

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0890607	(X3) Date Survey Completed 02/25/2021
Name of Provider or Supplier Cleve Dept Of Pb Hlth (Cdph) Lead Lab	Street Address, City, State 4242 Lorain Ave, 2nd Flr Mccafferty Hlth, Cleveland, 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 electronic mail (email) interview with the Laboratory Director, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor (TS) and the General Supervisor (GS), at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All patient routine chemistry and toxicology testing performed in this laboratory from 10/23/2018 to 02/25/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's competency assessment policy and procedure, provided for the date of the inspection, did not find any mention of the assessment of the TS and GS based on the responsibilities of each position, at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 12/11/2020, revealed one individual listed and qualified by the Laboratory Director to function as the TS and GS. 3. Review of the laboratory's 2018, 2019 and 2020 competency assessment documentation, provided for the date of the inspection, did not find any assessment documentation for the TS and GS based on the responsibilities of each position. 4. The Inspector requested the laboratory's policy and procedure for the assessment of the TS and GS and any competency assessment documentation for the TS and GS based on the responsibilities of each position from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure for the assessment of the TS and GS, did not assess the competency of the TS and GS based on the responsibilities of each position, at a</p>

frequency determined by the laboratory and was unable to provide the requested documentation on the date of the inspection. The email interview occurred on 02/24/2020 at 2:11 PM.