

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0524274	<b>(X3) Date Survey Completed</b> 08/16/2019
<b>Name of Provider or Supplier</b> Olympus Family Medicine	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2122</b>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review, CMS 155 report review, lack of documentation, and interview with staff, the laboratory failed to achieve a satisfactory proficiency testing score of at least 80% for the first American Academy of Family Physicians (AAFP) for the first complete blood cell testing event (A) of 2018. Findings include: 1. CMS 155 proficiency testing summary report review included scores of 0% for CBC testing for the first event of 2018. 2. Proficiency testing records review included test results from AAFP stating the results were not graded due to laboratory discontinued testing. 3. In an interview with staff on 08/16/2019 at approximately 1:27 P.M. staff stated the instrument did not provide test results (printouts included dashes only) at the time of proficiency testing. Patient testing was being performed and the laboratory had not discontinued testing.</p>
<b>D2123</b>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two</p>

proficiency testing events.

This STANDARD is not met as evidenced by:

Based on proficiency testing record review and interview with staff, the laboratory failed to participate in 3 of 3 American Academy of Family Physicians (AAFP) complete blood cell count (CBC) proficiency testing events in 2018. Findings include: 1. Proficiency testing records review included documentation the laboratory could not obtain test results for samples from event A of 2018 for CBC test samples. The laboratory reported discontinued testing to the AAFP testing agency for event A. 2. Proficiency testing records review failed to include documentation the laboratory reported CBC results to AAFP proficiency testing agency for the 2nd and 3rd (Events B and C) proficiency events of 2018. The records included instrument print outs for proficiency testing samples for both events. 3. Proficiency records review did not include scores of 0% for the 2nd and 3rd events for non participation when they failed to participate in the previous two events. The laboratory did not receive score of 0 percent for non participation subsequent to the first event when the laboratory reported they had discontinued CBC testing yet continued to receive Proficiency samples. 4. In an interview with staff on 08/16/2019 at approximately 1:30 staff stated the laboratory had problems with proficiency samples they could not resolve in time to report results to the AAFP PT agency.

**D5200**

**GENERAL LABORATORY SYSTEMS**

CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on proficiency testing records review, lack of documentation and interview with staff, the laboratory failed to review proficiency test results for 6 of 6 testing events to identify problems in reporting Complete Blood Count test results for 3 of 3 testing events the laboratory failed to participate in 2018. (SEE D5211 and D5215)

**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 and interview with staff, the laboratory failed to review American Academy of Family Physicians (AAFP) proficiency test results to identify complete blood count (CBC) test problems for 6 of 6 testing events reviewed from the 3rd event of 2017 to the 2nd event of 2019. Findings include: 1. Proficiency testing records review failed to include documentation of CBC proficiency testing results review for AAFP event C of 2017, events A, B, and C of

2018 and events A and B of 2019. 2. Proficiency testing records review failed to include documentation the laboratory participated in AAFP CBC event's A, B, and C of 2018. 3. Proficiency testing records review failed to include documentation test reports were evaluated to identify the failure to participate in CBC proficiency testing in 2018. 4. In an interview with staff on 08/16/2019 at approximately 1:27 P.M. staff stated the laboratory performed CBC testing in 2018.

**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 lack of documentation. proficiency testing records review, and interview with staff, the laboratory failed to verify Complete Blood Count (CBC) test accuracy when the lab failed to participate in CBC proficiency testing for 3 of 3 testing events in 2018. Findings include: 1. The laboratory failed to document they reviewed the instrument print out results for American Academy of Family Physicians (AAFP) against the intended result for testing events A, B, and C of 2018. 2. In an interview with staff on 08/16/2019 at approximately 4:00 P.M. staff confirmed the laboratory did not have documentation to demonstrate they verified CBC accuracy in 2018 when they failed to participate in 3 of 3 AAFP testing events.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on proficiency test records review, lack of documentation, and interview with staff, the laboratory director failed to ensure the laboratory participated in Proficiency testing for Complete Blood Cell Count (CBC) testing for 3of 6 testing events reviewed, events A, B, and C of 2018 as required.. The laboratory performed approximately 1000 CBC tests per year. 1. Proficiency testing records review included documentation the laboratory failed to participate in proficiency testing after Event A of 2018 when the laboratory reported to American Academy of Family Physicians, (AAFP) they were "not testing due to instrument broken." The proficiency test report stated the results were not graded - lab discontinued testing. 2. Patient records reviewed included documentation the laboratory continued to test patient samples (Dates of CBC testing reviewed include 02/19/2018 for Patient 05139702, 05/10/2018 Patient 1601, 07/19/2018 for patient 06018800, 0913/2018 for patient 558899567, and 12/06/2018 for patient 05531588.) 3. A. Proficiency testing records

review included instrument print outs from the CBC instrument, a graded AAFP report of 100% for microscopic testing, but lacked documentation of an agency report form for CBC result submission for AAFP testing event B. B Proficiency testing records review for AAFP event C failed to include an agency report form for submitted CBC results, included an AAFP proficiency test report form with an exclusion code 6 (the code 6 interpretation was not available). Instrument print outs were present and dated 10/12/2018 for specimens 11-15. 4. In an interview conducted with staff on 08/16/2019 at approximately 1:27 P.M. staff stated the laboratory failed to return the testing results prior to the cut off date for graded CBC results.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on lack of documentation and interview with staff, one of eight testing personnel failed to qualify as a moderate complexity testing person. (See D6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with staff, one of eight testing personnel lacked documentation to qualify as a moderate complexity testing person for performing complete blood count testing. Findings include: 1. Personnel qualification records review failed to include testing person H did not have documentation to meet the educational benchmarks to meet the moderate complexity qualifications. 2. In an interview with staff on 08/16/2019 and by phone on 09/05/2019 staff confirmed they had not received a diploma, GED or transcript meeting the educational benchmark requirements.