Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0433367	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Thomas H Boyd Memorial Hospital	800 School Street, Carrollton, IL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of documentation, direct observation, and interviews with the general supervisor and testing personnel; the laboratory failed to outline all components of test procedures in the specialty of microbiology (see D5403); the laboratory failed to perform calibration verifications every six months as required for two of two applicable analytes in the specialty of chemistry (see D5439); the laboratory failed to ensure negative and positive control materials were tested each day of patient testing in the specialty of microbiology (see D5449); the laboratory failed to ensure media checks were performed on blood culture medium in the specialty of microbiology (see D5477); and the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between separate analyzers performing the same analyte (see D5775).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of laboratory policies and procedures and interview with testing personnel (TP) #3; the laboratory failed to outline all components of test procedures for two of two procedures (Cepheid GeneXpert and Blood Cultures) in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedures titled, "Cepheid GeneXpert" and "Blood Cultures [on] the BD FX40", which failed to outline the following required components of a test procedure: a. Control procedures. b. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. Interview with TP #3 on 12/11/2024, at 11:34 am, confirmed the laboratory failed to outline all components of test procedures in the specialty of microbiology.
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 laboratory records, lack of documentation, and interview with the general supervisor (GS) #1; the laboratory failed to perform calibration verifications every six months as required for two of two applicable analytes (Vitamin B12 and Vitamin D) on the Orthos Vitros XT7600 chemistry analyzer in 2023 through the date of survey, 12/11/2024. Findings include: 1. Review of laboratory calibration documentation revealed the analytes Vitamin B12 and Vitamin D performed on the Orthos Vitros XT7600 only consisted of two calibration levels, resulting in the required calibration verification to be performed every six months. 2. Review of laboratory records revealed no documented calibration verifications performed for Vitamin B12 (Reference number: 1453489) or Vitamin D (Reference number: 6844056) on the Ortho Vitros XT7600 chemistry analyzer (Serial Number: J76000561) in the years 2023 and 2024. 3. Interview with GS #1 on 12/11/2024, at 12:51 am, confirmed no calibration verifications were performed every six months for Vitamin B12 and Vitamin D on the Ortho Vitros XT7600 chemistry analyzer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review the manufacturer's operations manual, laboratory records, lack of documentation, and interview with the general supervisor (GS) #l the laboratory failed to ensure negative and positive control materials were tested each day of patient testing on the Cepheid GeneXpert DX molecular system (Serial Number: 110021753) for four of four patients reviewed in the specialty of microbiology from the beginning of testing, 04/26/2024, to the date of survey, 12/11/2024. Findings include: 1. Review of the manufacturer's operations manual for the Cepheid GeneXpert DX molecular system revealed, under "External Controls", "Use external control material in accordance with local, state, federal regulations ...." 2. Review of laboratory records revealed the laboratory performing the following seven molecular analytes / panels on the Cepheid GeneXpert DX System in the specialty of microbiology: a) Clostridium difficile (C. diff) i) C. diff ii) BI/NAP1/027 strain (presumptive) b) CT/NG: i) Chlamydia trachomatis (CT) ii) Neisseria gonorrhea (NG) c) Trichomonas vaginalis (TV) d) Streptococcus pyogenes (Strep A) e) 4-Plex: i) Covid ii) Influenza A iii) Influenza B iv) Respiratory Syncytial Virus (RSV) f) Multiplex Vaginal Panel (MPV) i) TV ii) Candida group iii) Candida glabrata & Candida krusei iv) Bacterial Vaginosis (BV) g) Methicillin-Resistant Staphylococcus aureus (MRSA) 3. Review of laboratory quality control (QC) records for four of four patient testing dates review for molecular testing on the Cepheid GeneXpert DX found positive and negative control materials were not utilized on each day of patient testing. Date: Patient: Controls: 06 /12/2024 10499912 Not Performed 08/06/2024 10504731 Not Performed 10/06/2024 10509653 Not Performed 12/04/2024 10514446 Not Performed 4. Interview with the GS on 12/11/2024, at 2:04 pm, confirmed the laboratory failed to ensure negative and positive control materials were tested each day of patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review the manufacturer's operations manual, laboratory records, lack of documentation, and interview with the general supervisor (GS) #l; the laboratory failed to perform media control checks for 14 of 14 lots of aerobic and anaerobic blood culture media used for blood culture testing on the BD FX40 blood culture analyzer (Serial Number: FF6794) in the specialty of microbiology from the beginning of 2023 to the date of survey, 12/11/2024. Findings include: 1. Review of the manufacturer's operations manual for the BD BACTEC Plus Aerobic and Anaerobic medium revealed, under "Quality Control", "Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations ...." 2. Review of laboratory records revealed the laboratory performing blood cultures on the BD FX40 Blood Culture analyzer in the specialty of microbiology. 3. Review of laboratory records revealed the laboratory failed to perform and document control checks (sterility, support of growth, select or inhibit specific organisms, and physical characteristics) for each lot of BD BACTEC Plus Aerobic and Anaerobic medium received from the beginning of 2023 through the date of survey, 12/11/2024. Received date: Medium: Lot Number: 01/06/2023 Aerobic* 2290035 01/21/2023 Anaerobic** 2284980 06/02/2023 Aerobic 3061773 Anaerobic 3055808 09/18/2023*** Aerobic 3110070 Anaerobic 3145829 01/30/2024 Aerobic 3325200 Anaerobic 3340594 03/20/2024 Aerobic 4032374 Anaerobic 4032428 05/08/2024 Aerobic 4045950 07/17/2024 Aerobic 4122987 09/27/2024 Aerobic 4242515 Anaerobic 4235231 *=Reference Number: 442023 **=Reference Number: 442021 ***=Invoice date 4. Interview with the GS on 12/11/2024, at 2:04 pm, confirmed the laboratory failed to perform media control checks for blood culture testing in the specialty of microbiology.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interview with the general supervisor (GS) #1; the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between separate analyzers performing the same analyte for three of three applicable analytes (D-dimer, proBNP, and troponin) from the beginning of 2023 through the date of the survey, 12/11/2024. Findings include: 1. Review of laboratory records revealed a lack

	of documentation, including a policy/procedure and documents/results, of instrument-to-instrument test result comparisons for the following analytes performed on separate analyzers: a) D-dimer b) proBNP c) Troponin 2. Upon a tour of the laboratory on 12 /11/2024, at 12:28 pm, direct observation revealed separate analyzers were identified performing the following analytes: Analyte: Analyzer A: Analyzer B: D-dimer ACL Top 350* Pathfast** proBNP Vitros XT-7600*** Pathfast Troponin Vitros XT-7600 Pathfast *=Serial Number: 20092293 **=Serial Number: 2209D4531 ***=Serial Number: J76000561 3. Interview with the GS on 12/11/2024, at 12:49 pm, confirmed that the above analytes had been performed on both analyzers, but no instrument-to-instrument test result comparisons were available nor had been performed from the beginning of 2023 through the date of survey, 12/11/2024.