Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0622214	04/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oregon City Family Practice	1420 John Adams St, Oregon City, OR	

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 upon review of records and discussion with staff, records revealed that the Proficiency Testing (PT) is not divided equally among testing personnel. Findings include: 1. There are four (4) testing personnel listed on the CMS 209 form. Upon review of PT records it was noted that only two (2) of the four (4) performed PT in 2017 and 2018. 2. Primary testing personnel confirmed that the routine rotation of PT sample testing is not shared by all staff members during interview on 04/01/2019 at approximately 1300.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon review of Proficiency Testing (PT) records for 2017 and 2018 and discussion with staff, it was revealed that all attestation pages were not available for review for 2018. Findings include: 1. Upon review of the PT records notebook for

	2018, there was no attestation page available for PT event #1 and #3. 2. Primary testing personnel confirmed this during interview on 04/01/2019 at approximately 1300.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based upon review of records and interview with the staff, it was revealed that corrective action was not available for review for missed Proficency Testing (PT) samples on regulated analytes. Findings include: 1. In 2017, event #2, the laboratory scored an overall unsatisfactory score in Endocrinology, specifically for Thyroid Stimulating Hormone (TSH) and Free Thyroxine. There was no evidence of corrective action that could be produced during the survey. 2. In 2018, event #3, the laboratory scored unsatisfactory scores for Chloride and Sodium. There was no evidence of corrective action that could be produced during survey. 3. Primary testing staff confirmed that no written documentation of corrective action was available during interview 4/1/2019 at approximately 12:00 p.m.
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 upon review of records and discussion with staff, the laboratory failed to perform bi-annual verification for non-regulated analytes the Providers are performing on patient samples. Findings include: 1. No documentation of bi-annual verification of Providers performing potassium hydroxide (KOH) mounts, vaginal wet preps or microscopic urinalysis could be produced during the survey. 2. Primary testing staff verified during interview 4/1/2019 at approximately 1430 that there were no written records of bi-annual verification on site.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based upon limited records available for review during the survey 4/1/2019 and discussion with staff, it was determined that the Quality Assessment (QA) system at this facility was inadequate for 2017 and 2018. Findings include: 1. There was no written documentation of QA activities that could be produced during the survey for

	2017 and 2018. 2. Personnel competencies produced had been performed on some staff by personnel not qualified to perform such competencies. For example, the Office Manager was performing competency assessment on the lead Medical Assistant/ Laboratory Technician. The Office Manager is not a testing personnel nor is she qualified to perform such competency assessment. 3. Proficency Testing (PT) failures did not have evidence of review of failures or corrective action by the Laboratory Director (LD). 4. There is no written procedure that could be produced for addressing PT failures. 5. Primary testing staff confirmed all of the aforementioned during interview at approximately 1430.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based upon review of records and interviews with staff during the survey 4/1/2019, the laboratory failed to review and resolve problems associated with Quality Assessment (QA) activities necessary to prevent recurrence of possible adverse patient care issues. Findings include: 1. No documented assessment of QA subject matter could be produced during the survey 4/01/2019 for either 2017 and 2018, including failed Proficency Testing (PT). 2. No Laboratory policies were found to be ammended to reflect the laboratory's recognition of failures to follow through with failed PT performance. 2. Personnel competency was being performed by office staff personnel not qualified to perform such competency assessment.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based upon review of records and discussion with staff, the laboratory failed to ensure that temperature outliers were responded to. Findings include: 1. The small freezer in the lab has a temperature range documented to be -20 to -70 degrees Celcius. During the months of January and February of 2019, the recorded temperature was above -20 degrees twenty seven (27) out of forty six (46) days of clinic operation. 2. There was no documented corrective action for temperature outliers that could be produced by staff during survey. 3. Bio-Rad controls for the Chemistry analyzer require a storage temperature of -20 to -70 degrees according to manufacturer package inserts. In spite of the temperature outliers, these controls continued to be stored in this freezer in spite

	of the fluctuating temperature during January and February 2019. 4. The storage of these controls during the two (2) aforementioned months was confirmed by primary testing staff during interview 04/01/2019 at approximately 1430.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon inspection of the cabinets in the lab above the sink and discussion with staff, it was revealed that expired reagents and materials were being kept for patient use. Findings include: 1. An open vial of urine dipsticks (Chemstrip) was found with an expiration date of 07/31/2018. 2. A partial box (12 vials) of black top ova and parasite collection devices was found with an expiration date of 02/2019.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based upon review of records and interview with staff, the laboratory failed to follow the Hematology manufacturers recommendations for calibration of the Hematology Coulter AcT2 Diff instrument in place until March 2019. Findings include: 1. The Coulter Analyzer AcT2 Diff in place until March of 2019 was supposed to have calibration performed every 6 months. Review of calibration documentation for this instrument showed calibration occured 11/2017 and 06/2018, with the 2nd calibration being a month longer than the manufacturer allows. 2. Upon searching further for

	calibration of the aforementioned instrument for the next calibration due in 12/2018, no records could be produced to show calibration occurred as specified in the manufacturers operation manual.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based upon review of Proficiency Testing (PT) results in 2017 and 2018, the Laboratory Director (LD) failed to ensure corrective actions were employed when PT results were not 100 percent. Findings include: 1. In 2017, PT event # 2 had two (2) results that were not 100 percent (Thyroid Stimulating Hormone and Free Thyroxine). No corrective action or LD review was documented 2. In 2018, PT event #3 had two (2) results that were failures (Sodium and Chloride). No corrective action or LD review was documented.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based upon review of testing personnel records, it was revealed that the Laboratory Director (LD) failed to ensure that testing personnel were evaluated for competency using all six elements of competency. Findings include: 1. The element of problem solving skills is absent on all competency assessments available for review during the survey 04/01/2019. 2. Primary testing staff confirmed that this element had not been included in prior competency assessments including his own.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each

	consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of the job description for Laboratory Technicians, the Laboratory Director (LD) failed to ensure an accurate and updated job description was signed, approved and available for review. Findings include: 1. Upon review of the laboratory personnel binder, it was noted that the job description for a Laboratory Technician was outdated in so much that it included X-ray duties. X-ray is no longer performed at this site. 2. The job description had not been approved or signed by the LD. 3. There was no written documentation available of the duties assigned to each individual performing patient testing. 4. Upon review of competency records, it was noted that office personnel performed competency assessment on testing personnel.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based upon review of records and interview with staff during the survey on 4/01 /2019, it was noted that no person meeting the qualification of Technical Consultant was employed by this laboratory in 2017 or 2018. Findings include. 1. No person meeting the CLIA qualifications as Technical Consultant was employed by this laboratory in 2017 or 2018. Competency assessments of testing personnel were carried out by non-CLIA qualified individuals in both years.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based upon review of personnel competency records and discussion with staff, it was noted that problem solving skills have not been assessed for testing personnel. Findings include: 1. Upon review of four (4) different laboratory competency assessments for testing personnel, it was noted that none of them included being assessed for problem solving skills in 2017 and 2018.