Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0432460	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hopedale Medical Complex	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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with the laboratory technical supervisor (TS) #2; the laboratory failed to conduct calibration verifications as required for procalcitonin testing on the bioMerieux VIDAS analyzer. Findings include: 1. Direct observation of testing equipment during tour of the laboratory at 10:00 am, on 7-31-2018, identified the bioMerieux VIDAS analyzer. 2. Interview with TS#2, on 7-31-2018, at 10:00am, confirmed procalcitonin (PCT)

	testing is performed on the VIDAS. 3. Review of the laboratory procedure, "Vidas 3 Procalcitonin", failed to identify the calibration verification procedure for PCT testing on the VIDAS. 4. Review of calibration records for the VIDAS found no record of calibration verification for PCT testing in 2016 through the date of survey, 07-31-2018. 5. Laboratory test volume records indicate 175 patients were tested for PCT on the VIDAS from August of 2017 through July of 2018. 6. Interview on 7-31-2018, at 4:45 pm, with TS#2, confirmed PCT calibration verifications failed to be performed by the laboratory on the VIDAS analyzer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with technical supervisor (TS) #2; the laboratory failed to perform positive and negative controls for qualitative serum human chorionic gonadotropin (hcg) testing for 3 of 3 patient test dates reviewed. Findings Include: 1. Direct observations of laboratory testing on 7-31-2018, at 10:00 am, identified "Alere HCG Combo" kits used for qualitative serum hcg testing. 2. Review of the laboratory procedure manual identified the procedure, "Alere HCG Combo", which indicated controls are to be ran with each new lot and each new untrained operator. 3. Interview with TS#2, on 7-31-2018, at 1: 25pm, confirmed no individual quality control program was in place for qualitative serum hcg testing and the laboratory only performs quality controls on each new lot of test kits. 4. Review of 2 of 3 patient test results found no quality control testing was documented for 2 of 3 lots of Alere HCG Combo test kits. Patient Identification Test Kit Lot # Test Date P37 7020014 10-09-2017 P06 5080185 10-28-2016 5. Review of qualitative serum hcg patient test reports for 3 of 3 patient test dates found no external quality controls were performed or documented each day of testing. Patient Identification Test Date P37 10-09-2017 P06 10-28-2016 P38 05-31-2017 6. Review of the laboratory test volume worksheet indicated 23 patient test results were reported for serum hcg from August of 2017 through July of 2018. 7. Interview with TS#2, on 7-31-2018, at 4:35 pm, confirmed daily external quality controls were not performed for qualitative serum hcg and the quality control records for 2 of 3 lots of Alere HCG Combo test kits failed to be documented.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by:

	Based on direct observation, review of the laboratory records, and interview with technical supervisor (TS) #2; the laboratory failed to have a system in place that twice yearly evaluates the relationship between analyte testing on Triage MeterPro instruments. Findings Include: 1. Direct observation on 7-31-2018, at 10:00 AM, identified two Triage MeterPro analyzers (Serial Numbers: 00046469 and 00046592). 2. Review of laboratory records for the two Triage MeterPro analyzers found no instrument to instrument comparisons for D-Dimer, Cardiac Panel (myoglobin, creatine kinase MB fraction, and Troponin-I), and Drug toxicology screen (acetaminophen, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC, tricyclic antidepressants) testing in 2016 through date of survey, 7-31-2018. 3. On survey date 07-31-2018, at 4:35 PM, TS#2 confirmed the laboratory failed to evaluate the relationship between the two Triage MeterPros twice yearly for D-Dimer, Cardiac Panels, and Drug toxicology screens.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS) #2; the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. TP#7, 22, and 23, as listed on the CMS-209, failed to have documented training prior to analyzing patient specimens for moderate complexity testing. See D6066.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS) #2; the laboratory failed to have training documentation for 3 of 9 new moderate complexity TP listed on the CMS-209. Findings Include: 1. Review of laboratory personnel records found no training documentation for TP#7, TP#22, and TP#23 prior to analyzing patient specimens. 2. On survey date 07-31-2018, at 4:35 pm, TS#2 confirmed the laboratory failed to have training documentation for 3 of 9 (TP#7, 22, and 23) moderate complexity TP prior to analyzing patient specimens.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

	to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS) #2; the laboratory technical supervisors failed to ensure annual competency assessments were completed for TP in 2017. Findings Include: Repeat Deficiency 1. Review of the laboratory's policy and procedure manual identified the policy, "Laboratory Competency", which stated the following: "5. Competency and performance evaluations will be performed twice during the first year of employment and annually thereafter." 2. Review of competency assessment documentation found the TS failed to ensure annual competency assessments were completed for 14 of 14 TP reviewed in 2017. a. Testing Personnel (as listed on the CMS-209): #1, 2, 5, 6, 8, 9, 11, 12, 13, 15, 17, 18, 20, and 21. 3. On survey date 07-31-2018, at 4:35 pm, TS#2 confirmed annual competency assessments were not completed in 2017 for 14 of 14 TP reviewed.