

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0177589	(X3) Date Survey Completed 03/19/2021
Name of Provider or Supplier Zitelli & Brodland Pc	Street Address, City, State 5200 Centre Avenue S 303, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Procedure Manual and interview with the Laboratory Manager (LM), the laboratory failed to establish a competency assessment policy for 2 of 3 Clinical Consultant (CC), 2 of 3 Technical Supervisor (TS) and 2 of 3 General Supervisor (GS) (on the CMS 209 form, listed as personnel #2 and #3) for their supervisory responsibilities from 2018 to the date of survey. Findings include: 1. On the day of survey, 03/19/2021, the LM could not provide a competency assessment policy to assess 2 of 3 CC, 2 of 3 TS, and 2 of 3 GS (personal #2 and #3) for their supervisory responsibilities from 2018 to the date of survey 2. The LM confirmed the finding above on 03/19/2021 around 08:24 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour and interview with the Laboratory Manager (LM), the laboratory failed to perform yearly preventive maintenance (PM) for 1 of 1 Advantik QS 12 Cryostat from January 2021 to the day of survey Findings</p>

include: 1. On the day of survey, 03/19/2021, during the laboratory tour the surveyor observed that 1 of 1 Advantik QS 12 Cryostat was due for maintenance on January, 2021. 2. The laboratory failed to perform PM on the Advantik QS 12 Cryostat after January, 2021. 3. The LM confirmed the finding above on 03/19/2021 around 08:24 am.