

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0695151	(X3) Date Survey Completed 03/28/2024
Name of Provider or Supplier Dr Hinkebein, Davis, McCormick, Pllc	Street Address, City, State 9905 Shelbyville Road, Louisville, KY	
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
D0000	A recertification survey was conducted on 03/28/2024. The facility was found to be out of compliance with the following condition: 493.1421 Laboratories performing moderate complexity testing; testing personnel
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient test reports and confirmed staff interview, the laboratory failed to verify three (3) of (3) three reference intervals for Complete Blood Cell counts (CBC) for their patient population. Findings included: 1. Review of four (4) patient test reports titled "Hinkebein Davis and McCormick PLLC", for years 2022, 2023, and 2024 revealed three specific age reference intervals for CBC results: 18MO to 6Y 6Y TO 12 Y 12Y TO 18Y 2. During an interview on 03/28/2024 at 11:54 a.m. in the conference room located above the laboratory, Testing Personnel (TP) #1 was asked to provide documentation of verification of the reference intervals in use for their patient population. No documentation was provided. This confirmed the findings. Word Key: MO = months Y = Years</p>
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</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.

This CONDITION is not met as evidenced by:

Based on review of the Center for Medicaid and Medicare Services (CMS)-209 form, personnel records, and confirmed staff interview, the laboratory failed to have documentation of education to qualify one (1) of four (4) testing personnel (TP). Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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

This STANDARD is not met as evidenced by:

Based on review of the Center for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in staff interview, the laboratory failed to provide documentation to ensure minimum education requirements for performing moderate complexity testing for one (1) of four (4) testing personnel (TP). Findings included: 1. Review of the CMS 209 form listed a total of four (4) TPs qualified to perform moderate complexity testing. 2. Review of personnel records revealed no educational documentation to qualify TP#2 for moderate complexity testing. 3. During an interview on 03/28/2024 at 10:15 a.m. in the conference room located above the laboratory, TP #1 was asked to provide educational documentation for TP#2. No documentation was provided. This confirmed the findings.