

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0870786	<b>(X3) Date Survey Completed</b> 07/13/2023
<b>Name of Provider or Supplier</b> Jay B Herman Md Lab	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on an observation of the laboratory and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance policy to assess the maintenance /function of 1 of 1 thermometer used to monitor the temperature of refrigerators in the laboratory where Chemistry reagents and Quality Control Materials were stored from 06/08/2021 to the day of survey. Findings Include: 1. On the day of survey, 07/13 /2023 at 09:00 AM, the laboratory could not provide a maintenance policy for the thermometer used to record refrigerator temperature in the Laboratory. 2. The laboratory could not provide maintenance records for the following thermometers used to store reagents and Quality Controls for Fast Pack Ip system PSA Testing: BGC Analog Vertical Thermometer. 4. LD confirmed the findings above on 07/13 /2023 at 09:10 AM.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following</p>

for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of laboratory quality control (QC) records, a review of the procedure manual, and an interview with the Laboratory Director (LD), the laboratory failed to perform and document QC for Chemistry Testing from 06/03/2021 to 06/08/2023. Findings include: 1. On the day of the survey, 07/13/2023 at 08:37 AM, the laboratory failed to provide QC documentation for the Prostate Specific Antigen (PSA) performed in Chemistry from 06/03/2021 to 06/08/2023. 2. According to the laboratory's PSA procedure Positive and Negative QC is run each day of patient testing. 3. The laboratory performed 488 PSA tests in 2022 (CMS 116 annual volume). 4. LD confirmed the finding above on 07/13/2023 around 09:00 AM.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of the College of American Association of Bioanalysis (AAB) proficiency testing (PT) records and interview with the Laboratory Director (LD), the laboratory director (LD) failed to ensure that 5 of 5 AAB PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action from 06/08/2021 to 07/13/2023. Findings include: 1. On the date of the survey, 07/13/2023 at 08:27 AM, the laboratory could not provide documentation that the AAB PT results were reviewed and assessed by the LD for Prostate Specific Antigen (PSA) testing from 06/08/2021 to the date of the survey: 2. Laboratory Director (LD) confirmed the findings above on 07/13/2023 at 09:10 AM.