

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0405465	<b>(X3) Date Survey Completed</b>  07/17/2024
<b>Name of Provider or Supplier</b>  Sanford Canby Medical Center	<b>Street Address, City, State</b>  112 St Olaf Ave S, Canby, 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>	The Sanford Canby Medical Center 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 recertification survey performed on July 16, 2024 and July 17, 2024. The following standard-level deficiencies were cited: 493.1413(b)(7) Technical consultant responsibilities 493.1413(b)(8)(v) Technical consultant responsibilities .
<b>D6045</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</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 ensure initial training and competency assessment for one of one new testing personnel (TP) was performed and documented in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p.m. on 07/16/24. 2. A Cepheid GeneXpert molecular diagnostic system was observed as present and available for use during the tour. The laboratory performed Influenza A, Influenza B, Respiratory Syncytial Virus, SARS CoV-2, and Streptococcus A testing using this system. 3. Competency evaluation of new testing personnel was required prior to testing specimens independently as established in the Competency Assessment - Canby procedure found in the laboratory's electronic procedure software, PolicyTech. 4. TP6 was approved by the laboratory director to perform testing using the GeneXpert system in May 2023 as indicated in laboratory records. 5. GeneXpert system initial training and competency</p>

evaluation documents for TP6 were not found in laboratory records. The laboratory was unable to provide the missing training record and competency evaluation upon request. 6. In an interview at 5:45 p.m. on 07/16/24, the GS confirmed the above finding. .

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure one of one new testing personnel (TP) was assessed semi-annually through testing previously analyzed specimens, blind samples, or proficiency testing samples in 2023. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, Diagnostic Immunology, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p.m. on 07/16/24. 2. The following test systems were observed as present and available for use during the tour: Cepheid GeneXpert molecular test system Abbott Architect ci4100 general chemistry and immunoassay analyzer Stago Satellite coagulation analyzer Sysmex XN-550 hematology analyzer Olympus BH-2 microscopes - used for microscopic examinations for fungus, parasites, bacteria, manual differentials, and urine sediment BioRad ToxSee and Amnisure testing kits 3. Assessment of test performance using previously analyzed specimens, internal blind samples, or external proficiency samples was a required element of testing personnel competency assessment as established in the Competency Assessment - Canby procedure found in the laboratory's electronic procedure software, PolicyTech. 4. Testing personnel 6 (TP6) was approved by the laboratory director to perform testing using the GeneXpert system in May 2023 as indicated in laboratory records. Initial training and competency documents for this test system were not found in laboratory records for TP6. See D6045. 5. Initial training and competency documentation for the test systems listed above, with the exception of the Cepheid GeneXpert, were completed in September 2023. 6. Blind sample assessments were not included on TP6's 2023 semi-annual competency evaluation forms completed in December 2023 for the above test systems. The laboratory was unable to provide the missing blind sample evaluation documentation upon request. 7. In an interview at 5:45 p.m. on 07/16/24, the GS confirmed the above finding. .