

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0921062	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Coppe Laboratories	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory did not evaluate the accuracy for fifteen of fifteen ungraded PT results in event two of Tick Transmitted Diseases (TTD) in 2022. Findings include: 1. Review of College of American Pathologists (CAP) PT records showed CAP entered notes for the ungraded analytes stating "Educational Challenge" for fifteen results for TTD-B 2022. Further review showed the laboratory did not evaluate the accuracy of the fifteen results to include three Borrelia burgdorferi IgM results, three Borrelia burgdorferi IgG results, three Babesia microti IgG results, three Anaplasma phagocytophilum IgM results and three Anaplasma phagocytophilum IgG results. 2. Review of CAP PT evaluation for the event showed one of three Babesia microti IgG results obtained by the laboratory did not concur with the expected results provided in the evaluation. 3. Interview with the general supervisor on March 23, 2023 at 11:55 AM confirmed the laboratory did not evaluate the accuracy for fifteen of fifteen ungraded educational challenge PT results for the Tick Transmitted Disease testing for event two in 2022.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),</p>

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs and interview with the general supervisor, the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range for room temperature for one hundred forty of two hundred fifty-four days in 2022. Findings include: 1. Review of room temperature logs revealed no documentation of corrective action on temperature readings outside the acceptable range of 20-25 degrees Celsius (C) on the following days in 2022: January 19, 21, 24 February 14, 28 March 1-2, 4, 7-9, 16-18, 22, 29-30 April 5-8, 11, 18, 20-22, 26, 29 May 2-3, 9-13, 16, 18-20, 23, 25-26, 31 June 2-3, 7-10, 14-17, 20-24, 27-30 July 1, 5-8, 11-15, 18-22, 25-29 August 2-5, 8-12, 15-19, 22-26, 29-31 September 1-2, 6-9, 12-16, 19-23, 26-29 October 6-7, 10, 12-14, 17, 25-26, 31 November 1-2, 7, 9-10, 23 December 30 2. Interview with the general supervisor on March 23, 2022, at 1:30 PM confirmed the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on for room temperature for one hundred forty of two hundred fifty-four days in 2022.