

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0657014	<b>(X3) Date Survey Completed</b>  09/14/2021
<b>Name of Provider or Supplier</b>  Allegheny County Medical Examiners	<b>Street Address, City, State</b>  1520 Penn Avenue, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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:</p> <p>A. Based on review of the laboratory's Procedure Manual and interview with the Laboratory Manager (LM), the laboratory failed to have a competency assessment (CA) policy for 1 of 2 Clinical Consultants, 8 of 8 Technical Consultants (TC), and 8 of 8 General Supervisors (GS) for their supervisory responsibilities in 2019, 2020, and 2021. Findings include: 1. On the day of survey, 09/14/2021, the LM could not provide a competency assessment policy to assess the competency of the following personnel from 09/14/2019 to the date of survey: - 1 of 2 CC (on CMS 209, listed as personnel #10) - 8 of 8 TS (on CMS 209, listed as personnel #2, #3, #4, #5, #6, #7, #8, and #9) - 8 of 8 GS (on CMS 209, listed as personnel #2, #3, #4, #5, #6, #7, #8, and #9) 2. The LM confirmed the finding above on 09/14/2021 around 14:20 p.m.. B. Based on record review and interview with the Laboratory Manager (LM), the laboratory failed to establish a complete procedure that includes all six components required for competency assessment for 8 of 8 testing personnel (TP) in each testing methodologies for toxicology in 2019, 2020, and 2021. Findings include: 1. On the day of survey, 09/14/2021, record review revealed the laboratory only assessed 1 of the 6 required components required for competency assessment for 8 of 8 TP through external proficiency testing samples for each testing methodologies for toxicology in 2019, 2020, and 2021 2. The LM Confirmed the finding above on 09/14/2021 at 14:20 p.m.</p>