Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2130192	09/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grace Er	1851 Pearland Parkway, Pearland, 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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 9/27/19 Based on review of the laboratory policy, quality control report records, laboratory patient logs, and confirmed in interview, the laboratory failed to document 2 acceptable levels of controls prior to reporting patient test results for CBC analysis on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Control Policy revealed "for quantitative testing, two levels of controls shall be run for every procedure on each day of use...patient testing must not be performed or reported when controls results are outside the expected range for two of three controls per analyte." 2. Review of the laboratory quality control report from August and September 2019 for the Cell Dyn Emerald hematology analyzer revealed no quality control documented on 9/19 /19. 3. Review of the laboratory patient logs from September 2019 revealed the laboratory performed 3 patient testing without documentation of 2 acceptable levels of quality control for the above date. See patient alias list. 4. An interview with the primary testing person on 09/27/19 at 1050 hours confirmed the above findings. He was unaware the staff were not performing quality control per the laboratory policy.
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: An unannounced revisit was performed on 9/27/19. Based on review of the laboratory policy, quality control records, laboratory records, and confirmed in interview, the laboratory failed to document corrective actions taken when quality control was outside of the acceptable range. Findings were: 1. Review of the laboratory policy revealed "it is the policy of this laboratory to do the following when controls are not within range: ensure that controls are not expired then remix and rerun control sample; if controls fails then, open a new vial of controls and run; if controls fail then, verify that control ranges are correct and that the correct level of control is evaluated. Then, ensure that all specimens and reagents are at the correct temperature. Then, evaluate maintenance schedule, ensure that all of the manufacturer's recommendations are followed and that maintenance procedures are being done as required. Then, evaluate calibration; if necessary recalibrate unit and run controls. Then call technical support for help. Ensure that all remedial action steps are documented. Most importantly, ensure that no patients are reported if controls are out of range." 2. Random review of the quality control records from August and September 2019 revealed 1 of 10 days with 1 or more quality control failures and no documentation of the corrective action. 8/29/19 control lot L9182, exp 10/18/19 control lot N9182, exp 10/18/19 control lot H9182, exp 10/18/19 3. Review of the laboratory records from August and September 2019 revealed the laboratory performed 3 patient testing for the above date. Refer to patient alias list. 4. An interview with the primary testing person on 09/27/19 at 1050 hours confirmed the above findings. He was unaware the staff were not performing quality control per the laboratory policy.