

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2215852	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier Trugenomix Endeavor Lab	Street Address, City, State 11100 Endeavor Ct Suite 115, Manassas, 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 Trugenomix Endeavor Lab on May 24, 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:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, accuracy verification records, lack of documentation, and interviews, the laboratory failed to perform method accuracy verification twice annually for the the Yale Saliva Direct SARS CoV-2 (COVID-19) method in calendar year 2022 (dates of review 2021 until May 24, 2023). The findings include: 1. During an entrance interview with the laboratory director (LD) and technical supervisor (TS) on May 24, 2023 at approximately 9:00 AM, the LD and TS stated the laboratory performs COVID-19 testing utilizing the Yale Saliva Direct Method. 2. Review of the laboratory's policies and procedures revealed a policy, "Saliva Direct Split Sample Testing", with the following statements, "Spilt sample testing is used to compare lab methodology and testing result accuracy between clinical labs." 3. Review of the laboratory's "split sample" or twice annual accuracy verification records for the Yale Saliva Direct SARS CoV-2 (COVID-19) method from 2021 until May 24, 2023 revealed split sample testing performed with an outside laboratory in 5/2021, 12/2021 and 9/2022. The surveyor requested to review documentation of the laboratory's second accuracy verification for 2022. The laboratory provided no further documentation of the 2022 accuracy verification. The</p>

TS stated "We sent out a split-sample analysis with another laboratory on 5/18/2023."
4. In an exit interview with the LD and TS on May 24, 2023, at approximately 12:30 PM, the findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, equipment calibration records, interviews, and lack of documentation, the laboratory failed to follow manufacturer's instructions and perform pipette calibration every six (6) months for three (3) of 3 multi-channel pipettes and fourteen (14) of 14 fixed volume single channel pipettes utilized for SARS CoV-2 (COVID-19) testing in calendar year 2022 until the date of the survey on May 24, 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a "QA Review Plan" with the following statements: "In order to ensure that our lab is adhering to all protocols for best performance practices, the following quality parameters will be reviewed..." "May-Calibrations/Equipment, thermometer, pipettor (manual, electronic)." The surveyor requested to review a laboratory policy for pipette calibrations. The laboratory provided no policy for review. 2. In an interview with the technical supervisor (TS) on May 24, 2023 at approximately 10:30 AM, the surveyor inquired how pipette calibrations were performed. The TS stated, "The pipettes are sent to an outside vendor every 6 months for calibration". 3. Review of the laboratory's pipette calibration records from October 2021 until the date of the survey on May 24, 2023 revealed the following pipettes were calibrated on 11/10/2021 with expiration date of 5/10/2022, and 6/16/2022 with expiration date of 12/31/2022: Eppendorf multichannel pipettes-Serial Number (SN) O51546G and SN P59581G; Eppendorf single volume pipettes-SN J21211H and G32228H; Rainin Pipet-Lite multichannel pipette-SN B1208405T; Rainin Pipet-Lite single volume pipettes-SN B540516933, SN E0300306A, SN I0661464A; IVYX Scientific single volume pipettes-SN YE189AL0089337, SN YE188AL0081113, SN YE188AL0081118, SN YE189AL0117857, SN YE189AL0117874, SN YE193AM0059055; Genemate single volume pipettes-SN 641130139 and SN 841150010; Huawei single volume pipette-SN 17020708. The surveyor requested to review the pipette calibration records for May 2022, November 2022 and May 2023. The laboratory provided no documentation to review. The TS stated, "I sent the pipettes out for calibration on May 21, 2023." 4. Review of the Eppendorf, Rainin, IVYX Scientific, Genemate and Huawei pipette manufacturer's instructions for calibration/maintenance stated pipette calibrations should be performed at six month intervals. 5. In an exit interview with the Lab Director and TS on May 24, 2023, at approximately 12:30 PM, the findings were confirmed.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a tour, review of the laboratory's policies and procedures, maintenance documents, lack of documentation, and an interview, the laboratory failed to follow their established policy and document function checks for the Scientific Industries Microplate Genie, and Benchmark Scientific Platefuge Microcentrifuge monthly for five (5) of twenty (20) months from October 2021 until the date of the survey on May 24, 2023. The findings include: 1. During a tour of the laboratory on May 24, 2023 at approximately 9:00 AM, the surveyor noted the laboratory utilizes the Scientific Industries Microplate Genie, and Benchmark Scientific Platefuge Microcentrifuge with the Yale Saliva Direct method. 2. Review of the laboratory's maintenance records revealed a Scientific Industries Microplate Genie Validation Log (S/N: M4A-1463), and a Benchmark Scientific Platefuge Microcentrifuge Validation Log (S/N: A101804414). The logs stated "Validate at least once a month by a technician using a tachometer (Westward, MN:5URH0A)." Each log was completed with dates of validation from October 2021 until December 2022. The surveyor requested to review documentation of validations for the Microplate Genie and Platefuge Microcentrifuge from January 2023 until the date of the survey on May 24, 2023. The laboratory provided no documentation to review. 3. In an exit interview with the Lab Director and Technical Supervisor on May 24, 2023, at approximately 12:30 PM, the findings were confirmed.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, calibration and maintenance records, lack of documentation, and an interview, the laboratory failed to follow their established Quality Assurance (QA) policy for the review of their analytic systems for twenty (20) of 20 months from October 2021 until May 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "QA Review Plan", with the following statements: "In order to ensure that our lab is adhering to all protocols for best performance practices the following quality parameters will be reviewed. January-Sanitization/Temperature, February-Laboratory Personnel review/Personnel competency records, Personnel Training records up to date and signed appropriately, March-Test Menu, April-Reagents, May-Calibrations /Equipment, thermometer, pipettor, June-Bi-annual review, July-N/A, August-Equipment, September-Lab Maintenance/Safety, October-Lab Director Review/QC Plan/SOPs, November-Invoices/Receiving, and December-N/A." 2. Review of the laboratory's records revealed lack of documentation of the QA reviews from October

2021 until the date of the survey on May 24, 2023, a total of 20 months. The surveyor requested to review the missing QA documentation. The laboratory provided documentation of the "Lab Director Review of SOPs, Temperature Check, Proficiency Testing, Calibration and Maintenance of Instruments, and Competency Assessment" performed on May 19, 2023. The laboratory provided no further documentation to review. 3. In an exit interview with the Lab Director and Technical Supervisor on May 24, 2023 at approximately 12:30 PM, the findings were confirmed.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory policy and procedure manual, lack of documentation, and interviews, the laboratory director (LD) failed to follow the established policy and ensure the initial training/competency evaluation was performed for one (1) of 1 new testing personnel responsible for performing high complexity Yale Saliva Direct SARS CoV-2 (COVID-19) testing in calendar years 2022. The findings include: 1. Review of the CMS-209 form with the laboratory director (LD) and technical supervisor (TS), during an entrance interview on May 23, 2023 at approximately 9:15 AM, revealed 1 new testing personnel (TP) responsible for performing high complexity COVID-19 testing since the last inspection in September 2021. (See Personnel Code Sheet.) 2. Review of the laboratory personnel file for TP A revealed TP A was hired in August 2022. The surveyor requested to review the initial training/competency assessment documentation for TP A. The laboratory provided no documentation of TP A's training and initial competency for review. 3. Review of the laboratory's policies and procedures revealed a "Quality Assessment Plan" with the following statements, "Quality Control Type-Training. Frequency-With each new testing personnel and when indicated. Criteria for Acceptability (Range of Acceptable Values)-Successful demonstration of test performance. Document training." 4. In an exit interview with the LD and TS on May 24, 2023 at approximately 12:30 PM, the findings were confirmed.