

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1024207	<b>(X3) Date Survey Completed</b>  02/11/2025
<b>Name of Provider or Supplier</b>  Gu Inc	<b>Street Address, City, State</b>  522 West Newton Street Suite 300, Greensburg, PA	
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>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of the PT results obtained for 6 of 6 API Microbiology testing events in 2023 and 2024. Findings Include: 1. On the day of survey, 02/11/2025 at 12:41 pm., review of the laboratory's API Microbiology PT records revealed that the laboratory did not verify the accuracy for the following analytes (UTI panel) that were not graded by the PT agency in 2023 and 2024: 2023 1st event: Molecular Mycology - Candida tropicallis (UTI-01) Molecular Resistance Genes - CTX-M Group 1 (UTI-01 through UTI-04) - dfrA, KPC, NDM, qnr, sul (UTI-01, UTI-03, UTI-04) - mecA (UTI-01, UTI-02, UTI-03, UTI-05) - vanA/B (UTI-01 through UTI-05) 2023 2nd event: Molecular Resistance Genes - CTX-M Group 1, dfrA, KPC, NDM, qnr, sul (UTI-07, UTI-09) - mecA (UTI-06 through UTI-10) - vanA and vanB (UTI-06, UTI-08 through UTI-10) 2023 3rd event: Molecular Resistance Genes - AmpC , CTX-M, CTX-M Group 1, CTX-M Group 2 (UTI-12 through UTI-14) - dfrA, sul (UTI-12 through UTI-15) - mecA (UTI-11, UTI-12, UTI-14, UTI-15) - qnr (UTI-12, UTI-13) - vanA (UTI-11, UTI-12, UTI-14) - vanB (UTI-11 through UTI-14) 2024 1st event: Molecular Resistance Genes - CTX-M Group 1, dfrA, qnr, sul (UTI-02, UTI-03) - mecA, vanA, vanB (UTI-01 through UTI-05) 2024 2nd event: Molecular Resistance Genes - CTX-M Group 1, dfrA, KPC, NDM, sul (UTI-06, UTI-07, UTI-09, UTI-10) - mecA, vanA, vanB (UTI-06 through UTI-10) - qnr (UTI-06, UTI-08 through UTI-10) 2024 3rd event: Molecular Resistance Genes - CTX-M Group1, dfrA, KPC, NDM, qnr, sul (UTI-11, UTI-13 through UTI-15) - mecA (UTI-11 through UTI-15) - vanA (UTI-12</p>

through UTI-14) - vanB (UTI-11 through UTI-14) 2. The API Proficiency Testing performance Evaluation form states "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded. 3. The GS confirmed the findings above on 02/11/2025 at 2:15 pm.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of the PT results obtained for 4 of 6 API Microbiology testing events in 2023 and 2024. Findings Include: 1. On the day of survey, 02/11/2025 at 12:41 pm., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analytes (molecular bacteria-urine) that were not scored by the PT agency in 2023 and 2024: 2023: - 1st event: Enterobacter cloacae (UTI-05), Staphylococcus sp. (UTI-04). - 3rd event: Ureaplasma urealyticum (UTI-14) 2024: - 2nd event: Streptococcus pyogenes (UTI-06) - 3rd event: Staphylococcus sp (UTI-15) 2. The API Proficiency Testing performance Evaluation form states " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. The GS confirmed the findings above on 02/11/2025 at 2:15 pm.