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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0283099 | <b>(X3) Date Survey Completed</b><br><br>12/05/2019 |
| <b>Name of Provider or Supplier</b><br><br>Toxicology Testing Service Inc  | <b>Street Address, City, State</b><br><br>5426 Nw 79 Ave, Doral, FL        |   |
| 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>   |
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| <b>D0000</b>              | A recertification survey conducted at Toxicology Testing Service Inc on 12/3-5/2019, found the laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.   |
| <b>D2007</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of CMS 209 Laboratory Personnel form, personnel files review, review of College of American Pathologists (CAP) proficiency testing (PT) records and staff interviews, the laboratory failed to have all testing personnel (TP) rotate through PT for the specialty of Chemistry for 2018 and 2019. Findings include: 1- Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 11/22 /2019 had 4 testing personnel listed (TPA same as LD, TP B, TP C and TP D) 2- Review of CAP PT records for 2018 and 2019, revealed that, there was no documentation of PT testing in 2019 for the specialty of Chemistry for TP A and TP C. During an interview on 12/03/2019 at 12:00 PM, the General Supervisor confirmed that TP A and C failed to participate in PT during 2019.</p> |
| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>   |

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on analyzer manual review and staff interview, the laboratory failed to document room humidity and temperature requirement to ensure optimal operation for the Hitachi 705 for 2 out of 2 years reviewed. The findings include: A review of Hitachi 705 Analyzer manual revealed a requirement for optimal operation range of room temperature of 15 to 35 C and Humidity 40 to 75 %. A review of temperature logs for 2018 and 2019, revealed no documentation of room humidity and temperature was kept by the lab. During an interview on 12:30 pm at 12/3/19, General Supervisor (GS) confirmed that there was no documentation of the room temperature and humidity for the period of reference.