

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0432460	(X3) Date Survey Completed 06/04/2024
Name of Provider or Supplier Hopedale Medical Complex	Street Address, City, State 107 S Tremont St, Hopedale, IL	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based direct observation, review of laboratory records, lack of documentation, and interview with the General Supervisor (GS); the laboratory failed to have a system in place that twice yearly evaluates the relationship between testing on two of two Siemens Epc analyzers (Serial Numbers: 6324 and 26795) utilized for blood gas testing from 2022 through the date of survey, 06/04/2024. Findings include: 1. Upon a tour of the laboratory on 06/04/2024, at 11:45 am, direct observation identified two Siemens Epc analyzers (Serial Numbers: 6324 and 26795) utilized for blood gas testing. 2. Review of the laboratory's procedure for blood gas analyte testing identified that the procedure failed to address how the relationship between the two analyzers will be evaluated twice yearly. 3. Review of the laboratory "I [Instrument] to I [Instrument]" records revealed no instrument to instrument comparisons for blood gas analytes performed on two of two Siemens Epc analyzers in 2022 through the date of survey, 06/04/2024. 4. On survey date 06/04/2024, at 02:55 pm, the GS confirmed the above findings.</p>