

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0895971	<b>(X3) Date Survey Completed</b>  04/02/2024
<b>Name of Provider or Supplier</b>  Wardenburg Health Center	<b>Street Address, City, State</b>  1900 Wardenburg Drive, Boulder, CO	
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>D5205</b>	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment plan (QA plan), the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to establish a policy or procedure to document complaints, or establish a policy or procedure to investigate complaints as needed since the laboratory's last survey was conducted on 2/22/2022. The laboratory performs approximately 44,802 tests annually. Findings include: 1. Based on a review of the laboratory's QA plan revealed the laboratory failed to establish a policy or procedure to document complaints, or establish a policy or procedure to investigate complaints as needed. 2. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a policy or procedure to document complaints, or establish a policy or procedure to investigate complaints as needed. 3. An interview with the GS, on 4/2/2024, at approximately 1:00 PM, confirmed that the laboratory failed to establish a policy or procedure to document complaints, or establish a policy or procedure to investigate complaints as needed.</p>
<b>D5207</b>	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's quality assessment plan (QA plan), the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results since the laboratory's last survey was conducted on 2/22/2022. The laboratory performs approximately 44,802 tests annually. Findings include: 1. Based on a review of the laboratory's QA plan, revealed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Based on a review of the laboratory's policies and procedures manual revealed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 3. Based on an interview with the GS, on 4/2/2024, at approximately 1:05 PM confirmed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.