

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0668316	(X3) Date Survey Completed 06/02/2022
Name of Provider or Supplier Johnson Memorial Health Services	Street Address, City, State 1282 Walnut Street, Dawson, MN	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on document review and interview with laboratory personnel, the laboratory director failed to ensure initial training on two new chemistry analyzers was documented for one of four testing personnel in 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor during a tour of the laboratory on 06/02/22 at 8:05 a.m. 2. Testing personnel 5 (TP5) began working in the laboratory in October 2021 as indicated in laboratory records. TP5 met the qualifications to perform moderate complexity testing at 493.1423(b)(2) based on a review of education documents. 3. The laboratory implemented testing on two new Chemistry analyzers, the Beckman Coulter AU480 and the Beckman Coulter Access 2, in December 2021 as indicated in laboratory records. 4. Training documents for the two new chemistry analyzers were not found during review of TP5's personnel records. The laboratory was unable to provide the missing documents upon request. 5. In an interview at 11:35 a.m. on 06/02/22, the Technical Consultant confirmed the above finding.</p>