Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1021135	07/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Cleveland Family Health Care Center	2020 Westland Drive Sw, Cleveland, TN	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, review of final patient test report, review of test system records, and staff interview, the laboratory failed to establish reference ranges for patient population type "U" for complete blood count (CBC) patient testing on the date of the survey (07.01.2026). The findings include: 1. Observation of the laboratory on 07.01.2026 at 8:30 a.m. revealed a Sysmex XP300 (serial number C6323) analyzer used for CBC patient testing. 2. Review of a final patient test report (patient 94346) revealed that the laboratory included this patient in the population "U." 3. Review of test system records for CBC testing revealed no established reference ranges (normal values) for CBC for the patient population titled "U," on the date of the survey (07.01.2026). 4. An interview on 07.01.2026 at 11:45 a.m. with the Chief Financial Officer and the Quality Manager confirmed the above survey findings.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on laboratory observation, a review of final patient test reports, and staff interviews, the laboratory failed to include reference ranges for one of six final patient test reports for complete blood count (CBC) patient testing on the date of the survey (07.01.2026). The findings include: 1. Observation of the laboratory on 07.01.2026 at 8:30 a.m. revealed a Sysmex XP300 (serial number C6323) analyzer used for CBC patient testing. 2. A review of final patient test reports for CBC revealed that one (patient 94346, population type "U," reported on 06.30.2026) of six final test reports reviewed did not include reference ranges for CBC. 3. An interview on 07.01.2026 at 11:45 a.m. with the Chief Financial Officer and the Quality Manager confirmed the above survey findings.