

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  47D0090617	<b>(X3) Date Survey Completed</b>  09/12/2018
<b>Name of Provider or Supplier</b>  White River Family Practice, Pc	<b>Street Address, City, State</b>  331 Olcott Drive Suite U3, White River Junction, VT	
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><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 record review and staff interview, the laboratory failed to verify the accuracy of mycology and parasitology in 2016, 2017, and 2018. Findings include: 1) Review on 9/12/2018 of potassium hydroxide (KOH) preparation and wet mount slide examination test logs from November 22, 2016 through present revealed the laboratory failed to verify the accuracy of KOH and wet mounts at least twice in 2016, 2017, and 2018. 2) Interview on 9/12/2018 at 10:20 a.m. confirmed the above finding. 3) The laboratory performs 24 KOH and wet mount slide examinations annually.</p>
<b>D5447</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform chemistry control testing each day of patient specimens were assayed in 2017 and 2018. Findings include: 1) Review on 9/12/2018 of control records for thyroid stimulating</p>

hormone (TSH) revealed two levels of controls were tested for each new lot number of TSH reagent and every 30 days. 2) Review on 9/12/2018 of the control procedure for TSH revealed instruction to perform two levels of controls for each new lot number of TSH reagent and every 30 days. 3) Interview on 9/12/2018 at 12:15 p.m. with testing personnel confirmed the above findings and revealed that the laboratory did not develop an individualized quality control plan (IQCP) to support its alternative control practices for TSH. 4) The laboratory performs 1,028 TSH tests annually.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the technical consultant failed to assess the test performance of testing personnel performing mycology and parasitology slide examinations in 2016, 2017 and 2018. Findings include: 1) Review on 9/12/2018 of potassium hydroxide (KOH) preparation and wet mount slide examination test logs from November 22, 2016 through present revealed three of three testing personnel failed to be evaluated for test performance in 2016, 2017 and 2018. 2) Interview on 9/12/2018 at 10:20 a.m. confirmed the three testing personnel were not assessed for test performance of KOH and wet mount slide examinations. 3) The laboratory performs 24 KOH and wet mount slide examinations annually.