

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0033970	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Kettering Medical Center Pulmonary Lab	Street Address, City, State 3535 Southern Boulevard, Kettering, 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
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP#1), the laboratory failed to ensure the individuals who performed moderate complexity testing met the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the testing procedures performed. Findings Include: 1. The laboratory failed to ensure Testing Personnel (TP) met the education requirements, as specified in subpart M for moderate complexity testing procedures performed. (Refer to D6065)</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

Based on document reviews and an interview with Testing Personnel (TP#1), the Laboratory Director failed to ensure prior to testing patients' specimens, TP had the appropriate education to perform all test operations reliably to provide and report accurate results. This deficient practice had the potential to affect all patients tested under the specialties of hematology and chemistry. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated on 10/11/2019 by the Laboratory Director revealed 56 testing personnel. 2. The inspector requested education documents for all TP listed on the Form CMS-209 from TP #1. TP#1 confirmed the laboratory did not have education documentation available for TP#4-5, TP#8, TP#11, TP#17, TP#23, TP#25, TP#28, TP#32, TP#36-38, TP#52, TP#55-56 and was unable to provide the requested documentation on the date or within seven days of the validation inspection. The interview occurred 10/30/2019 at 10:35 AM.