

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0343847	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Bellevue Hospital Laboratory, The	Street Address, City, State 1400 West Main Street, Bellevue, 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:</p> <p>Item I: Based on record review and an interview with Technical Supervisor (TS) #1, the laboratory failed to establish and follow a written policy and procedure to assess competency of the TS, General Supervisor (GS) and the Technical Consultant (TC), based on the regulatory responsibility of that assigned role, at a frequency determined by the lab, as specified in the personnel requirements in subpart M. All patients tested at this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 'Form CMS-209 Personnel Report (CLIA)', approved and signed by the Laboratory Director on 10/14/19, found two individuals serving as the TS, one individual serving as the GS and one individual serving as the TC. 2. Review of the laboratory's policies and procedures failed to find instructions for competency assessment of the TS, GS, and TC, based on the regulatory responsibility of that assigned role, at a frequency determined by the lab. 3. Review of the laboratory's competency assessment documentation failed to find evidence that the TS #1, TS #2, the GS and the TC were assessed for competency based on the regulatory responsibility of that assigned role, at a frequency determined by the lab. 4. An interview with the TS #1, on 12/19/19 at 2:03 pm, confirmed that the lab failed to establish and follow a policy and procedure for assessing the competency of the TS, GS, and TC, based on the regulatory responsibility of that assigned role, at a frequency determined by the laboratory. Item II: Based on record review and an interview with the Technical Supervisor (TS) #1, the laboratory failed to evaluate the competency of 13 out of 13 Testing Personnel (TP) and to assure they maintained their competency to perform moderate and high complexity test procedures and report</p>

test results promptly, accurately, and proficiently in 2018 and 2019. All patients tested at this laboratory had the potential to be affected by this deficient practice. Findings include 1. Review of the laboratory's policies and procedures found the following statements: "Laboratory Competency Assessment Program ...New employees must be assessed prior to 6 months of service and all employees must be assessed at least annually..." "New Hire 90 day assessment 120 day assessment 180 day assessment 1yr assessment" "Current Employee Annual Assessment" "Competency or Performance Issues 60 day assessment 90 day assessment Annual assessment" "Microbiology Competency Testing Employees receive initial training for all duties performed. Thereafter, during the first year of employment, competency will be assessed at six months and again at one year. After one year, competency will be assessed on an annual basis..." 2. Review of competency assessment documentation found assessments for 13 out of 13 TP were not signed by the General Supervisor or Laboratory Director, for 2018 and 2019. 3. An interview with TS #1, on 12-19-19 at 2:05 pm, confirmed that competency assessments for 13 out of 13 TP were not signed by the General Supervisor or Laboratory Director, for 2018 and 2019.