

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0375684	(X3) Date Survey Completed 01/31/2024
Name of Provider or Supplier Kathleen Knapp, Do Pc	Street Address, City, State 1320 Byron Rd, Howell, MI	
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 a lack of documentation, the laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing. 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> <p>This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure</p>

testing personnel were qualified prior to performing moderately complex testing for 2 (Testing Personnel #3 and #4) of 5 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel qualifications revealed a lack of documentation for Testing Personnel #3 and #4 to meet moderate complexity testing personnel qualification requirements at 493.1423. 2. The surveyor requested additional qualification documentation for Testing Personnel #3 and #4 on 1/31/24 at 1:33 pm and they were not made available. 3. The laboratory was provided and additional 7 days to provide the missing qualification documents and they were not made available.