Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0655616	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Broadway Clinic	737 N Broadway Dr, Fargo, ND	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to follow their policy regarding treatment of proficiency testing samples for two Event B-2021 electrophoresis samples reviewed by sending the proficiency testing samples to another laboratory for test interpretation, resulting in proficiency testing referral. (Refer to D2013)
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally

accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on record review, policy review, and staff interview, the laboratory failed to ensure staff did not send proficiency testing samples to another laboratory for interpretive testing for two of two electrophoresis proficiency testing samples reviewed (Samples #03 and #04 for ELP-B [electrophoresis-Event B] 2021), resulting in proficiency testing referral. Findings include: During a telephone interview at 2:05 p.m. on 08/25/21, an administrative laboratory staff member (Personnel #1) called to self-report proficiency testing referral at Sanford Broadway Clinic for electrophoresis during Event B of 2021. Personnel #1 stated the Sanford Broadway Clinic performed the quantitative electrophoresis testing and sent the electrophoresis proficiency testing sample plates to Laboratory B (a laboratory in the same system) where a pathologist would interpret results for patient specimens. Personnel #1 stated Laboratory B did not perform the interpretations for the proficiency testing samples and returned the samples to the Sanford Broadway Clinic. Reviewed on 09/08/21, the policy "Proficiency Testing Procedure - General 30.02," revised 05/26/21, stated, ". . . Purpose: Establish guidelines for receipt, testing, reporting and review of proficiency tests . . . Alternative Proficiency Testing: Various methods are used for PT [proficiency testing] on analytes that are unregulated . . . 1. Electrophoresis (Broadway and [name of Laboratory B]): A. The Core Laboratory at the Broadway Clinic performs the analytical portion of the electrophoresis and one of the Hematopathologists at [name of Laboratory B] does the interpretations. B. For proficiency testing, the Broadway Clinic laboratory subscribes to the SPE [serum protein electrophoresis] PT program. C. All of the specimens from the PT challenge are performed on separate plates with no patients on the plate. This is to ensure the PT does not leave the Broadway Clinic lab before the due date for the PT submission. D. The Broadway Clinic Laboratory reports all of the quantitative values for the PT challenges and the qualitative results for the Bence Jones proteins. The interpretation of type of monoclonal protein present and the diagnostic interpretation for the serum portion are not reported. E. After the evaluation comes back from CAP [College of American Pathologists proficiency company], the plates, scans, and form . . . are sent to the Hematopathologist at [name of Laboratory B]. . . ." Reviewed on 09/08/21, the laboratory's CAP ELP-B 2021 results form lacked results for Specimens #03 and #04 for all tests (total protein, protein electrophoresis, component identification and quantitation, immunoglobulins quantitation, and urinary Bence Jones protein). The laboratory had marked exception code "11" (unable to analyze) for all the test results. Review of the laboratory's undated document "Investigation into Rerunning and Referred the Electrophoresis Plates." occurred on 09/08/21. A technical director (Personnel #2) prepared the document. The document stated, "When I arrived at work on 8/24/21, there was an IFE [immunofixation] gel on my desk. . . . There were patients and CAP proficiency samples on the plate. . . . [initials of Personnel #3] was the Electrophoresis Tech on 8/20 and 8/23/21. I asked her about the plate dated 8/23 /21 #2. She said she was concerned that she might have pipetted wrong on Friday because both specimens were negative and since she had room on the patient plate on 8/23/21 she reran CAP-03 and CAP-04. I asked if she had sent any paper work such

	as the densitomer [sic] print out to the [name of reference laboratory] for the 2 CAP specimens. She said she did not so that the Pathologist wouldn't perform an interpretation. Upon further review of the Serum Protein Electrophoresis plates from 8 /20/21 . . . and discussion with [initials of Personnel #3] patients 39 and 40 are the CAP samples on the SPE [serum protein electrophoresis] plate number 1 . . . The plate was sent to [name of Laboratory B] on 8/20/21. The lanes were not labelled and the CAP samples were not listed on the packing list; therefore, the Pathologist would have treated them as extra lanes and ignored them. [Initials of Personnel #3] also made a second plate on 8/20/21 which was just CAP samples as indicated by the number 2 in the upper right corner. Plate number 2 was held at the Broadway lab to be used as an alternative proficiency . . ." During a telephone interview at 4:30 p.m. on 09/08/21, an administrative laboratory staff member (Personnel #1) stated CAP had advised the technical director (Personnel #2) to not report any results and use exception code 11. Personnel #1 confirmed the normal procedure for electrophoresis proficiency testing samples would be to not send the ELP plates to Laboratory B for interpretation.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory director failed to ensure staff did not send proficiency testing samples to another laboratory for interpretive testing for two Event B electrophoresis samples reviewed, resulting in proficiency testing referral. (Refer to D6089)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory director failed to ensure staff did not send proficiency testing samples to another laboratory for interpretive testing for two of two electrophoresis proficiency testing samples reviewed (samples #03 and #04 for ELP-B [electrophoresis-Event B] 2021) resulting in proficiency testing referral. Findings include: During a telephone interview at 2:05 p.m. on 08/25/21, an administrative laboratory staff member (Personnel #1) called to self-report proficiency testing referral at Sanford Broadway Clinic for electrophoresis during Event B of 2021. Personnel #1 stated the Sanford Broadway Clinic performed the quantitative electrophoresis testing and sent the electrophoresis proficiency testing sample plates to Laboratory B (a laboratory in the same system) where a pathologist would interpret results for patient specimens. Personnel #1 stated Laboratory B did not perform the interpretations for the proficiency testing samples and returned the samples to the Sanford Broadway Clinic. Reviewed on 09/08/21, the policy "Proficiency Testing Procedure - General 30.02," revised 05/26/21, stated, ". . . Purpose: Establish guidelines for receipt, testing, reporting and review of proficiency

tests . . . Alternative Proficiency Testing: Various methods are used for PT [proficiency testing] on analytes that are unregulated . . . 1. Electrophoresis (Broadway and [name of Laboratory B]): A. The Core Laboratory at the Broadway Clinic performs the analytical portion of the electrophoresis and one of the Hematopathologists at [name of reference laboratory] does the interpretations. B. For proficiency testing, the Broadway Clinic laboratory subscribes to the SPE [serum protein electrophoresis] PT program. C. All of the specimens from the PT challenge are performed on separate plates with no patients on the plate. This is to ensure the PT does not leave the Broadway Clinic lab before the due date for the PT submission. D. The Broadway Clinic Laboratory reports all of the quantitative values for the PT challenges and the qualitative results for the Bence Jones proteins. The interpretation of type of monoclonal protein present and the diagnostic interpretation for the serum portion are not reported. E. After the evaluation comes back from CAP [College of American Pathologists proficiency company], the plates, scans, and form . . . are sent to the Hematopathologist at [name of Laboratory B]. . . ." Reviewed on 09/08/21, the laboratory's CAP ELP-B 2021 results form lacked results for Specimens #03 and #04 for all tests (total protein, protein electrophoresis, component identification and quantitation, immunoglobulins quantitation, and urinary Bence Jones protein). The laboratory had marked exception code "11" (unable to analyze) for all the test results. Review of the laboratory's undated document "Investigation into Rerunning and Referred the Electrophoresis Plates." occurred on 09/08/21. A technical director (Personnel #2) prepared the document. The document stated, "When I arrived at work on 8/24/21, there was an IFE [immunofixation] gel on my desk. . . . There were patients and CAP proficiency samples on the plate. . . . [initials of Personnel #3] was the Electrophoresis Tech on 8/20 and 8/23/21. I asked her about the plate dated 8/23 /21 #2. She said she was concerned that she might have pipetted wrong on Friday because both specimens were negative and since she had room on the patient plate on 8/23/21 she reran CAP-03 and CAP-04. I asked if she had sent any paper work such as the densitomer [sic] print out to the [name of Laboratory B] for the 2 CAP specimens. She said she did not so that the Pathologist wouldn't perform an interpretation. Upon further review of the Serum Protein Electrophoresis plates from 8 /20/21 . . . and discussion with [initials of Personnel #3] patients 39 and 40 are the CAP samples on the SPE [serum protein electrophoresis] plate number 1 . . . The plate was sent to [name of Laboratory B] on 8/20/21. The lanes were not labelled and the CAP samples were not listed on the packing list; therefore, the Pathologist would have treated them as extra lanes and ignored them. [Initials of Personnel #3] also made a second plate on 8/20/21 which was just CAP samples as indicated by the number 2 in the upper right corner. Plate number 2 was held at the Broadway lab to be used as an alternative proficiency . . ." During a telephone interview at 4:30 p.m. on 09/08/21, an administrative laboratory staff member (Personnel #1) stated CAP had advised the technical director (Personnel #2) to not report any results and use exception code 11. Personnel #1 confirmed the normal procedure for electrophoresis proficiency testing samples would be to not send the ELP plates to Laboratory B for interpretation.