

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D2033373	<b>(X3) Date Survey Completed</b> 08/21/2019
<b>Name of Provider or Supplier</b> Synergy Women's Health Care	<b>Street Address, City, State</b> 2525 Nw Lovejoy, Suite 300, Portland, OR	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing records and discussion with the staff the laboratory failed to verify the accuracy of the test or procedure twice annually for the Potassium Hydroxide (KOH) test system. Findings include: 1. The surveyor requested and the laboratory failed to provide biannual verification for the KOH test system for 2018 and 2019. 2. The last biannual verification documentation was done 07/13/2017. 3. The Lead testing personnel and the Nurse Practitioner confirmed these findings on 08/21/2019 at 05:00PM.</p>
<b>D6000</b>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel, training and competency records the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6029 and D6030.</p>
<b>D6029</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p>

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 on review of Personnel and training records and discussion with the staff the Laboratory Director failed to ensure that prior to patient testing the laboratory testing personnels have the proper education and training documentation. Findings include. 1. The surveyor requested and the laboratory failed to provide copies of diplomas or transcript of records of 5 out of 6 testing personnel (TP) performing moderately complexity testing at the time of survey. 2. The lead and the assistant lead testing personnel confirmed these findings on 08/21/2019 at 05:00 PM.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on review of Personnel competency records and discussion with the staff the Laboratory Director who also served as the Technical Consultant failed to document competency assessment of the testing personnels performing moderate complex testing. Findings include: 1. The surveyor requested and the laboratory failed to provide documentations of competency assessment for the testing personnels performing moderate complexity testing at the time of survey. 2. 3 testing personnels that started working in the laboratory on 06/2018 have their initial training documentations but do not have their 6 months and annual comptency assessments. 2. 2 testing personnel that were hired 03/2019 and 04/2019 have their intial training documentations but do not have their 6 months competency assessments. 3. The lead testing personnel have annual competency documentation for 2017 and 2019 but no documentation for 2018. 4. The lead and the assistant lead testing personnel confirmed these findings on 08/21/2019 at 05:00PM.