

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2090400	<b>(X3) Date Survey Completed</b>  04/09/2024
<b>Name of Provider or Supplier</b>  Ut Medical Group, Inc	<b>Street Address, City, State</b>  930 Madison Ave, 5th Floor, 544a And 545a, Memphis, TN	
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>	A complaint survey was completed on April 9, 2024. The laboratory was found NOT to be in compliance with the following 42 CFR PART 493, Requirements for Laboratories. The complaint was substantiated. The laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: CFR 493.801 Condition: Enrollment and testing of samples CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory failed to ensure testing and reporting of proficiency samples of another CLIA laboratory did not occur. (Refer to D2013).</p>
<b>D2013</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency</p>

testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of the laboratory's College of American Pathologists (CAP) PT records, and staff interviews, the laboratory failed to ensure the receipt of Sudden Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) proficiency testing samples from another laboratory was reported to the Center of Medicaid and Medicare Services (CMS) in four of four testing events. The findings include: 1. Observation of the laboratory on 03.18.2024 at 12:30 pm revealed patient testing performed for SARS- CoV-2. 2. A review of the laboratory's CAP proficiency testing records revealed the evaluation and enrollment reports were for a laboratory with CLIA number 44D2091956 for the following events: a. 2022 event two, COV2-04, COV2-05, COV2-06 b. 2023 event one, COV2-01, COV2-02, COV2-03 c. 2023 event two, COV2-04, COV2-05, COV2-06 d. 2024 event one, COV2-01, COV2-02, COV2-03 The PT attestation statements had all been signed by current and previous testing personnel. The 2024 PT enrollment showed the SARS-CoV-2 enrollment using the CLIA number for another laboratory (44D2091956). 3. Interview with the quality manager and lead histotech on 03/19/24 at 4:30 pm confirmed the laboratory was participating in proficiency for SARS CoV-2 using PT samples that were assigned to a laboratory with the CLIA number 44D2091956 in 2022, 2023 and 2024.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's CAP proficiency testing records, laboratory procedure manual and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. (Refer to D6089).

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's CAP PT records, and staff interview, the Laboratory Director failed to ensure receipt of proficiency testing samples from another laboratory was reported to CMS for four of four proficiency testing events in 2022-2024. (Refer to D2013)