Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473136	05/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital Claremore	1202 N Muskogee Pl, Claremore, OK	

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 Hillcrest Hospital Claremore was found in compliance with 42 CFR Part 493 requirements for laboratories as a result of a validation survey on 05/28/26. Standard level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: A. Based on laboratory's written procedure, record review, and interview with technical supervisor #1 (TS #1), the laboratory failed to follow its own procedure for Quality Control (QC) for one of one hemostasis reagent new lot number roll-over verification. Findings included: 1. During an interview on 05/28/26 at 03:00 pm, TS #1 confirmed the laboratory performed Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) testing using the Sysmex CA 660 analyzer. 2. Review of the laboratory's written procedure titled, "Hemostasis Reagent New Lot Number Roll-Over Verification" section, "III. Quality Control" stated, "B. When a minimum of 30 data points have been collected, set the mean and 2 SD range.". 3. Review of the 2025 hemostasis reagent new lot number roll-over verification records revealed the following: a. Dade CiTrol PT QC Level 1 (Lot#564903) and Level 3 (Lot# 556595A) mean and 2 SD set with 24 data points not 30 data points per laboratory procedure. b. Dade CiTrol APTT QC Level 1 (Lot#564903) and Level 3 (Lot# 556595A) mean and 2 SD set with 24 data points not 30 data points per laboratory procedure. 4. During an interview on 05/28/26 at 03:15 pm, TS #1 confirmed the findings above. B. Based on laboratory's written procedure, record review, and interview with the infection prevention and quality safety manager, the laboratory failed to follow its own

	procedure for the evaluation of a suspected blood transfusion reaction for one of one patient. Finding included: 1. Review of the laboratory's written procedure titled, "Blood Transfusion Reaction" stated the following: a. "1. STOP the transfusion: ... " b. "4. Monitor: ... a. Vital signs (VS) every 15 minutes until stable then every 2 hours X2 then every 4 hours or as indicated by severity and type of reaction." 2. Review of suspected transfusion reaction workup revealed the laboratory failed to follow the laboratory's procedure for monitoring vital signs for one of one patient. a. Patient# 0000141229 - transfusion stopped on 03/08/24 at 04:50 pm, vital signs taken 05:15 pm (25 minutes later). 3. During an interview on 05/28/26 at 10:21 am, infection prevention and quality safety manager confirmed the findings above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, record review, and interview with technical supervisor #1 (TS #1), the laboratory failed to follow manufacturer's instructions for Procalcitonin testing for three of six patients. Findings included: 1. During an interview on 05/28/26 at 01:00 pm, TS #1 confirmed the laboratory performed Procalcitonin (PCT) testing using the Beckman Coulter Access 2 Analyzer. 2. Review of the manufacturer's "Instructions for Use" section "PRINCIPLE" stated, "INTENDED USE ...Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock." 3. Review of patient testing records from 02/19/26 through 04/18 /26 revealed the laboratory failed to follow the manufacturer's instructions for three of six patients. a. Patient #1013245 - Specimen collected in the Emergency Department on 04/05/26 not ICU. b. Patient #7791542 - Specimen collected in the Emergency Department on 04/07/26 not ICU. c. Patient #6984257 - Specimen collected and reported back to Med Surge 2 North on 04/15/26 not ICU. 4. During an interview on 05/28/26 at 03:45 pm, TS #1 confirmed the findings above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review, patient test reports, and interview with technical supervisor #1 (TS #1), the laboratory failed to perform two levels of control materials each day of patient testing for three of three days. Findings include: 1. During an interview on 05/28/26 at 02:40 pm, TS #1 confirmed the laboratory performed Clostridium difficile toxins A and B in stool specimens. 2. Review of Quality Control (QC) records and patient testing records on 03/21/26, 04/06/26, and 04/15/26 revealed no evidence of two levels of QC material on each day of patient testing for three of three days of patient testing. a. Patient #1565608 - specimen collected on 03/21/26, received into

	the laboratory at 03/21/26, and reported on 03/21/26. b. Patient #1013245 - specimen collected on 04/05/26, received into the laboratory on 04/05/26, and reported on 04/06 /26. c. Patient #1864340 - specimen collected on 04/15/26, received into the laboratory on 04/15/26, and reported on 04/15/26. 3. During an interview on 05/28/26 at 03:30 pm, TS #1 confirmed the findings above.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #1 (TS #1), the laboratory failed to check each batch for positive and negative reactivity of BacT /ALERT PF Plus Culture Bottles for one of one lot number. Findings included: 1. During an interview on 05/28/26 at 02:30 pm, TS #1 confirmed the laboratory used the BacT/Alert PF Plus Culture Bottles in the recovery and detection of aerobic and anaerobic microorganisms. 2. Record review of Lot# 004103530 BacT/Alert PF Plus Culture Bottles revealed no evidence of Quality Control (QC) for positive and negative reactivity. 3. Sampling of patients tested from 05/26/26 through 05/28/26: a. Patient# 2140473 - collected on 05/26/26, received into the laboratory on 05/26/26, and Preliminary Report: No Growth at 42 hours. b. Patient# 1595432 - collected on 05 /26/26, received into the laboratory on 05/26/26, and Preliminary Report: No Growth at 42 hours. c. Patient# 1937939 - collected on 05/27/26, received into the laboratory on 05/27/26, and Preliminary Report: No Growth at 18 hours. d. Patient# 5918908 - collected on 05/27/26, received into the laboratory on 05/27/26, and Preliminary Report: No Growth at 12 hours. e. Patient# 6652147 - collected on 05/27/26, received into the laboratory on 05/27/26, and Preliminary Report: No Growth at 12 hours. f. Patient# 7443883 - collected on 05/28/26, received into the laboratory on 05/28/26, and Preliminary Report: No Growth at 6 hours. g. Patient# 4396095 - collected on 05 /28/26, received into the laboratory on 05/28/26, and Preliminary Report: No Growth at 6 hours. 4. During an interview on 05/28/26 at 02:45 pm, TS #1 confirmed the findings above.