Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397433	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier Encircle Health Thedacare Physician Laboratory	**Street Address, City, State** 2500 E Capitol Dr, Appleton, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the technical consultants, the laboratory did not perform proficiency testing in the same manner as patient tests since September 6, 2018. Findings include: 1. The American Proficiency Institute (API) PT records from the second hematology event of 2018 included an email from September 6, 2018 to "ECH Lab Staff" from a previous supervisor (staff C) stating: "Team - Going forward I will be asking another team member to result PT results that were entered into API manually. I do verify all upload results to API before submitting, along with the manual enter errors, but need a second pair of eyes for the manual part that is entered. After reviewing please place your initials on the API result form." 2. Interview with the technical consultants (staff A and B) on February 27, 2019 at 10:30 AM confirmed testing personnel report patient test results without review by a second person. Further interview confirmed testing personnel did not perform proficiency testing in the same manner as patient testing since September 6, 2018.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of performance verification records, laboratory procedures, and interview with the laboratory's technical consultants, the laboratory did not evaluate the full reportable range for ESR (Erythrocyte Sedimentation Rate) testing to show it was comparable to the reportable range of the manufacturer for the HemaTechnologies ESR Stat Plus analyzer. Findings include: 1. Review of the performance verification records for the HemaTechnologies ESR Stat Plus analyzer showed the laboratory evaluated specimens ranging from 3 - 90 millimeters per hour (mm/hr). 2. Review of the "Erythrocyte Sedimentation Rate ESR Stat Plus Policy 104" procedure showed the laboratory's stated reportable range for the ESR test is 1-140 mm/hr. 3. Interview with the laboratory's technical consultants (staff A and B) on February 27, 2019 at 3:00 PM confirmed the reportable range identified in the procedure was the manufacturer's reportable range. Further interview confirmed the laboratory did not evaluate samples with results between 90 and 140 mm/hr and did not evaluate the full reportable range for the HemaTechnologies ESR Stat Plus analyzer.