Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0920264	(X3) Date Survey Completed 11/12/2024
Name of Provider or Supplier Southside Medical Clinic	**Street Address, City, State** 546 West Seminary Drive, Fort Worth, 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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, patient test records, and confirmed in staff interview, the laboratory failed to ensure one of ten patient CBC test records reviewed were accurate and reliable in November 2024 (random review). Findings included: 1. Review of the XN-L series XN-530/XN-430 /XN-330 Basic Operation manual stated: "Chapter 5 Checking Analysis Results (Sample Explorer) ... 5.11.2 Display of analysis result data When an analysis result could not be obtained due to an error or other problem, the result is masked. When an analysis is determined to be abnormal, a mark appears ... Marks Display [*] Meaning Low reliability Description Indicates that the reliability of the data is low." Review of the XN-L series XN-530/XN-430/XN-330 Troubleshooting manual stated: "Chapter 5 IP Messages With respect to the following IP messages, when a sample judgement is Positive, the analysis results are regarded as having a low reliability due the abnormality, and "*" is displayed to the right of the data ..." 2. Review of the laboratory's policies stated: "Tab 7 Post Analytical Policies and Procedure ...

	Procedures for: Interpreting Results Once a result is obtained, examine the report. Items to look for are: Are there low or high flags? Is the automated diff flagged for any cell type ... When patient results are flagged repeat the sample after 10-30 minutes. If he repeated sample has no flags, give that result to the physician. If the flags repeat, refer to Troubleshooting and Diagnostics Section of the Operations Manual [sic] Suspect a problem CBC when ... Asterisk "*" appears next to results data [sic] Alert messages pertaining to specimens, either patient or QC, are displayed in place of or next to the affected result(s) ...The parameter result is printed with an asterisk (*) on the ticket printout. The name of each flag, location of the flag on the display, the cause of the flag, and the action to be taken are given in the Operational Messages and Data Flagging section of the Operators Manual." 3. A random review of ten patient reports from November 2024 revealed one of ten patient CBC reports with an "*" for the following analytes and differential parameters: WBC, PLT, MPV, NEUT, LYMPH, MONO, EO, BASO, IG Note: The laboratory did not have a LIS, therefore CBC reports were manually scanned into the patient's electronic medical record and then placed into the paper medical record. 4. During an interview on 11/12 /2024 at 11:48 a.m., laboratory representatives after a review of records, confirmed the laboratory failed to ensure patient CBC test records were accurate and reliable. Word Key: CBC - complete blood count diff - differential WBC - white blood cell PLT - platelet MPV - mean platelet volume NEUT - neutrophil LYMPH - lymphocyte MONO - monocyte EO - eosinophil BASO - basophil IG - immature granulocyte LIS- laboratory information system