

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D1066600	<b>(X3) Date Survey Completed</b> 10/20/2025
<b>Name of Provider or Supplier</b> O'Bryon Family Medicine Inc	<b>Street Address, City, State</b> 898 Beaver Drive, Dubois, PA	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of maintenance records, and interview with the Technical Consultant (TC), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 VWR traceable thermometer used to monitor temperature in the chemistry laboratory from 10/23 /2023 to 10/20/2025. Findings include: 1. On the day of survey, 10/20/2025 at 2:15 pm, observation of the laboratory revealed 1 of 1 VWR traceable thermometer (serial number 130767722) was due for calibration on 12/19/2015. 2. The laboratory failed to provide documentation of maintenance and function checks for 1 of 1 VWR traceable thermometer used to monitor refrigerator temperature in the chemistry laboratory from 10/23/2023 to 10/20/2025. 3. The TC confirmed the above findings on 10/20/25 at 2:35 pm.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with the Technical Consultant (TC), the TC failed to assess the test performance of 1 of 2 testing personnel (TP) through testing previously analyzed specimens, internal blind testing samples or external proficiency</p>

testing samples for routine chemistry tests performed from 10/23/23 to 10/20/2025. Findings Include: 1. On the day of the survey, 10/20/2025 at 1:15 pm, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) attestation records for routine chemistry analyses revealed TP # 2 (CMS 209, dated 10/07/2025) performed all of the PT samples for the events in 2024 and 2025. 2. The laboratory failed to provide documentation for the evaluation of test performance through internal blind testing or external PT samples for routine chemistry for 1 of 2 TP (CMS 209, TP # 1) that did not perform PT testing from 10/23/2023 to 10/20/2025. 3. The laboratory performed 830 routine chemistry and endocrinology tests in 2024 (CMS 116, estimated annual volume, dated 10/06/2025). 4. The TC confirmed the findings above on 10/20/2025 at 2:35 pm.