

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0721755	(X3) Date Survey Completed 11/23/2020
Name of Provider or Supplier Skippack Medical Lab, Llc	Street Address, City, State 200 Rittenhouse Circle East, Suite 9, Bristol, PA	
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 the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to identify problems that required corrective actions for the AAB PT for chemistry, High-density lipoprotein (HDL), Thyroid-stimulating hormone (TSH) and Triiodothyronine during the 1st event of 2019. Findings include: 1. On the date of survey, 11/23/2020, a surveyor review of AAB PT records revealed, in 2019 the following PT results did not have corrective actions documented: - AAB 1st event, Chemistry, HDL - 80% score. - AAB 1st event, Chemistry, TSH - 80% score. - AAB 1st event, Chemistry, Triiodothyronine - 80% score. 2. The LD confirmed the findings above on 11/23/2020 around 10:20 am.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the laboratory director (LD), the TC (LD) failed to evaluate the test performance for 4 of 5 testing personnel (TP) through internal blind</p>

testing samples or external PT samples for Routine chemistry and Hematology testing performed in 2019 and 2020. Findings Include: 1. On the day of survey, 11/23/2020, review of AAB PT records revealed, 2 of 5 TP (TP#1 and TP#2) performed all the external PT samples for Routine chemistry (TP#2) and Hematology (TP#1) testing performed for 3 of 3 events in 2019 and 3 of 3 events in 2020. 2. Personnel competency assessment recorded for the test performance through internal blind testing samples or external PT samples for Routine chemistry and Hematology testing were check as completed in 2019 and 2020 for all testing personnel. 3. The LD could not provide documentation of internal blind testing evaluations performed for: - 3 of 5 TP (TP#3, 4 and 5) for Routine chemistry testing in 2019 and 2020. - 4 of 5 TP (TP#2, 3, 4 and 5) for Hematology testing in 2019 and 2020. 4. The LD confirmed the findings above on 11/23/2020 at 10:50 a.m.