology and Virology testing was performed from 05/10/2022 to 03/06/2024: - Lot number and expiration date of RPR antigen reagent: 12 of 12 days in May 2022, 13 of 13 days in June 2022, and 5 of 8 days in December 2022. - Temperature of RPR antigen reagent to meet the laboratory's established acceptable range (23-29 C) prior to use: 12 of 12 days in May 2022, 13 of 13 days in June 2022, and 5 of 8 days in December 2022. - Weekly verification of accuracy of Sure-Vue RPR card testing (dispensing bottle and speed check) for 5 of 5 weeks in May 2022, 4 of 4 weeks in June 2022, and 3 of 4 weeks in December 2022. - Corrective action taken when the % relative humidity fell outside the laboratory's established acceptable criteria for the Panther 2 (20-85%) for 11 of 20 days in January 2023 and 9 of 19 days in February 2023. - Maintenance performed on the Ambient Digital Hygrometer (serial number: 200780143) expired: 12/05/2022. 2. The laboratory could not provide

	documentation for the corrective actions taken when failures occurred in the analytic system from 05/10/2022 to 03/06/2024. 3. TS #2 and TS #3 confirmed the findings above on 03/06/2024 at 2:10 pm.