Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2026672	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
New Life Family Medicine	118 3rd Street Southeast, Huron, SD	

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 for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 11/17/21. The New Life Family Medicine laboratory was found not in compliance with the following requirements: D2015, D5215, and D5805.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the laboratory failed to maintain a copy of the submitted results for two of seven proficiency testing (PT) events (American Proficiency Institute [API] 2021 Hematology/Coagulation first and second PT events) submitted to API for grading. Findings include: 1. Review of the records for the API 2021 first and second Hematology/Coagulation PT events on 11/17/21 at 1:25 p.m. revealed the PT result forms had not been printed after the results had been submitted electronically. These forms would have documented the results the laboratory submitted to API for evaluation. The PT policy was requested on 11/17/21 at 1:25 p.m. No policy or procedure related to PT was available to review. Interview on 11/17/21 at 1:25 p.m. with laboratory personnel A confirmed the PT result forms

	had not been printed and retained after the results were electronically submitted. She did not think the laboratory had a policy or procedure for PT.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to review PT results to ensure their accuracy for 27 of 27 "not graded" PT samples reviewed (Blood Cell Identification Educational, 2019 Hematology/Coagulation second and third PT events and 2020 Hematology/Coagulation first, second and third PT events; Urine Sediment 2020 Hematology/Coagulation third PT event; and Blood Cell ID 2021 Hematology/Coagulation second PT event). Findings include: 1. Review of the American Proficiency Institute (API) PT records for 2019, 2020 and 2021 on 11/17/21 at 1:25 p.m. revealed: *There had been no documentation the following samples had been reviewed for their accuracy. These samples had not been graded due to lack of consensus. -API 2020 Hematology/Coagulation third testing event specimen Urine sediment specimen US-06. -API 2021 Hematology/Coagulation second testing event specimen Blood Cell Identification specimen BCI-07 *There had been no documentation the following samples had been reviewed for their accuracy. These samples had not been graded due to their designation as educational challenges. -API 2019 Hematology/Coagulation second testing event samples Blood Cell Identification Educational ECI-06, 07, 08, 09, and 10. -API 2019 Hematology/Coagulation third testing event samples Blood Cell Identification Educational ECI-11, 12, 13, 14, and 15. -API 2020 Hematology/Coagulation first testing event samples Blood Cell Identification Educational ECI-01, 02, 03, 04, and 05. -API 2020 Hematology /Coagulation second testing event samples Blood Cell Identification Educational ECI-06, 07, 08, 09, and 10. -API 2020 Hematology/Coagulation third testing event samples Blood Cell Identification Educational ECI-11, 12, 13, 14, and 15. Review of quality assessment activities for the above PT events revealed no documentation the "not graded" results had been evaluated for their accuracy. The PT policy was requested on 11/17/21 at 1:25 p.m. No policy or procedure related to PT was available to review. Interview on 11/17/21 at 1:25 p.m. with laboratory personnel A confirmed the "not graded" results had not been reviewed. She stated "I thought it had been done. It should be in the book if it was done." She did not think the laboratory had a policy or procedure for PT.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a patient's completed test report and the CMS (Centers for Medicare and Medicaid Services) 116 form; and interview with laboratory staff, the laboratory failed to clearly identify the name and location of the laboratory that had performed testing of one of one sampled patient specimen (complete blood count [CBC] reported 11/17/21) which would allow a provider viewing those results to contact the testing laboratory in the event additional information or interpretation was needed. Findings include: 1. Review on 11/17/21 at 3:40 p.m. of the test results for a random patient's CBC test dated 11/17/21 revealed the laboratory report header identified the reporting facility as Huron Regional Medical Center, 172 4th St SE, Huron, SD 57350. The testing laboratory was identified as HRMC NL Laboratory. The address of the testing facility was not documented on the patient test report. Review of the CMS 116 form revealed the name of the laboratory was New Life Family Medicine, located at 118 3rd St SE, Huron SD 57730. Interview with testing personnel A on 11/17/21 at 3:40 p.m. revealed: *She confirmed the test report did not contain the laboratory's full name or address. *They had installed a new computer system in May 2021. *This system was operated by Huron Regional Medical Center. *All laboratory reports completed since the new system had been installed, printed in this manner.