Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0870786	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Jay B Herman Md Lab	**Street Address, City, State** 532 South Aiken Avenue Suite 210, Pittsburgh, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of patient records and interview with the laboratory director (LD), the laboratory was unable to retrieve 2 years of patient records for Thyroid Stimulating Hormone (TSH) and Testosterone from 2017 to 2018. Findings include: 1. On the day of survey, 11/27/2018, the LD was unable to provide patient preliminary and final report records from 6/22/2017 to 11/27/2018. 2. From 06/22 /2017 to 11/27/2018, the labortaory performed 760 Testosterone and TSH patient tests. 3. The LD confirmed the findings above on 11/27/2018 around 12:30 pm.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment record review and interview with the Laboratory Director (LD), the labortaory failed to follow their Quality Assessment (QA) Program for the FastPack testing from 06/22/2018 to the date of survey. Findings include: 1.

	The labortaory's Quality Assessment Program for FastPAck Testing states, "Our lab assesses the QA plan monthly, using the QA checklist". 2. On the day of survey, 11/27/2018, review of the laboratory's monthly QA checklist revealed that labortaory has not documented monthly quality assessment since December of 2014. 3. The LD confirmed the findings above on 11/27/2018 around 11: 45 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on, the review of the labortaory equipment operators manuals, maintenance records and interview with the Laboratory Director (LD), the laboratory failed to, establish a maintenance protocol that ensures equipment performance is accurate and reliable for the Van Guard Compact V6000 Centrifuge and the TriContinent Scientific Inc. 100 microliter pipette used for Testosterone and Thyroid Stimulating Hormone (TSH) testing from 06/22/2017 to the date of survey. Findings Include: 1. The Van Guard Compact V6000 Centrifuge Operator Manual, under Maintenance, point 6 states, "Check rotor periodically for structural integrity". 2. On the day of survey, 11/27/2018, the LD could not provide maintenance protocols and maintenance records for 1 of 1 Guard Compact V6000 Centrifuge and 1 of 1 TriContinent Scientific Inc. 100 microliter pipette used for Testosterone and TSH testing from 06/22/2017 to 11/27/2018. 3. From 06/22/2017 to 11/27/2018, the labortaory performed 760 Testosterone and TSH patient tests. 4. The LD confirmed the findings above on 11/27/2018 around 12:45 pm.