Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506634	06/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hereford Regional Medical Center	540 West 15th Street, Hereford, 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	An onsite recertification survey conducted June 4, 2024 through June 5, 2024, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on review of laboratory policy, laboratory blood culture worksheets, patient final reports, and confirmed in interview, the laboratory failed to follow policy for the subculture and identification of positive blood culture vials for 12 of 17 sets of cultures on patients that had a previously positive identified on the BD Bactec FX40 blood culture analyzer for records reviewed in 2023. The findings included: 1. Review of the laboratory policy titled "Automated Blood Culture Instrument Procedure BD Bactec FX40" stated the following under section "I. Principle": "When positive vials are identified, the lab technologist pulls them from the instrument for confirmation of results, and for isolation and identification of the organism." 2. In review of patient final reports for blood cultures that had been identified as positive the surveyor noted the following statement on occasional final reports: "See paired result." Surveyor asked for clarification on the statement and the microbiology technical supervisor stated that when one of the two bottles from a set (aerobic and anaerobic bottles) with the same accession number, or one bottle from a paired set (separate accession number same patient) was identified as a positive, the subsequent positive bottles identified from the same accession number, or paired set, would not be cultured for bacterial identification. 3. Review of laboratory blood culture worksheets and patient final reports for 2023 included the following 12 blood cultures identified as positive

	by the BD Bactec FX40 blood culture analyzer that were not cultured for the identification of bacterial organism: Collection Date MRN Accession Number 01/14 /2023 280180 24-23-014-0067 03/22/2023 30568 24-23-081-0010 04/24/2023 80028501 24-23-114-0151 09/06/2023 80023094 24-23-249-0174 09/23/2024 29413 24-23-266-0045 10/11/2023 35100 24-23-284-0142 11/08/2023 21237 24-23-314-0159 11/24/2023 24106 24-23-328-0086 12/04/2023 80018826 24-23-338-0031 12/08 /2023 36239 24-23-342-0131 12/11/2023 22808 24-23-345-0196 12/15/2023 26235 24-23-349-0051 3. In an interview on 6/5/2024 at 10:20, in the office, the technical supervisor (TS)2 confirmed the above positive blood culture bottled were not subcultured for the identification of the bacterial organism.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer instructions, calibration verification records, and interview with laboratory personnel, the laboratory failed to perform calibration verification at least every six months for nine months between July 2023 and April 2024 for the analyte Fibrinogen on the coagulation analyzer. The findings included: 1. Based on review of the policy "Fibrinogen Standard Curve", effective 5/22/2023, the policy stated: "Policy: Fibrinogen reagent needs to be calibrated yearly an as needed to have QC within range." 2. Based on review of the manufacturer's instructions "Sysmex CA-600 Series Lot Rollover Information", on page 3 of 6, the instructions stated "Calibrated Assays: A calibration is required with reagent lot number change. Calibration/calibration verification is required every six (6) months per CLIA. Calibration may be required after major preventive maintenance or replacement of critical parts. Calibration may be required with control shift, trend, or outside acceptable limits. Ensure analyzer is performing properly before recalibration." 3. Based on review of calibration records, the fibrinogen reagent was calibrated on 7/13/2023 and 4/5/2024. The elapsed time between calibrations was 8 months and 23 days. 4. In an interview at 15:00 hours on 6/5/2024 in the office, the Laboratory Manager confirmed the laboratory had not performed calibration

	verification studies on the fibrinogen reagent at least every six months or calibrated at least every six months with at least a three-part calibration.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory blood culture worksheets, final patient reports, and confirmed in interview, the laboratory failed to include the site of culture for 35 of 37 blood cultures reviewed in 2023. The findings included: 1. Review of the laboratory policy titled "Automated Blood Culture Instrument Procedure BD Bactec FX40", section "III Specimen" had the following collection instructions: "A. Collection 1. Site Selection a. Select a different body site for each culture [set] drawn." 2. Review of laboratory blood culture worksheets included the site from which the blood culture set (aerobic and anaerobic bottles) was drawn from the patient which was not included on the patient final report: Date of Collection MRN Accession Site 01/14/2023 at 21:19 280180 24-23-014-0067 "L AC" 01/14 /2023 at 21:19 280180 24-23-014-0070 "R AC" 03/22/2023 at 07:27 30568 24-23-081-0010 "L AC" 03/22/2023 at 07:27 30568 24-23-081-0011 "R Arm" 04/24/2023 at 22:21 80028501 24-23-114-0151 "central line" 04/24/2023 at 22:25 80028501 24-23-114-0152 "R Hand" 05/12/2023 at 22:30 35737 24-23-132-0164 "L Arm" 05/12/2023 at 22:50 35737 24-23-123-0165 "R Arm" 08/03/2023 at 09:45 80024930 24-23-215-0040 "R AC" 08/03/2023 at 10:26 80024930 24-23-215-0041 "L AC" 09/01/2023 at 17:21 80031221 24-23-244-0131 "R AC" 09/01/2023 at 1715 80031221 24-23-244-0130 "L AC" 09/06/2023 at 16:30 80023094 24-23-249-0174 "L AC" 09/06/2023 at 16:30 80023094 24-23-249-0177 "R AC" 09/23/2024 at 23:15 29413 24-23-266-0045 "R hand" 09/23/2024 at 23:20 29413 24-23-266-0046 "R arm" 10/11/2023 at 21:55 35100 24-23-284-0142 "R Hand" 10/11/2023 at 21:55 35100 24-23-284-0139 "R Arm" 10/27/2023 at 07:38 80024527 24-23-300-0025 "L AC" 10/28/2023 at 06:23 80024527 24-23-301-0006 "L Hand" 10/28/2023 at 06:53 80024527 24-23-301-0005 "L AC" 10/31/2023 at 10:20 80024527 24-23-304-0058 "not indicated" 10/31/2023 at 10:20 80024527 24-23-304-0059 "not indicated" 11/08/2023 at 21:10 21237 24-23-312-0156 "R AC" 11/08/2023 at 22:00 21237 24-23-314-0159 "R AC" 11/10/2023 at 13:35 80031861 24-23-314-0119 "not indicated" 11/10/2023 to 13:40 80031861 24-23-314-0122 "not indicated" 11/24/2023 at 21:43 24106 24-23-328-0086 "L AC" 11 /24/2023 at 21:53 24106 24-23-328-0087 "L Hand" 12/08/2023 at 18:19 36239 24-23-342-0130 "RW" 12/08/2023 at 18:27 36239 24-23-342-0131 "LH" 12/11/2023 at 09: 55 22808 24-23-345-0196 "not indicated" 12/11/2023 at 09:55 22808 24-23-345-0197 "not indicated" 12/15/2023 at 12:17 26235 24-23-349-0050 "L forearm" 12/15/2023 at 14:24 26235 24-23-349-0051 "L wrist" 3. In an interview on 6/5/2024 at 09:45, in the office, the microbiology technical supervisor confirmed that the body site where the blood culture set was drawn from, was not included on the patient final report. Key: L: Left R: Right AC: Accessory Cephalic Vein RW: Right wrist LH: Left hand

D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions for use, patient reports, and confirmed in interview, the laboratory director failed to ensure that reports of test results included pertinent information required for the interpretation of blood culture results, body site and positive vial type from set drawn (aerobic and anaerobic, or peds), for 37 patient reports reviewed in 2023. The findings included: 1. Review of the laboratory policy titled "Automated Blood Culture Instrument Procedure BD Bactec FX40", section "III Specimen" had the following collection instructions: "A. Collection 1. Site Selection a. Select a different body site for each culture [set] drawn." 2. Review of the "BD BACTEC Plus Aerobic/F Culture Vials", "BD BACTEC Plus Anaerobic/F Culture Vials", and "BD BACTEC Peds Plus/F Culture Vials" intended use stated the following for the type of microorganism recovered in each culture vial: a. "BD BACTEC Plus Aerobic/F Culture Vials Intended use: BD BACTEC Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood." b. "BD BACTEC Plus Anaerobic/F Culture Vials Intended use: BD BACTED Plus Anaerobic/F medium is used in a qualitative procedure for the anaerobic culture of microorganisms (bacteria) from blood." c. "BD BACTEC Peds Plus/F Culture Vials Intended use: BD BACTEC Peds Plus/F culture vials (enriched Soybean-Casein Digest broth with CO2) are for aerobic blood cultures." 3. Review of patient preliminary and final reports for blood cultures positive for growth did not include the body site from which the blood culture set was obtained, or the vial type that obtained the microorganism growth. 4. In an interview on 6/5/2024 at 09:45, in the office, the microbiology technical supervisor confirmed that the final patient reports did not include the pertinent information required for interpretation of the positive blood culture results.