Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0356548	11/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Elkhart General Hospital Laboratory	600 East Blvd, Elkhart, IN	

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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to define the criteria for acceptability of quality control (QC) for 1 of 76 clinical chemistry assays tested (potassium) in the specialty of Chemistry. Annual potassium testing=90,636. Findings Include: 1) Review of policy titled, "Cobas 6000 Routine Operation," signed by the lab director on July 23, 2018, reads on page 4 of 32 under "Quality Control Review" section, "...3. Quality control values are evaluated using Westgard Rules." The policy did not have criteria for bias nor indicate which Westgard Rules are to be applied. 2) Review of the laboratory's Levey-Jennings chart (laboratory quality control chart) for potassium, quality control (level 2), run during the period of 10/1-10/12/18, indicated 15 consecutive data points were above the mean without any bias rejection criteria (Westgard Rule 10x) being implemented. It could not be determined the QC was acceptable, since the director had not defined bias criteria, nor indicated which Westgard Rules would be used. 3) Medical record review indicated the following

	patients had potassium testing performed between 10/11-10/12/18 after 12 quality control data points fell above the mean for level 2: a. PT#21=10/11/18 /Potassium=3.8 mEq/L (milliequivalents per liter) b. PT#22=10/12/18/Potassium=3.6 mEq/L 4) In interview on 11/28/18 at 10:00 am, SP-2 confirmed the laboratory failed to follow 10x bias rejection criteria (one of six possible Westgard Rules) when performing two levels of quality control on the Cobas 6000 chemistry analyzer. SP-2 further confirmed 15 consecutive data points above the mean for level 2 (potassium) during the period of 10/1-10/12/18.