

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0991303	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Orem Family Medicine	Street Address, City, State 173 N 400 W Ste C-11, Orem, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing reports review, lack of documentation and interview with staff, the laboratory failed to review and evaluate American Proficiency Institute (API) testing results for 4 of 4 testing events the laboratory scored 0% or 60% for Trichomonas presence or absence identification. Findings include: 1. The first event of 2017 the laboratory reported the instrument was not in service. The laboratory was excused from participation. 2. The second event of 2017 the laboratory received a 60% score for Trichomonas presence or absence, The laboratory reported VP 07 as negative for Trichomonas. The correct response was positive. The laboratory reported VP 08 as positive. The correct response was negative. 3. The third event of 2017 the laboratory failed to return proficiency testing results within the established timeframe and received a score of 0% for Trichomonas identification presence or absence. The laboratory did not self grade their test results to those expected. (The lab would have passed with an 80% score had they self graded.) 4. The first event of 2018 the laboratory failed to participate in proficiency testing receiving a score of 0%. The laboratory lacked documentation they performed the test samples. 5. In an interview conducted on 04/17/2019 at approximately 4:40 P.M. staff stated the laboratory lacked documentation they evaluated their results and verified the test was performing accurately and precisely when their scores did not reflect passing performance.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on Affirm VP manufacturer's instructions for DNA extraction review, patient test records review, and confirmation by staff, the laboratory failed to ensure specimens were incubated at 85 degrees for at least 10 minutes, but less than 20 minutes, for 3 of approximately 160 specimens reviewed from 06/16/2019 to 04/08/2019. Findings include: 1. VP Affirm manufacturer's instructions stated the laboratory was to incubate vaginal specimens at 85 degrees using the extraction reagent for 10 minutes but not more than 20 minutes. The instructions stated the lab should use a timer. 2. Laboratory test records reviewed included documentation the laboratory failed to monitor the incubation times for specimens 791819 on 06/21/2017, 128337 on 04/29/2017, 1375985 on 10/04/2017, and 1147587 on 03/24/2019. 3. In an interview with staff on 04/17/2019 the laboratory staff stated testing personnel were to set the timers on their cell phones to remind them to return to the location where the specimen was incubating. It was not determined if timers were not set, not heard, or if staff was not able to return to complete the DNA extraction process for 24 hour specimen stabilization for testing within 24 hours. THIS IS A REPEAT DEFICIENCY.

D5461

CONTROL PROCEDURES

CFR(s): 493.1256(d)(6)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to perform quality control for new lot numbers of Affirm VP tests for 3 of 12 lot numbers reviewed from 06/16/2017 to 04/08/2019. The laboratory performed approximately 160 tests per year for Candida, Gardnerella, and Trichomonas presence or absence using the Affirm VP test system. Findings include: 1. Patient test records review included documentation the laboratory performed patient testing using VP Affirm Kit lot numbers 8312959 for patient testing for patient 429991 on 03/13/2019 without performing a known positive Trichomonas quality control; for Kit lot number 732562 for patient number 428491 on 05/01/2018 ; Kit lot number 732562 on 11/08/2017 for patient 886041; and for Kit lot number 6286517 on 08/03/2017 for patient number 424568 the laboratory reported patient test results without performing external known positive and negative quality control for Candida, Gardnerella, and Trichomonas . 2. The laboratory lacked documentation kit lot numbers listed in finding number 1 had 2 levels of external controls for Candida, Gardnerella, and Trichomonas performed prior to testing patient specimens. 3. In an interview conducted on 04/17/2019 at approximately 4:45 P.M. the laboratory staff confirmed the laboratory did not have quality control performance documentation recorded prior to testing patient samples. THIS IS A REPEAT DEFICIENCY.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on competency evaluations review, lack of the technical consultant's signature, and confirmation by staff, the laboratory technical consultant failed to evaluate testing personnel for one of two years of testing performed (2018) for 4 of 4 testing personnel performing moderate complexity testing in 2018. Findings include: 1. Testing personnel competency evaluations review lacked the signature of the laboratory technical consultant as documentation the qualified technical consultant evaluated moderate complexity testing personnel by directly observing routine patient testing performance, recording and reporting test results, reviewing intermediate test results or worksheets, quality control records, directly observing instrument maintenance and function checks, assessing test performance through previously tested specimens, internal blind testing samples or external proficiency tests (proficiency tests not self graded), assessment of problem solving skills and evaluating personnel annually after the first year of testing for AffrimVP testing for the presence or absence of Candida, Gardnerella, and Trichomonas organisms. 2. In an interview conducted on 04/17/2019 at approximately 4:50 P.M. laboratory staff confirmed competency evaluations were performed by other testing staff members who were not qualified to be the technical consultant.

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, the laboratory failed to ensure 1 of 7 new testing personnel met the qualifications for moderate complexity testing personnel. (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 personnel test list review, testing personnel qualification records review, lack of documentation, and interview with staff, one of seven new testing personnel failed to have education documentation to qualify as a moderate complexity testing person. Findings include: 1. Personnel test list review included test person B who was trained to perform Affirm VP testing for the presence or absence of Candida, Gardnerella, and Trichomonas organisms from vaginal swabs on 02/27/2019. 2. Personnel qualification records review failed to include a diploma or transcript for Test person B to qualify as a moderate complexity testing person. 3. In an interview with the laboratory staff, on 04/17/2019 at approximately 4:50 P.M. staff confirmed Test person B did not have a copy of a transcript or diploma to qualify as a moderate complexity testing person.