

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1015539	<b>(X3) Date Survey Completed</b>  09/24/2024
<b>Name of Provider or Supplier</b>  Alfredo Gonzales Md Pa	<b>Street Address, City, State</b>  1301 W Sam Houston Ste A, Pharr, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records and interview of facility personnel, the laboratory failed to document corrective actions when Hematology controls failed to meet the laboratory's acceptable limits on 9 of 31 days in August 2024. The findings included: 1. Review of the policy titled CONTROL POLICY found: "Control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All control results and remedial actions must be recorded and records kept for at least two (2) years. Patient testing must not be performed or reported when control test results are outside the expected range. Use the "QC Out-Of-Limits Log Sheet" to record controls and remedial actions when controls are outside the expected range. Additionally, use the "Daily Sample Troubleshooting Checklist" found in this section, to help you resolve daily control problems. All control records and Remedial Action Sheets will be reviewed, signed/initialed and dated monthly by the Laboratory Technical Consultant. Every month the Technical Consultant will report to the Laboratory Director and the Testing Personnel his findings about the laboratory's performance of quality control, quality assurance, and proficiency testing." 2. Review of Hematology Quality Control</p>

records for August 2024 found the laboratory failed to document corrective actions on 9 of 31 days when Boule Con-Diff Tri-Level lot 224031 quality control results failed to meet acceptable limits: a. August 7, 2024 Hemoglobin (HGB) - the lab obtained unacceptable results on 2 of 3 runs for level 1 with no documentation of corrective actions. b. August 8, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 2 of 3 runs for levels 1 and 3 with no documentation of corrective actions. c. August 9, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 1 of 2 runs for level 2 with no documentation of corrective actions. d. August 12, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 1 of 2 runs for level 2 with no documentation of corrective actions. e. August 13, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 3 of 7 runs for level 2 with no documentation of corrective actions. Hemoglobin (HGB) - the lab obtained unacceptable results on 6 of 7 runs for level 1 with no documentation of corrective actions. f. August 16, 2024 - Hemoglobin (HGB) - the lab obtained unacceptable results on 6 of 7 runs for level 1 with no documentation of corrective actions. g. August 19, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 3 of 4 runs for level 2 with no documentation of corrective actions. h. August 20, 2024 - White Blood Cell (WBC) - the lab obtained unacceptable results on 1 of 2 runs for level 2 with no documentation of corrective actions. i. August 21, 2024 - Hemoglobin (HGB) - the lab obtained unacceptable results on 2 of 3 runs for level 3 with no documentation of corrective actions. 5. During interview of the technical consultant conducted September 24, 2024 at 08:35 AM, he confirmed that if the corrective actions were not written on the daily printouts they may not be documenting corrective actions.