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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0670586 | (X3) Date Survey Completed 05/25/2022 |
| Name of Provider or Supplier Fairfax County Health Dept Laboratory | Street Address, City, State 10310 Layton Hall Drive, Fairfax, VA | |
| 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 | An announced CLIA Recertification survey was conducted at the Fairfax County Health Department Lab on May 24-25, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. |
| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, lack of documentation and interviews, the lab failed to retain API E Reagent QC records from 03/06/20 up to 04/30/21 (total 13 months). Findings include: 1. Review of the API E Reagent QC records revealed lack of documentation of the performance of QC procedures from 03/06/20 up to 04/30/21 (total 13 months). An interview with the technical supervisor on 05/24/22 at approximately 10 AM revealed that the records could not be located at the date of survey on 05/24/22. 2. An exit interview with the technical supervisors, lab director, and quality assurance manager on 05/24/22 at approximately 1500 confirmed the findings.</p> |
| D5479 | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies</p> |

and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the review of daily logs, quality control (QC) records, manufacturer instructions, lack of documentation, and interviews, the lab failed to follow the manufacturer instructions for utilizing fresh 18-24 hour cultures when performing QC procedures with the API 20 E Reagent QC on 05/06/21. Findings include: 1. Review of the daily logs for bacteriology and interview with the technical supervisor on 05/24/22 at approximately 10 AM revealed the testing personnel re-sub the *Enterobacter cloacae*, *Proteus hauseri* and *Myroides odoratus* QC organisms each week for fresh growth. 2. Review of the API 20 E Reagent QC Test Kit QC logs from April 2020 up to April 2022 revealed QC organisms cultured on 04/26/21. The lab performed QC procedures on 05/06/21. The records lacked documentation of testing personnel re-culturing or fresh culture growth of QC organisms 18-24 hours prior to performing the QC procedures on 05/06/21. The surveyor requested to review documentation of the testing personnel re-subbing the aforementioned QC organisms 18-24 hours prior to performing API 20 E Reagent QC procedures on 05/06/21. The documentation was not available for review. 3. Review of the API 20 E Reagent QC manufacturer instructions revealed the following statement, "Preparation of Cultures- Fresh 18-24 hour cultures of the recommended organism should be used for quality control procedures." 4. An exit interview with the technical supervisors, lab director, and quality assurance manager on 05/24/22 at approximately 1500 confirmed the findings.