

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1009503	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Omega Laboratories Inc	Street Address, City, State 400 North Cleveland Avenue, Mogadore, 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 review of the laboratory's policies and procedures, competency assessment documentation, and an interview with Laboratory Director (LD), the laboratory failed to follow their written policy and procedure to assess competency of Technical Supervisors (TS) #1, #2 and #3, as specified in the personnel requirements in subpart M. Findings Include: 1. Review of the laboratory's "Omega Laboratories Standard Operating Procedure Manual SOPM-1 Rev 07.18" section 5.1.6 protocol found the following statement: "All laboratory personnel will be re-evaluated in each department which they work at least once per year and then yearly thereafter." 3. Review of the laboratory's 2016, 2017 and 2018 competency assessment documentation for TS #1, #2 and #3, provided on the date of the inspection, did not find any indication that competency was assessed in 2017. 4. The LD confirmed the 2017 competencies of TS #1, #2 and #3 were not assessed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/20/2018 at 11:12 AM.</p>