Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0454747	09/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine	3307 Bill Schock Boulevard, Falls City, NE	

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 observation, review of proficiency records, and interviews, the laboratory improperly referred proficiency testing specimens to another laboratory. (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 observation, review of 2019 and 2020 proficiency testing (PT) records, and interview with testing personnel (TP) #8 and #11, the laboratory failed to ensure PT specimens for AAFP event 2020-A were not referred to another laboratory. Findings: 1. Observation of the laboratory on September 23, 2020 showed a refrigerator where the facility routinely kept all specimens. The specimens in the refrigerator meant for retrieval by the reference laboratory were placed in bags imprinted with the reference lab's name and logo. 2. Review of PT for 2019 and 2020 showed the laboratory received modules 613 and 639 from AAFP. Module 613 includes auto diff I and module 639 includes complete urinalysis package. 3. On April 9, 2020 the Nebraska CLIA program received a phone call complaint from a reference laboratory reporting that (6) six PT specimens from Family Medicine 28D0454747 were sent to the reference lab without instructions or test requisitions. A digital photograph provided by the complainant showed an AAFP PT 2020-A UA-1 (for urinalysis), an AAFP PT 2020-A SYX-1, SYX-2, SYX-3, SYX-4, and SYX-5 (for complete blood count, auto diff I). 4. Interview on September 23, 2020 at 12:00PM with TP #11 confirmed that the laboratory did refer six PT specimens to a reference laboratory. 5. Interview on September 23, 2020 at 1:00PM with TP #8 revealed PT specimens from AAFP are placed in the same refrigerator as specimens going to the reference laboratory.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of a procedure for proficiency testing and an interview with the technical consultant, the laboratory failed to have a procedure for proficiency testing. Findings: 1. No procedure for proficiency testing could be presented during the time of survey on 9/23/2020. 2. Interview with the technical consultant on 9/23/2020 at 11: 30AM confirmed the laboratory did not have a procedure for proficiency testing.