Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	37D0475918	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Prague Regional Memorial Hospital	1322 Klabzuba Avenue, Prague, OK	

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
D0000	The recertification survey was performed 09/17/18 through 09/20/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and the hospital chief executive officer at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to follow its policy for performing calibration procedures. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor, on 06/09/17 the laboratory began using the Beckman Coulter AcT 5 diff CP analyzer to perform CBC (Complete Blood Count) testing; (2) On the second day of the survey, the surveyor reviewed the laboratory's written policy, "Calibration Frequency" for the calibration procedure on the Beckman Coulter AcT 5 diff CP analyzer. The policy stated, "Calibrate during installation before analyzing samples, after major service has been performed on the instrument, at least every 6 months, or when instructed by a Beckman Coulter representative"; (3) The surveyor then reviewed records which showed the laboratory performed a calibration procedure on 06/03/17 during the implementation of the new analyzer and on 02/09/18, but could not find documentation a calibration procedure had been performed each 6 months between 06/03/17 and 02/09/18 as required by the laboratory's written

	policy; (4) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor calibration materials could not be obtained and the calibration procedure had not been performed each 6 months.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturers' instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturers' specifications for control materials. Findings include: BECKMAN COULTER ACCESS 2 ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory began using the Beckman Coulter Access 2 Immunoassay analyzer on 07/06/17 to perform Troponin I testing; (2) The laboratory manager also stated to the surveyor, the laboratory used 2 levels (Level 1 and Level 3) of Bio-Rad Liquichek Cardiac Markers Plus Control materials each day of patient testing to monitor acceptability of the testing; (3) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (package insert) for the QC (Quality Control) materials. Under "Assignment of Values" it stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are lot specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides."; (4) The surveyor then reviewed QC records of the 4 lot numbers used from 07/06/17 through 08/07/18. The surveyor identified the laboratory utilized the manufacturer's mean and assay limits from the package insert of the Bio-Rad Liquichek Cardiac Markers Plus Control QC materials and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability, for 4 of the 4 QC lot numbers used: (a) Level 1, Lot #29861 and Level, Lot #29863 (i) Used from 07/06/17-03/28/18 (ii) Used from 05/01/18-05/31/18 (iii) Used from 07/01/18-07/31/18 (b) Level 1, Lot #23681 and Level 3, Lot #23683 (i) Used from 04/01/18-04/30/18 (ii) Used from 06/01/18-06/30/18 (iii) Used from 08/01/18-08/07/18 (5) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory used the package insert means and limits for the QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits. BECKMAN COULTER AU480 ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory began using the Beckman Coulter AU480 analyzer on 08/07/17 to perform chemistry testing (e.g., Albumin, Glucose, CK (Creatinine Kinase), Potassium, Digoxin, etc.); (2) The laboratory manager also stated to the surveyor, the laboratory used 2 levels (Level 1 and Level 3) of Bio-Rad Liquid Assayed Multiqual control materials each day of patient testing to monitor acceptability of the testing; (3) On the third day of the survey, the surveyor reviewed the manufacturer's instructions (package insert) for the QC materials. Under "Assignment of Values" it stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data

	Charts (available separately) were derived from replicate analyses and are lot specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides."; (4) The surveyor then reviewed the QC records from 5 months (September and December 2017; April, July, and August 2018) for the 4 lot numbers used since the analyzer was put into use. The surveyor identified the laboratory utilized the manufacturer's mean and assay limits from the package insert of the Bio-Rad Liquid Assayed Multiqual QC materials and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability, for 4 of the 4 QC lot numbers used: (a) Level 1, Lot #45781 and Level 3, Lot #45783 (i) Used from 09/01/17-09/30/17 (ii) Used from 12 /01/17-12/31/17 (iii) Used from 04/01/18-04/30/18 (b) Level 1, Lot #45791 and Level 3, Lot #45793 (i) Used from 07/01/18-07/31/18 (ii) Used from 08/01/18-08/31/18 (5) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory used the package insert means and limits for the QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits. ACL IL ELITE ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory used the ACL IL Elite analyzer to perform PT/INR (Prothrombin/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) The laboratory manager also stated to the surveyor, the laboratory used 2 levels (Normal and Abnormal) of HemosIL control materials each day of patient testing to monitor acceptability of the testing; (3) The surveyor reviewed the manufacturer's instructions (package insert) for the QC materials. Under "Expected Values," it stated, "The reported ranges were determined over multiple runs of IL Coagulation Systems using specific lots of reagents. The mean of the control range determined in your laboratory may vary due to the lot of reagent used. Due to differences in reagents and instrumentation, each laboratory should establish its own Target Value and Acceptance Range (mean and standard deviation). However, any properly functioning coagulation system should yield mean values within the Acceptance Range on the package insert."; (4) The surveyor then reviewed the QC records from 11 months (March, June, August, and December 2017; February, March, April, May, June, July, and August 2018) for the QC lot numbers used during the review period. The surveyor identified the laboratory utilized the manufacturer's mean and assay limits from the package insert of the Normal and Abnormal QC materials and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability, for 5 of the 5 QC lot numbers used during the review period: (a) Normal Control: (i) 03/01/18-08/06/18: Lot #N1166511 (ii) 08/07/18-08/31/18: Lot #N0670338 (b) Abnormal Control: (i) 03/01/18-04/28/18: Lot #N1166277 (ii) 05/01/18-05/31/18: Lot #N0965208 (iii) 06/01/18-07/24/18: Lot #N0965208 (iv) 07/27/18-08/31/18: Lot #N0871604 (5) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory used the package insert means and limits for the QC materials listed above, and failed to follow the manufacturer's specifications to establish its own means and limits.