Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0524274	06/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Olympus Family Medicine	4624 S Holladay Blvd Suite 100, Holladay, UT	

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
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 on record review of proficiency testing performance evaluations and interview with the testing personnel 1 (TP1), the laboratory failed to attest that proficiency testing samples were tested in the same manner as patient specimens, for 3 of 3 proficiency testing performance evaluations in 2021. Findings include: 1. A review of the proficiency testing performance evaluations on 06/30/22 at 2:55 PM revealed that the laboratory director failed to sign the attestation statement for the American Academy of Family Physicians (AAFP) 2021 events A, B, and C for the categories of clinical microscopy identification, hematology, and urinalysis microbiology. 2. In an interview on 06/30/22 at 3:00 PM, TP1 confirmed that the laboratory director failed to sign the attestation statements.
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 proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to document each step in the testing an reporting of results of proficiency testing for 3 of 3 proficiency testing performance evaluations in 2021. Findings include: 1. Proficiency testing record review failed to include which testing personnel performed the processing and examination proficiency testing for the American Academy of Family Physicians (AAFP) 2021 events A, B, and C for the categories of clinical microscopy identification, hematology, and urinalysis microbiology. 2. In an interview on 06/30/22 at 3:10 PM, TP1 confirmed that the laboratory did not keep records of which testing personnel performed the processing and examination of proficiency testing samples.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with laboratory personnel, the laboratory failed to take remedial action and correct problems when proficiency testing (PT) was unsatisfactory. The laboratory performed approximately 6,000 hematology tests annually on the Beckman Coulter Ac-T diff2 analyzer. Findings include: 1. American Academy of Family Physicians (AAFP) PT event 2022-A review found a performance of "Unsatisfactory" for the White Blood Cell Count with a score of 60%. 2. Record review failed to include documentation that remedial action was taken to correct problems for the unsatisfactory PT testing results. 3. In an interview on 06/30/22 at 2:40 PM, TP1 confirmed that no remedial action was taken for the unsatisfactory PT testing results.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record review and an interview with testing personnel, the laboratory failed establish a written policy to assess personnel for testing on the Beckman Coulter AcT diff2 hematology analyzer and microscopic urinalysis and mycology testing since the last survey on August, 16, 2019. Findings include: 1. Review of

	laboratory policies and procedures revealed the laboratory failed to establish and perform competency assessment for 19 of 19 testing personnel. 2. Interview with testing personnel on June 30, 2022 at approximately 2:15 PM, confirmed there was no competency assessment policy established or performed for testing personnel.
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 on proficiency testing records review, lack of documentation, and interview with laboratory personnel, the laboratory failed to document they reviewed the results of proficiency testing for 3 of 3 proficiency testing performance evaluations in 2021 and 1 of 1 evaluation in 2022. Findings include: 1. Proficiency testing record review failed to include documentation that proficiency testing results were reviewed for American Academy of Family Physicians (AAFP) 2021 events A, B, and C and 2022 event A for the categories of clinical microscopy identification, hematology, and urinalysis microbiology. 2. In an interview on 06/30/22 at 3:05 PM, TP1 confirmed that the proficiency testing records failed to include documentation results were reviewed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the complete blood count procedure manual and an interview with the testing personnel, the laboratory failed to include reportable range for test results for the test system as established or verified, corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability, imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedure

	manual. Findings include: 1. Review of the procedure manual revealed a lack of reportable range for test results for the test system as established or verified, corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability, imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable. 2. Interview with the TP1 on 06/30/2022 at 4:00 PM confirmed the laboratory failed to include reportable range for test results for the test system as established or verified, corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability, imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedure manual.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with the testing personnel, expiration dates were not written on open vials of hematology controls (Coulter 4C-ES Cell Control). The laboratory performed approximately 6,000 hematology tests annually on the Beckman Coulter Ac-T diff2 analyzer. Findings include: 1. Record review of the package insert for Coulter 4C-ES Cell Control stated that control vials had a 35 day expiration date from the day the vial was initially opened. 2. Direct observation on 06/30/2022, at 16:15, revealed the expiration dates failed to be written on three of three hematology controls. 3. In an interview on 06/30/2022 at 16:15, with the TP1, confirmed that expiration dates are not written on the controls.
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 on direct observation and interview with testing personnel, the laboratory failed to ensure that Potassium Hydroxide solution was not used past its expiration date. The laboratory performs approximately 18 microbiology tests annually. Findings include: 1. Direct observation of EDM3 Solutions Potassium Hydroxide 10% in DMSO Lot 0043 had an expiration date of 02-12-2022. The date of the survey was 06-30-2022. 2. Interview with the TP1 on 06-30-2022 at 16:20 confirmed the EDM3 Solutions Potassium Hydroxide 10% in DMSO was being utilized for patient testing past its expiration date.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control record's review, lack of documentation, and interview with laboratory personnel, the laboratory reported patient results when controls were out of range. The laboratory performed approximately 6,000 hematology tests annually on the Beckman Coulter Ac-T diff2 analyzer. Findings include: 1. A record review of quality control logs showed that on 05/10/22 the WBC/Diff control L was out of range, no corrective action was taken, and patient test results were reported. 2. In an interview on 06/30/22 at 3:50 PM, TP1 confirmed that no remedial action was taken for the control that was out of range and patient test results were reported.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with testing personnel the laboratory failed to document any corrective actions taken when room humidity was out of established operating parameters. The laboratory performed approximately 6,000 hematology tests annually on the Beckman Coulter Ac-T diff2 analyzer. Findings include: 1. Beckman Coulter Ac-T diff2 instrument manual states to keep "humidity to between 20 and 85 percent without condensation." 2. Record review of "Humidity Chart" revealed that the humidity was below 20% on 153 of 154 days where humidity was recorded in 2022. 3. Record review of "corrective action-coulter" logs revealed a lack of documentation of correction action taken when humidity was less than 20%. 4. Direct observation of laboratory hygrometer on 06/30/2022 at approximately 16:10 showed room humidity was less than 20%. 5. In an interview on 06/30/2022 at approximately 16:15, the testing personnel confirmed room humidity was less than 20% and no corrective action was taken.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview with laboratory staff, the laboratory director failed to provide management and direction to the laboratory by failure to that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory (See D6019); and failure to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur (See D6022).
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 on proficiency testing records review, lack of documentation, and interview with laboratory personnel, the laboratory director failed to ensure that the laboratory follow a corrective action plan for unsatisfactory proficiency (PT) testing results. The laboratory performed approximately 6,000 hematology tests annually on the Beckman Coulter Ac-T diff2 analyzer. Findings include: 1. American Academy of Family Physicians (AAFP) PT event 2022-A review found a performance of "Unsatisfactory" for the White Blood Cell Count with a score of 60%. 2. Record review failed to include documentation that the laboratory director ensured that an approved corrective plan was followed to correct problems for the unsatisfactory PT testing results. 3. In an interview on 06/30/22 at 2:40 PM, TP1 confirmed that no corrective action plan was followed for the unsatisfactory PT testing results.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with testing personnel. The laboratory director failed to establish a quality assessment program and identify failures in quality control in their quality control samples for the Beckman Coulter Ac-T diff2 instrument. The laboratory performs approximately 6,000 hematology tests annually. Findings include: 1. Record review failed to show that a written policy or procedure for performing quality assessment had been established in the laboratory. 2. During document review of the laboratory's Beckman Coulter Ac-T diff2 analyzer's quality control logs there was no evidence to show that the laboratory director performed a review of the quality control data. 3. In an interview on 06/30/2022 at

	approximately 4:00 PM, TP1 confirmed that the lab did not have a quality assessment program and the laboratory director did not review quality control logs.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review training documentation and staff interview, the laboratory director failed to provide evidence that training assessed the skills required for patient testing. The laboratory performs approximately 6,000 hematology tests annually. Findings include: 1. Record review failed to produce a policy on what skills were required for the training of testing personnel. Training sign off documentation also failed to include the skills were assessed. 2. In an interview conducted on 06/30/2021 at approximately 2:15 PM, TP1 confirmed that laboratory did not have a policy or procedure for initial training documentation for testing personnel on what skills were assessed.