Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1051834	**(X3) Date Survey Completed** 09/28/2018
Name of Provider or Supplier Primary Health Physicians, Pllc	**Street Address, City, State** 565 W I-30, Garland, 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 #1 and #2 (TC-1, TC-2) were at the entrance conference conducted 09/28/2018. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with TC-1 and TC-2 on 09/28/2018. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Health and Human Services Commission, Health Facility Compliance Arlington Group.
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 review of the laboratory's procedure manual, patient test report, and in interview with staff, the laboratory failed to follow their own written policy for documenting notification of the attending physician of a patient panic value on 08/04 /2018. Findings included: 1. Review of the laboratory's procedure manual stated, "Panic/Alert Value Procedures: When certain test results are much higher or lower than normal, the patient may need immediate attention by a physician. If a 'Medical Alert Value' is obtained: 1. Repeat the test to confirm the result. 2. Notify a physician if the result is confirmed. 3. If a 'Medical Alert Value' is called to the lab from the reference laboratory immediately notify a physician of the report. 4. Date, time and initial that the result was given to physician." Medical Alert Values included: "Hemoglobin: Low Value: 8.0 g/dL and High Value: 20.0 g/dL." 2. Review of Patient #3364350 instrument printout (Coulter AcT Diff 2 analyzer) test results from 08/04

	/2018 revealed a Hemoglobin result of 7.6 g/dL. The instrument printout included a section to document that the attending physician was notified of the panic value: "Provider notified of panic value: Date: Time:." The instrument printout for Patient #3364350 did not include documentation that the attending physician was notified of the Hemoglobin panic value of 7.6 g/dL. The laboratory did not follow their own written policy for documenting notification of the attending physician. 3. During an interview on 09/28/2018 at 11:30 am, Technical Consultants #1 and #2 reviewed and confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, quality control (QC) data, corrective action, "Lab Daily Accession Log," and in interview with staff, the laboratory reported 5 patient test results when QC did not meet criteria for acceptability on 07/17/2018. Findings included: 1. Review of the laboratory's procedure manual for "QC Procedures" stated, "Test three levels of AcT diff2 controls (low, normal and high) each before patient testing. Compare control results to the expected results (located on the Coulter 4C PLUS cell control package insert). Recovered values of new control lot(s) are confirmed to be within the Table of Expected Results before the current cell lot(s) expire. Control results must be in expected ranges for a minimum of two of three control levels before patient test results are reported. If controls results are not within within expected ranges, repeat the control determination. If results are still outside the expected range, call Coulter Technical Service at [phone number]. Do not test patient samples until a minimum of two of three controls are in range." Coulter AcT Diff 2 manufacturer's instructions for "Flag/Code" stated, "Flag/Code: X; Indication: Review results. X flag indicates that one of the multiple Aperture Alert criteria was not met; Suggested Action: 1. Thoroughly mix and rerun the sample. 2. If flag does not repeat, report result. 3. If flag repeats, clean the aperture as instructed in Zapping the Aperture. 4. If after cleaning, problem persists, contact your Beckman Coulter Representative." 2. Review of AcT Diff 2 analyzer QC data from 07/2018 revealed QC levels "High" and "Low" did not meet the criteria for acceptability: 07/17/2018 at 8:33 am - Level Low (Lot #067500; expiration date: 09/24/2018) Flag/Code "X" was attached to RBC, HGB, HCT, MCV, MCHC, PLT, MPV and RDW values. 07/17/2018 at 8:48 am - Level High (Lot #087500; expiration date: 09/24/2018) RBC value was not within range: 4.95 x 10^6/uL (4.97 - 5.57). There was no corrective action taken and documented for the above unacceptable QC levels. 3. Review of the "Lab Daily Accession Log" for 07/17/2018 revealed 5 patients were analyzed and complete blood count results were reported from the AcT Diff 2, when QC did not meet the criteria for acceptability: Patient #1965287, Patient #1828788, Patient #2277004, Patient #1701769, Patient #3329639. The laboratory did not ensure a minimum of two of three levels of QC were within acceptable criteria prior to reporting patient test results. 4. During an interview on 09/28/2018 at 10:50 am, Technical Consultant #1 (TC-1) stated when QC is not within the acceptable limits, it would normally be repeated and if it is still not within limits, Beckman Coulter is called for troubleshooting. TC-1 reviewed and confirmed the above findings. Word Key: RBC -

	red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCHC - mean corpuscular hemoglobin concentration PLT - platelet MPV - mean platelet volume