

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1104050	(X3) Date Survey Completed 06/22/2022
Name of Provider or Supplier Accupath Diagnostic Laboratories Inc	Street Address, City, State 1737 Tennessee Avenue, Suite B, Cincinnati, OH	
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 record review, and an interview with the General Supervisor (GS), the laboratory failed to establish and follow a written policy and procedure to assess competency of the General Supervisor (GS) at the specific CLIA site, and as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect 739 patients tested from 11/05/2021 through 06/22/2022. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 04/21/2022, found one individual listed as the GS. 2. Review of the laboratory's Competency Assessment policy and procedure titled, "Training and Competency Assessment Policy, SOP Number IO-GL-GN-SOP-0041.010", revealed the following statement: "Note: Site specific training must occur at the specific CLIA site" 3. Review of the laboratory's Competency Assessment documentation found a trainer's signature not listed on the CMS-209 Personnel Report form. 4. On 06/22/2022 at 10:25 AM, the GS stated competency assessment training had been conducted at a different location by the trainer listed on the competency assessment documents and confirmed the lab did not follow their policy and procedure for assessing the competency at the CLIA specific site.</p>