Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1058856	08/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Texas Emergency Physicians, Pa	8501 Justin Rd, Double Oak, TX	

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 Technical Consultants were at the entrance conference conducted on 08/02/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Technical Consultants and Office Supervisor on 08/02/2019. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiency cited was discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Department of State Health Services, Health Facility Compliance Arlington Group.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records, corrective action documentation, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 5 of 5 patients in 2019 (random sampling 03/2019) Findings: 1.Review of the Quality Control and Calibration laboratory policy revealed: "VII. QC Troubleshooting Steps ... B. General troubleshooting steps are as follows: ... 3. Rerun the controls. If QC comes in acceptable ranges, accept the run and patient results may be reported. 4. If they are still outside acceptable limits, open fresh controls and rerun.

	If the controls are within limits, run and report patient results ... 6. If control values are still out of range, troubleshoot according to manufacturer's guidelines ... 9. When necessary and possible, repeat patient testing from the time controls were last in range." 2. Mindray BC-3200 hematology analyzer data and corrective action documentation revealed the troubleshooting the laboratory performed for the following sampling of QC test events in March 2019: 03/24/2019: QC low level lot# 90210422, expiration date 07/29/2019 was ran at 07:59 and resulted in a failure for the platelet analyte. QC was repeated at 08:07 and it passed. QC normal level lot#90210423, expiration date 07/29/2019 was ran at 08:00 and resulted in a failure for the hemoglobin and platelet analytes. QC was repeated at 08:10 and resulted in a failure for the platelet analyte. QC high level lot# 90210424, expiration date 07/29 /2019 was ran at 08:02 and resulted in a failure for the hemoglobin and platelet analytes. QC was repeated at 11:04 and it passed. Review of the corrective action log for all three levels of QC was documented as "Did internal probe clean X10." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (03/23/2019): Patient IDs: 229306, 2662514, 213614, 249582, 251789 3. During an interview on 08 /02/2019 at 11:20 am, the Technical Consultant-1 (TC-1) confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results.