

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0870786	(X3) Date Survey Completed 06/08/2021
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, review of Quality Assessment (QA) procedures, and interview with the Laboratory Director (LD), the laboratory failed to follow their Quality Assessment (QA) program for the Qualigen FastPack Prostate-specific antigen (PSA) testing for 2 of 2 years. Findings include: 1. On the day of survey, 06/08 /2021 at 07:41 a.m. Reviewed of the QA program procedure states: " laboratory assesses the QA plan yearly" 2. the LD could not provide documentation for their yearly QA program for 2019 and 2020 3. The LD confirmed the findings above. *** REPEAT DEFICIENCY ***</p>