

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0336805	(X3) Date Survey Completed 02/25/2021
Name of Provider or Supplier Cdph J Glen Smith Health Center Lab	Street Address, City, State 11100 St Clair Avenue, 2nd Floor, 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 Technical Consultant (TC) #1, at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All patient bacteriology, mycology, parasitology, syphilis serology and urine microscopic testing performed in this laboratory from 05/10/2018 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 TC based on the responsibilities of the 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 two individuals, including the Laboratory Director, listed and qualified by the Laboratory Director to function as TC. 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 TC#1 based on the responsibilities of the TC position. 4. The Inspector requested the laboratory's policy and procedure for the assessment of the TC and any competency assessment documentation for TC#1 based on the responsibilities of the position from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure for the assessment of the TC, did not assess the</p>

competency of TC#1 based on the responsibilities of the position, at a 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.