Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2175258	11/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Smg Pediatric Clinic Seymour	11021 Chapman Hwy, Seymour, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on laboratory observation and staff interviews, the laboratory failed to ensure it did not use heel incision devices for blood collection and blood collection tubes for patient testing past their expiration date on the survey date, 11.06.2025. The findings include: 1. Observation of the laboratory on 11.06.2025 at 9:05 a.m. revealed a Sysmex XP-300 (Serial Number B5909) hematology analyzer used for complete blood count (CBC) patient testing and an Advanced Instruments Advanced Bilirubin STAT-analyzer (serial number 19060893C) used for neonatal bilirubin patient testing. Also observed were the following: - Two Cardinal Health GentleHeel incision devices, lot number: 200821F, expiration date of 08.20.2025. - Four bags (containing 50 tubes per bag) 125 microliter (L) RAM Scientific Safe-T-Fill Capillary Blood Collection System, Lithium Heparin tubes (used for collecting heel stick neonatal bilirubin samples), lot number: 23J4032, expiration date of 10.31.2025. -One 500L Becton Dickinson (BD) Dipotassium Ethylenediaminetetraacetic Acid (EDTA) microtainer capillary blood collector tube (used for collecting fingerstick/heel stick CBC with automated differential samples), lot number: 2161933, expiration date of 11.30.2023. 2. An interview with the laboratory supervisor and lead testing person on 11.06.2025 at 9:15 a.m. confirmed the above survey findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the operator's manual, a review of the laboratory's temperature/humidity log, the lack of records, and staff interviews, the laboratory failed to document corrective action for recorded relative humidity that exceeded the laboratory's established acceptable range for 37 of 669 days reviewed from January 2024 through October 2025. The findings include: 1. Observation of the laboratory on 11.06.2025 at 9:05 a.m. revealed a Sysmex XP-300 (Serial Number B5909) hematology analyzer used for complete blood count (CBC) patient testing. 2. A review of the Sysmex operator's manual revealed an operating relative humidity range of 30% to 85%. 3. A review of the laboratory's "Laboratory Temp Check Off Sheet" revealed an acceptable humidity range of 30%-85%. The log also revealed the following recorded humidities; -01.11.2024: 27% -01.24.2024: 27% -01.02.2025: 27% -01.03.2025: 26% -01.06.2025: 26% -01.07.2025: 23% -01.08.2025: 24% -01.09.2025: 24% -01.10.2025: 24% -01.13.2025: 23% -01.14.2025: 23% -01.15.2025: 23% -01.16.2025: 23% -01.17.2025: 26% -01.20.2025: 26% -01.21.2025: 22% -01.22.2025:22% -01.23.2025: 21% -01.24.2025: 22% -01.27.2025: 24% -01.28.2025: 22% -02.03.2025: 27% -02.17.2025: 27% -02.20.2025: 23% -02.21.2025: 27% -02.24.2025: 27% -02.25.2025: 27% -03.03.2025: 28% -03.04.2025: 25% -03.05.2025: 25% -03.06.2025: 25% -03.07.2025: 25% -03.18.2025: 29% -03.25.2025: 29% -04.04.2025: 29% -04.17.2025: 26% -04.18.2025: 29% 4. A request for corrective action documentation for the 37 days when the recorded humidities exceeded the laboratory's established acceptable range revealed that no corrective action documentation was available for surveyor review. 5. An interview with the laboratory supervisor and lead testing person on 11.06.2025 at 11:30 a.m. confirmed the above survey findings. Word Key: % = percent