

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0921062	<b>(X3) Date Survey Completed</b>  03/06/2019
<b>Name of Provider or Supplier</b>  Coppe Laboratories	<b>Street Address, City, State</b>  W229 N1870 Westwood Dr, Waukesha, WI	
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>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of proficiency testing (PT) reports and interview with the technical supervisor, the laboratory director did not verify the accuracy of Anaplasma phagocytophilum immunoglobulin testing for two of two ungraded results in 2018. Findings include: 1. Review of College of American Pathologist (CAP) PT reports for the first event of 2018 showed the laboratory reported "positive" for specimen TTD-03 for the Anaplasma phagocytophilum immunoglobulin M (IgM) test. The PT provider did not grade the result; sixty percent of reporting laboratories reported "negative". The laboratory's records did not include a review of the ungraded result to verify the accuracy of the test system. 2. Review of CAP PT reports for the second event of 2018 showed the laboratory reported "positive" for specimen TTD-05 for the Anaplasma phagocytophilum immunoglobulin G (IgG) test. The PT provider did not grade the result; seventy-seven percent of reporting laboratories reported "negative". The laboratory's records did not include a review of the ungraded result. 3. Interview with the technical supervisor, staff A, on March 6, 2019 at 10:45 AM confirmed the laboratory director did not evaluate the accuracy of Anaplasma phagocytophilum immunoglobulin results for the two ungraded samples in 2018. Item 2: Based on surveyor review of proficiency testing (PT) reports and interview with the technical supervisor, the laboratory director did not verify the accuracy of the class designation reported for peanut allergy for three ungraded results in 2018. Findings include: 1. Review of College of American Pathologists (CAP) PT reports for the first</p>

event of 2018 showed the laboratory reported "Class Four" for specimen SE-03 for peanut allergy. Seventy-eight percent of laboratories reported "Class Two". The laboratory director noted, "Will monitor" on the report. 2. Review of CAP PT reports for the second event of 2018 showed the laboratory reported "Class Four" for specimen SE-07 for peanut allergy. Eighty-eight percent of laboratories reported "Class Two". The laboratory director noted, "Will monitor" on the report. 3. Review of CAP PT reports for the third event of 2018 showed the laboratory reported "Class Four" for specimen SE-12 for peanut allergy. Eighty-seven percent of laboratories reported "Class Two". The laboratory director noted, "Will monitor" on the report. 4. Interview with the technical supervisor, staff A, on March 6, 2019 at 11:15 AM confirmed the laboratory director did not verify the accuracy of the class designation reported for peanut allergy for three immunology PT events in 2018.