

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2180522	<b>(X3) Date Survey Completed</b>  06/06/2022
<b>Name of Provider or Supplier</b>  Contamination Source Identification, Llc	<b>Street Address, City, State</b>  419 14th Street, Huntingdon, 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>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Quality Manager (QM), the laboratory failed to evaluate and document the relationship between 2 of 2 Thermofisher ABI-7500 rt-q Polymerase Chain Reaction (PCR) for SARS-CoV-2 RNA test result at least twice in 2020 and 2021. Findings Include: 1. On the day of survey, 06/06/2022 at 12:55 pm, the laboratory could not provide documentation for the comparison of test results between 2 of 2 Thermofisher ABI-7500 rt-q PCR twice annually from 07/21/2020 to 12/31/2021. 2. The laboratory performed the following SARS-CoV-2 RNA examinations: - 07/21/2020 to 12/31/2020: 47,234 patient testing - 01/01/2021 to 12/31/2021: 9, 298 patient testing 3. The QM confirmed the findings above on 06/06/222 around 02:45 pm.</p>