

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2236975	(X3) Date Survey Completed 10/18/2022
Name of Provider or Supplier Advanced Molecular Diagnostics	Street Address, City, State 1381 Kinnear Rd #104, Columbus, 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) #1 laboratory failed to follow a written policy and procedure to assess competency of the Testing Personnel (TP) #5 and TP #6 as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect all patients tested at the laboratory by two out of 10 TP in the subspecialty of virology from 08/06/2022 through 10/18/2022. Findings Include: 1. A review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 10/18/2022, found 10 individuals listed as TP. 2. A review of the laboratory's "Competency Checklist" for the "Fast 2.0" saliva test found the following statement: "This employee has successfully completed all required elements for training and has been evaluated for proper test performance and/or proper processing performance. This evaluation showed that this employee is proficient to begin patient testing and/or processing of samples." 3. A review of the laboratory's initial competency assessment data for the "Fast 2.0" saliva test system found the following: TP #5 initial training: "8-25-22" TP #6 initial training: "8-18-22" 4. A review of the laboratory's test and Quality Control (QC) records for the "Fast 2.0" saliva test system found the following: "Date... Initials 8/9/22 [TP #6] 8/9/22 [TP #6] 8/11/22 [TP #6]8/11/22 [TP #6] 8/11/22 [TP #6] 8/11/22 [TP #6]8/12/22 [TP #6] 8/12/22 [TP #6] 8/15/22 [TP #6] 8/15/22 [TP #6] 8/16/22 [TP #5] 8/17/22 [TP #5] 8/17/22 [TP #5] 8/17/22 [TP #5]" 5. An interview with the GS #1, on 10/18/2022 at 3:12 PM, confirmed that the laboratory failed to perform an initial competency assessment for TP #5 and TP #6 prior to patient testing.</p>