Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307950	04/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Three Rivers Hospital	451 Highway 13 South, Waverly, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's information system, a review of the manufacturer's package insert, a review of the laboratory procedure manual, and staff interviews, the laboratory's procedure for the i-STAT high-sensitivity Troponin I assay (hs-TnI) failed to have the stated normal range for female population that was consistent with the range used by the laboratory and the range stated by the manufacturer. The findings include: 1. Laboratory observation on 04/27 /26 at approximately 8:45 a.m. revealed the i-STAT instrument used for performing

	hs-TnI as a backup method. 2. A review of the hs-TnI ranges programmed into the laboratory information system revealed a normal range of 0 to 13 pg/mL for females. 3. A review of the -STAT manufacturer's package insert for the hs-TnI revealed the normal range for females listed as 13 pg/mL at the 99th percentile. 4. A review of the laboratory procedure revealed that the normal range for the i-STAT hs-TnI for females was listed as 0-28 pg/mL. 5. The general supervisor stated that no female patients had been tested using the i-STAT hs-TnI assay during interview on 04/27/26 at approximately 3:00 p.m. 6. The Regional Laboratory Operations Manager confirmed the survey findings during an interview on 04/28/26 at approximately 2:30 p.m.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of control package inserts, laboratory procedure manual, and staff interview, the laboratory failed to ensure the Erythrocyte Sedimentation Rate (ESR) controls were labeled with a corrected expiration date after opening, and failed to ensure a secondary container of saline was labeled with the lot number of the original container on the date of the survey. The findings include: 1. Laboratory observation on 04/27/26 at 9:30 a.m. revealed open vials of Seditrol control material (Lot numbers C148 and C248) used to perform quality control on the Alcor miniiSED ESR instrument. The controls were labeled with an open date of 03 /04/26 with no corrected expiration date. Saline (used in the performance of wet prep analysis) was observed that had been poured from an original container into a secondary container. The secondary container was not labeled with a lot number. 2. A review of the Seditrol control package insert instructions revealed that the controls were stable for 60 days after opening when stored tightly capped at room temperature and used with the Alco miniiSED ESR instrument. 3. The laboratory procedure titled "Alco miniiSED ESR Analyzer" stated the controls were good for 31 days after opening. 4. The general supervisor confirmed the survey findings during an interview on 04/27/26 at 9:30 a.m.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, a review of a patient test report, review of the laboratory's Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) quality control (QC) data, lack of documentation, staff interview, and review of an electronic mail

	communication, the laboratory failed to follow the established quality assessment procedure for review of CBC w/Diff QC data, and failed to have a process in place for review of CBC w/Diff background counts, for three of three months, one of one master lot reviewed from 2025 and 2026, with approximately 48,678 patients reported annually. The findings include: 1. Laboratory observation on 04/27/26 at approximately 8:45 a.m. revealed the Sysmex XN 450 used for patient testing for CBC w/Diff. 2. A review of the laboratory policy titled "Quality Assessment /Improvement Plan for Ascension Saint Thomas Laboratories" revealed the following statement: "Levy-Jennings reports are visually reviewed weekly and printed monthly for all analytes on all instruments." "The any issues identified from the review of the Levy-Jennings charts, such as shifts, or trends are addressed and documented." 3. A review of a patient test report revealed patient testing for CBC w/Diff performed on 12 /31/25 for patient identification number 436969. 4. A review of the CBC w/Diff QC data for master lot number 5335 (levels low, normal and high) revealed the following: The lot was used from 12/13/25 to 02/22/26. There were no printed monthly Levy-Jennings charts; monthly review of the Levy-Jennings charts was not documented for any of the three months the lot was used. 5. There was no documented review of the background counts for the months of December 2025, January 2026, or February 2026. 6. The general supervisor stated during an interview on 04/27/26 at 2:30 p.m. that only the Sysmex Peer Group Insight reports are printed for review, the monthly Levy-Jennings are not printed or reviewed, and stated the laboratory did not have a process in place for review of background counts. This confirmed the survey findings. 7. A review of an electronic mail communication received on 04/30/26 at 11:58 a.m., from the general supervisor, revealed that approximately 48,678 patient tests are reported annually for CBC and/or CBC w/Diff analytes.
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 a review of patient test reports, staff interview, and review of an electronic mail communication, the laboratory failed to use the race-free equation for the estimated glomerular filtration rate (eGFR) in 2025 and 2026 with approximately 7,478 eGFRs reported annually. The findings include: 1. A review of patient test reports revealed that the laboratory failed to use the race-free equation for the estimated glomerular filtration rate (eGFR) for the following patients: Patient #434491 reported on 08/12/25, and patient #439004 reported on 04/27/26. 2. The general supervisor confirmed the laboratory did not use the race-free equation for calculation of the eGFR in 2025 or 2026 during an interview on 04/28/26 at approximately 2:00 p.m. 3. The general supervisor stated in an electronic mail communication received on 04/30/26 at 1:49 p.m. that approximately 7,478 creatinine tests with calculated eGFR are reported annually.