

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2165628	(X3) Date Survey Completed 03/29/2023
Name of Provider or Supplier Accurate Medical Laboratories	Street Address, City, State 3927 Blenheim Blvd Unit 102-D, 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 Accurate Medical Laboratories on March 30, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
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: A. Based on the review of the laboratory's policy and procedures, quality control (QC) records, lack of documentation, and interviews, the lab failed to follow their established policy and retain documentation of the performance of the QC procedures for CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method for fifty-three (53) of fifty-nine (59) patient testing days from November 14, 2021 up to March 16, 2022. The findings include: 1. Review of the laboratory's policies and procedures revealed a procedure, "CLARCS SARS COV-2 RT PCR 1.0" Laboratory Developed Test (LDT) method utilizing the real-time PCR instrument, Analytik Jenna Q-Tower 84-G. The procedure stated, "5.3 Reaction Setup...Make sure that at least one Positive Control and one Negative Control is used per run." On March 29, 2023 at approximately 10:30 AM, the inspector inquired with the Laboratory Director (LD) the location of the above listed instrument. The LD stated the instrument was sent back to the company in September 2022. 2. Review of the laboratory's policies and procedures revealed a policy, "General Laboratory Operational Policies" (signed by Laboratory Director on 5/21/2020), which stated, "ANALYTICAL TESTING: 1. At least 2 levels of control will be run and have values within acceptable ranges each day of testing for all procedures before patient values are tested and reported. 2. QC</p>

results will be maintained for a minimum of 2 years... DOCUMENT STORAGE: 1. All instrument printouts will be saved for a minimum of two years." 3. Review of available QC documents for the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method revealed a handwritten document, "QC LOG COVID-19 RT-PCR", with handwritten QC results for 59 patient testing days from November 14, 2021 up to March 16, 2022. The inspector requested to review the instrument printouts for the QC performed utilizing the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method. The laboratory provided no QC instrument records to review for the following 53 dates: 11/14/2021, 11/15/2021, 11/17/2021, 11/18/2021, 11/19/2021, 11/20/2021, 11/21/2021, 11/22/2021, 11/23/2021, 11/24/2021, 11/25/2021, 12/03/2021, 12/07/2021, 12/14/2021, 12/15/2021, 12/21/2021, 12/28/2021, 12/30/2021, 01/02/2022, 01/05/2022, 01/06/2022, 01/07/2022, 01/08/2022, 01/09/2022, 01/13/2022, 01/15/2022, 01/16/2022, 01/26/2022, 01/27/2022, 02/01/2022, 02/02/2022, 02/04/2022, 02/05/2022, 02/08/2022, 02/09/2022, 02/10/2022, 02/12/2022, 02/16/2022, 02/19/2022, 02/20/2022, 02/23/2022, 02/24/2022, 02/25/2022, 02/26/2022, 02/28/2022, 03/01/2022, 03/02/2022, 03/03/2022, 03/07/2022, 03/09/2022, 03/10/2022, 03/11/2022, and 03/16/2022. A total of 53 dates. In an interview with the LD on March 29, 2023 at approximately 11:00 AM, the LD stated, "The instrument was sent back in September 2022 and I do not have access to the files. They are stored on the instrument. I will try to retrieve them from the company." The laboratory provided no instrument printouts to review. 4. In an exit interview with the laboratory director, on March 29, 2023 at approximately 12:15 PM, the findings were confirmed. B. Based on the review of the laboratory's policy and procedures, patient records, lack of documentation, and interviews, the lab failed to follow their established policy and retain documentation of the patient's instrument records for the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method for one-hundred fourteen (114) of one-hundred seventy (170) patients from November 14, 2021 up to March 16, 2022. The findings include: 1. Review of the laboratory's policies and procedures revealed a procedure, "CLARCS SARS COV-2 RT PCR 1.0" Laboratory Developed Test (LDT) method utilizing the real-time PCR instrument, Analytik Jenna Q-Tower 84-G. On March 29, 2023 at approximately 10:30 AM, the inspector inquired with the Laboratory Director (LD) the location of the above listed instrument. The LD stated the instrument was sent back to the company in September 2022. 2. Review of the laboratory's policies and procedures revealed a policy, "General Laboratory Operational Policies" (signed by Laboratory Director on 5/21/2020), which stated, "POST ANALYTICAL TESTING: 1. Results will be printed out from each analyzer, manually recorded for each test kit, and put in the patient's medical record for permanent storage. 2. Duplicate copies of all patient results generated in the laboratory will be saved for a minimum of 2 years...DOCUMENT STORAGE: 1. All instrument printouts will be saved for a minimum of two years." 3. Review of available patient test result documents for the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method revealed a handwritten document, "Patient's Test Result Log", with handwritten results for 170 patients from November 14, 2021 up to March 16, 2022. The inspector requested to review the patient instrument records for the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method. The laboratory provided patient instrument records for 56 patients to review. The inspector requested to review the patient instrument records for the remaining 114 patients. In an interview with the LD on March 29, 2023 at approximately 11:00 AM, the LD stated, "The instrument was sent back in September 2022 and I do not have access to the files. They are stored on the instrument. I will try to retrieve them from the company." The laboratory provided no instrument printouts to review. 4. In an exit interview with the laboratory director, on March 29, 2023 at approximately 12:15 PM, the findings were confirmed.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), initial performance specification records, testing personnel (TP) records, lack of documentation, and interview, the technical supervisor failed to provide documentation of the evaluation of training of one of one TP for the CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method prior to patient testing on November 14, 2021. Findings include: 1. Review of the CLIA CMS-209 Form revealed one TP performing patient testing. 2. Review of the initial performance specifications records for the new CLARCS SARS COV-2 RT PCR 1.0 Laboratory Developed Test (LDT) method revealed patient testing utilizing the new method began on November 14, 2021. 3. Review of TP records revealed a training document for the TP completed on November 11, 2022. Further review of the TP's record revealed a lack of documentation of the evaluation of the training for the new CLARCS SARS COV-2 method prior to patient testing on November 14, 2021. The surveyor requested documentation of the evaluation of the TP's training. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director, on March 29, 2023 at approximately 12:15 PM, the findings were confirmed.