Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0997934	02/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lake Pointe Medical Center	20912 Se 29th Street, Harrah, 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 findings were reviewed with testing person #1 at the conclusion of the survey.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to document testing issues in the quality assessment records. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g., WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet Count, automated WBC differential (Granulocytes, Lymphocytes, and Monocytes, in percentage and absolute numbers), etc.) using the Beckman Coulter AcT diff 2 analyzer; (2) The surveyor reviewed the manufacturer's IQAP Peer Reports and QC (Quality Control) records from 04/01/16 through 01/31/18 for 15 QC lot numbers, which were: (a) 04/26 /16 - 07/27/16: Lots: #069300 (Low Control), #073900 (Normal Control), and #089300 (High Control) (b) 10/03/16 - 12/29/16: Lots: #067900 (Low Control), #077900 (Normal Control), and #087900 (High Control) (c) 04/03/17 - 06/30/17: Lots: #069200 (Low Control), #079200, (Normal Control), and #089200 (High Control) (d) 07/03/17 - 09/25/17: Lots: #069800 (Low Control), #079800 (Normal Control), #089800 (High Control) (e) 09/25/17 - 12/27/17: Lots: #068000 (Low Control), #078000 (Normal Control), #088000 (High Control) (3) From the review, the following was identified for lot numbers #067900, #077900, and #087900 during 10/03/16 - 12/29/16: (a) IQAP reports: (i) Documentation stated the laboratory's

	WBC, RBC, and Hemoglobin obtained CVI's (Coefficient of Variation Index =The ratio of the laboratory's CV to the CV of the peer group and is a measure of testing precision. Parameters with a CVI of Greater than 2.00 will be flagged) greater than 2.00 during the review period. (b) Laboratory's QC corrective action log: (i) Documentation stated the laboratory noted a few CVI issues had been noticed on the IQAP report for the analytes WBC, RBC and Hemoglobin; (ii) Documentation stated the laboratory contacted technical service and that technical service reviewed the data; (iii) Documentation stated the technical service came to the laboratory to address the problems. (4) The surveyor then reviewed the "Laboratory Quality Assessment Review Monthly Report" forms (the laboratory's method of performing monthly quality assessment reviews) dated October 2016 through December 2016 to obtain information concerning the differences in the laboratory's CV and the peer CV for the QC lot numbers #067900, #077900, and #087900. The following was identified: (a) "No problem noted," was checked on the monthly quality assessment checklists dated 11/30/16 and 12/23/16 under "Monthly Quality Control Review;" (b) There was no documentation which indicated flags were obtained on the IQAP reports; (c) In addition, there was no documentation of the corrective action (i.e., review of QC, review of patient test results, etc.), if the problem had been resolved, and the steps taken to correct the problems. (5) The surveyor explained to testing person #1 the laboratory must document all quality assessment activities which would include steps taken to identify and correct problems, prevent the recurrence, and note any policies or procedures changed due to the QA activities.