

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2215852	<b>(X3) Date Survey Completed</b> 08/14/2024
<b>Name of Provider or Supplier</b> TruGenomix Endeavor Lab	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An off-site CLIA proficiency testing desk review of TruGenomix Endeavor Lab was completed on August 14, 2024 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was found not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
<b>D2004</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and an email, the laboratory failed to remain enrolled with their designated 2024 PT program for the subspecialty of Virology for the calendar year of 2024 before designating a change in PT program.. Record review was from January 2024 until August 2024. The findings include: 1. Review of the laboratory's PT records and CASPER-0155 report revealed the laboratory participated in the following events and PT programs: American Proficiency Institute-Virology 2024 Events 1 and 2; College of American Pathologists (CAP)-Virology 2024 Event 2. 2. In an email from the technical supervisor (TS) on August 13, 2024 at 7:42 PM, the TS stated, "We received the PT samples from CAP as part of our annual contract before deciding to close the laboratory services and decided to run just as practice but not as proof of proficiency for the COVID-19 qPCR test. We have not run any patient samples since March 2023."</p>
<b>D2016</b>	<b>SUCCESSFUL PARTICIPATION</b>

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and American Proficiency Institute (API) for 2024 (Events one, and two), the laboratory failed to successfully participate in a proficiency testing program approved by Health and Human Services (HHS) for the subspecialty of Virology. Refer to D2064.

**D2064**

**VIROLOGY**

CFR(s): 493.831(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report, American Proficiency (API) evaluation reports for 2024 (Events one, and two), and an email, the laboratory failed to achieve satisfactory performance (80%) for the subspecialty Virology for two consecutive proficiency testing (PT) events reviewed. The laboratory had unsatisfactory scores for Virology for API 2024 Event one (1) and Event two (2) resulting in an initial unsuccessful participation. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2024 Event 1: Virology = 0%, 2024 Event 2: Virology = 0%, Failure to participate. 2. A review of the laboratory's 2024 API PT scores for the subspecialty virology confirmed the above findings resulting in an initial unsuccessful participation for the subspecialty of Virology. 3. In an email from the laboratory director (LD) on August 12, 2024 at 11: 14 PM, the LD confirmed the unsuccessful participation.