

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0975548	<b>(X3) Date Survey Completed</b>  09/24/2025
<b>Name of Provider or Supplier</b>  Sanford Clinic Egf 621 Demers	<b>Street Address, City, State</b>  621 Demers Ave, East Grand Forks, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>. The Sanford Clinic EGF 621 Demers laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on September 24, 2025. The following standard-level deficiency was cited: 493.1413 Technical consultant responsibilities .</p>
<b>D6053</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of one testing personnel hired in 2024. Findings are as follows: 1. The laboratory performed microscopic testing for fungal elements as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 1:40 p.m. on 09/24/25. 2. A Nikon Eclipse E200 microscope and Potassium Hydroxide solution were observed as present and available for use during the tour: 3. Competency evaluation of new testing personnel was required within 7 months and 12 months of initial evaluation as established in the Training and Competency Assessment procedure found in the laboratory's document management software PolicyTech. 4. TP2 received an initial competency evaluation for microscopic fungal element testing on 01/22/24 as indicated on the Competency Assessment Provider Performed Microscopy form found in the Initial Training and Competency manual. 5. Semi-annual competency evaluation documentation for TP2</p>

was not found during review of laboratory records. The laboratory was unable to provide the missing competency evaluation upon request. 6. In an interview at 2:20 p. m. on 09/24/25, the LS confirmed the above finding. .