Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307353	01/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Expertus Health Llc	2718 Squirrel Hollow Drive 1st Floor, Linden, TN	

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
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 review of validation data for the lactic acid assay, patient report number one, the manufacturer's package insert and interview with the laboratory supervisor, the laboratory failed to verify manufacturer's reference range in 2017. The findings include: 1. Review of the validation data for the lactic acid assay performed October 17, 2017 revealed no studies to verify manufacturer's reference range. 2. Review of patient number one report for lactic acid dated November 3, 2017 revealed a reference range of 0.4-2.0 mmol/L. 3. Review of the manufacturer's package insert revealed a reference range of 0.4 - 2.0 mmol/L. 4. Interview with the laboratory supervisor on January 3, 2018 at 5:00 pm confirmed the laboratory performs lactic acid testing beginning October 2017, uses the manufacturer's reference range, and failed to verify the manufacturer's reference range prior to patient testing in October 2017.
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 observation of the laboratory, review of manufacturer's package inserts, and interview with the laboratory supervisor, the laboratory failed to perform calibration verification at least every six month for the analytes Sodium (Na), Potassium (K), Chloride (CL), and Triglyceride in 2016 and 2017. 1. Observation of the laboratory on January 3, 2017 at 9:00 am revealed the Siemens Dimension EXL in use for patient testing. 2. Review of the manufacturer's package insert for Na, K, Cl, and Triglyceride revealed the following: Na, K, Cl, - two calibration points Triglyceride assay range = 15 - 1000 mg/dL, Calibration levels = 120, 240, 485 mg/dL 3. Interview with the laboratory supervisor on January 4, 2018 at 10:00 am confirmed the laboratory uses the Siemens Dimension EXL for patient chemistry testing beginning July 2016 and no calibration verification records were available. The laboratory failed to perform calibration verification of Na, K, Chloride, and triglyceride analytes at least every six months using at least three calibration points that include a minimal, mid and maximum value in 2016 and 2017.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy titled "Crossmatching Procedure", the document titled "Transfusion Service Testing Record", the policies titled "Immunohematology Quality Improvement", "Quality Assessment and Performance Improvement Program", the form used for daily quality assessment, and interview with the laboratory supervisor, the laboratory failed to identify and correct problems with immunohematology testing in 2016 and 2017. The findings include: 1. Review of the laboratory's policy titled "Crossmatching Procedure" revealed that the crossmatch will include "ABO and Rh typing of the patient and donor blood." 2. Review of the document titled 'Transfusion Service Testing Record" revealed no secondary review

	of the transfusion service testing record with the following errors noted: Crossmatch testing performed on 4-22-16 for patient number two, 4-26-16 for patient numbers three and four, 5-20-17 for patient number five, and 10-18-17 for patient number six with no documentation of the donor Rh. Crossmatch testing performed on 11-22-17 for patient number seven with incomplete documentation and no interpretation of the crossmatch. 3. Review of the policies titled "Immunohematology Quality Improvement", "Quality Assessment and Performance Improvement Program", and the form for used for daily quality assessment revealed no requirement for review of patient testing on the transfusion service testing record. 4. Interview with the laboratory supervisor on January 4, 2018 at 3:30 pm confirmed the laboratory failed to identify and correct problems with immunohematology testing in 2016 and 2017.