Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0911491	**(X3) Date Survey Completed** 07/18/2023
Name of Provider or Supplier Rohit Kapoor Md Pa	**Street Address, City, State** 12602 Toepperwein Suite 114, San Antonio, 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	A validation survey was conducted 07/18/2023. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference.
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 procedures, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of following its procedure for addressing flagged CBC (complete blood count) results. The findings include: 1. A review of the laboratory's procedure titled "CBC Analyzer Pentra 60C+" (approved by the laboratory director on 09/01/2018) under the section titled "Handling of Abnormal Results" revealed: "Specimen results with instrument error flags that cannot be resolved are sent to the reference lab for testing." 2. Further review of the procedure under the section titled "Flags on WBC Distribution curve" revealed: "LMNE matrix flags Reject (on LMNE matrix) - reject on the LMNE channel indicates a poor correlation between the resistive and the optical measurements on the matrix... - the result is not reliable, and the specimen must be rerun. 3. A sampling of patients test results from April 19, 2023 identified 14 of 19 patient's whose results had LMNE flags which were reported to the provider: Sample Identification: 2 4 5 6 7 11 12 13 14 15 16 17 18 19 4. The laboratory was asked to provide documentation of sending the identified patient samples to the reference lab as required by its procedure. No documentation was provided. 5. An interview with the technical consultant on 07/18/2023 at 1330 hours in the laboratory - after her review of the records- confirmed the findings.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Hematek slide stainer, review of the laboratory's instrument maintenance records from May 2021 to May 2023, and staff interview, it was revealed the laboratory failed to have documentation of performing 6 of 8 quarterly maintenances and 1 of 2 annual maintenances. The findings include: 1. A review of the manufacturer's instructions for the Hematek slide stainer revealed the manufacturer required the following maintenance: a) quarterly - replace all tubing b) annually - replace under plate tubing 2. A review of the laboratory's instrument maintenance records from May 2021 to May 2023 revealed the laboratory failed to have documentation of performing: a) quarterly maintenance missing: Quarter 2 2021 Quarter 4 2021 Quarter 1 2022 Quarter 3 2022 Quarter 4 2022 Quarter 1 2023 b) annual maintenance missing: 2022 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the technical consultant on 07/18 /2023 at 1115 hours in the break room - after her review of the records- confirmed the findings.