Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520334	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Practice Group, Pa	1951 Bench Rd #B, Pocatello, ID	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records of urine sediment from American Proficiency Institute (API), policies and procedures and an interview with the laboratory lead on 3/9/2021, the laboratory failed to examine PT samples using the laboratory's routine methods. The findings include: 1. A review of urine sediment PT records from API for hematology/coagulation 2020 3rd event identified that two testing personnel examined both of samples, US-05 and US-06, before the submission date. 2. A review of the laboratory's "Urine Sediment Examination" procedure identified that the laboratory does not routinely use more than one testing individual to perform urine sedimentation examinations. 3. An interview with the laboratory lead on 3/9/2021 at 9:30 am confirmed that multiple testing personnel examine both PT samples prior to the submission date for training and competency purposes. 4. The laboratory reports performing 1065 urine sedimentation examinations annually.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by:

	Based on a review of patient test records and an interview with the laboratory lead on 3/9/21 the laboratory failed to retain patient test records for urine sedimentation examinations for at least two (2) years. The findings include: 1. A review of patient test records identified that the laboratory failed to retain transcribed results for urine sediment examinations that are then input into the patient electronic record. 2. An interview with the laboratory lead on 3/9/21 at 10:36 am confirmed that the laboratory discards the transcribed results after they are input into the patient electronic record. 3. The laboratory reports performing 1065 urine sedimentation examinations annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review of proficiency testing from American Proficiency Institute (API) and an interview with the laboratory lead on 3/9/2021, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) and semen analysis at least twice annually. The findings include: 1. A review of proficiency testing records from API identified that the laboratory failed to verify the accuracy of KOH and semen analysis biannually for 2019 and 2020. 2. An interview with the laboratory supervisor on 3/9 /2021 at 9:55 am confirmed that the laboratory failed to verify the accuracy of KOH and semen analysis biannually for 2019 and 2020. 3. This deficient practice was identified during the previous inspection on 4/10/18 for failure to verify the accuracy of KOH and semen analysis. 4. The laboratory reports performing 35 KOH and semen analysis annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of refrigerator temperature logs and interview with the laboratory supervisor on 3/9/2021 the laboratory failed to document corrective actions when the proper storage temperatures for reagents and specimens were not met. The findings include: 1. A review of 2020 refrigerator temperature logs identified that the laboratory failed to document corrective actions when the sample storage refrigerator temperatures were outside of the established range of 36-46 F. Corrective actions were not documented for 17 of 24 days in January 2020, 22 of 22 days in February 2020, 1 of 26 days in April 2020, 20 of 25 days in September 2020, 25 of 26 days in October 2020, 21 of 22 days in November 2020 and 18 of 24 days in December 2020. 2. An interview with the laboratory supervisor on 3/9/2021 at 10:25 am confirmed that the laboratory failed to document corrective actions for the above days when the refrigerator temperatures were document out of the acceptable range for sample storage.