

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0707898	(X3) Date Survey Completed 05/21/2026
Name of Provider or Supplier Brookwood Baptist Medical Center	Street Address, City, State 2010 Brookwood Medical Center Dr, Homewood, AL	
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	A validation survey was conducted on 5/20/2026 to 5/21/2026. The laboratory was found NOT in compliance with the CLIA regulations with the following CONDITIONS: 42 C.F.R 493.1240 Condition: Preanalytic systems; and 42 C.F.R 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, lack of competency document and interview with Technical Supervisor #1, the laboratory failed to follow their written policies and procedure to assess consultant competency for the past 2 of 2 years reviewed, as evidenced by: 1. In review of the laboratory policy titled, "Initial Training and Competency Program," under Supervisor Performance Assessment stated, " The performance of the Medical Director, Laboratory Director, Manager, Coordinators and supervisors is assessed annually. The system Medical Director delegates the responsibilities of the Technical Supervisor to the Medical Director of Transfusion Medicine, the chief of Pathology Services and oversight. The performance of the Technical Supervisors and Clinical Consultant will be performed by the system medical director and documented on the appropriate performance assessment tool." 2. The laboratory could not provide documentation that competencies were done for any of the Technical Consultants, Technical Supervisors, or General Supervisor. According to the CMS-209, there are five consultants. 3. In interview with Technical Supervisor #1 on 5-20-2026 at 1001, confirmed that the

	laboratory did not have annual documentation of competency for any of the Technical Consultants, Technical Supervisor, and General Supervisors.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's patient test records, laboratory's policies, manufacturer's instructions, and interview with laboratory staff, the laboratory failed to meet the requirements for the overall quality of preanalytic system, as evidenced by: 1. The laboratory failed to follow its laboratory policy and manufacturer's instructions (Unicel DXl chemistry analyzer) for specimen collection and handling with the 30-minute analysis time frame for 15 of 64 ammonia specimens tested. (See D5311-I). 2. The laboratory failed to follow its laboratory policy and manufacturer's instructions (RapidPoint 500e system for specimen collection and handling with the 30 minute testing time frame for 10 of 1457 blood gas specimens tested (See D5311-II).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policy, patient test reports and interview with Technical Supervisor #1 , the laboratory failed to follow its laboratory policy and manufacturer's instructions (Unicel DXl chemistry analyzer) for specimen collection and handling with the 30-minute analysis time frame for 15 of 64 ammonia specimens tested, as evidenced by" 1. In review of the manufacturer's instructions for the Unicel DXl chemistry analyzer stated, "Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes at an RCF of 1500 G and analyzed within 30 minutes. Samples should not be frozen. The tubes should be tightly stopper at all times." 2. In review of the laboratory policy, the laboratory adopted the manufacturer's instructions which stated,"Tubes should be filled completely, mixed gently by inversion, placed on ice, centrifuged immediately for 10 minutes at an RCF of 1500 G and analyzed within 30 minutes. Samples should not be frozen. The tubes should be tightly stopper at all times." In review of the patient test reports 15 of 64 in the month of February 2026, the following patients were past the 30-minute time frame. a. patient #2018624 date

collection and time: 02/08/2026 22:16 date and time received in laboratory: 02/09/2026 00:38, 1 hour 52 minutes past the time frame. b. patient #209350 date collection and time: 02/09/2026 13:29 date and time received in laboratory: 02/09/2026 15:53, 1 hour 54 minutes past the time frame. c. patient # 218552 date collection and time: 02/09/2026 00:01, date and time received in laboratory: 02/09/2026 02:06, 1 hour 35 minutes past the time frame. d. patient #2026871 date collection and time: 02/10/2026 05:42, date and time received in laboratory: 02/10/2026 06:37, 25 minutes past the time frame e .patient # 2031864 ate collection and time: 02/11/2026 04:37, date and time received in laboratory: 02/11/2026 05:31, 24 minutes past the time frame. f. patient # 289039 date collection and time: 02/10/2026 11:00, date and time received in laboratory: 02/10/2026 11:41, 11 minutes past the time frame. h. patient # 2032545 date collection and time: 02/14/2026 03:28, date and time received in laboratory: 02/14/2026 04:07, 9 minutes past the time frame. i. patient # 2032064 date collection and time: 02/09/2026 02:32, date and time received in laboratory: 02/09/2026 03:10, 8 minutes past the time frame. j. patient # 289039 date collection and time: 02/07/2026 04:47, date and time received in laboratory: 02/07/2026 05:22, 5 minutes past the time frame. k. patient # 2032215 date collection and time: 02/10/2026 15:18, date and time received in laboratory: 02/10/2026 15:51, 3 minutes past the time frame. l. patient # 2031959 date collection and time: 02/06/2026 09:15, date and time received in laboratory: 02/06/2026 09:47, 2 minutes past the time frame. m. patient # 321356 date collection and time: 02/01/2026 19:13, date and time received in laboratory: 02/01/2026 19:45, 2 minutes past the time frame. n. patient # 422813 date collection and time: 02/04/2026 02:27, date and time received in laboratory: 02/04/2026 02:58, 1 minute past the time frame. o. patient # 2032298 date collection and time: 02/11/2026 03:24, date and time received in laboratory: 02/11/2026 03:55, 1 minute past the time frame. p. patient # 2031395 date collection and time: 02/14/2026 01:03, date and time received in laboratory: 02/14/2026 01:34, 1 minute past the time frame. 3. In interview with Technical Supervisor #1 on 5-20-2026 at 1455, confirmed that the laboratory was over the 30-minute time frame as per their policy and manufacturer's instructions 4. The laboratory performs 1716 ammonias per year II. Based on review of the manufacturer's instructions, the laboratory's procedure, patient test reports, and interview with Testing Person #35 (CMS 209, "POC Resp") , the laboratory failed to follow its laboratory policy and manufacturer's instructions (RapidPoint 500e system for specimen collection and handling with the 30 minute testing time frame for 10 of 1457 blood gas specimens reviewed in February 2026, as evidenced by: a. In review of the manufacturer's instructions for the RapidPoint 500e system stated, "Perform analysis within 10 minutes of collection for standard blood gas samples, especially in order to obtain accurate results for: pO₂, pCO₂, pH, glucose, lactate, and bili. If analysis cannot be performed within 10 minutes, samples in plastic syringes or capillaries should be kept at room temperature, as long as analysis is performed within 30 minutes." b. In review of the laboratory's procedure for the RapidPoint 500e system stated, "Perform analysis within 10 minutes of collection for standard blood gas samples, especially in order to obtain accurate results for: pO₂, pCO₂, pH, glucose, lactate, and bili. If analysis cannot be performed within 10 minutes, samples in plastic syringes or capillaries should be kept at room temperature, as long as analysis is performed within 30 minutes." 2. In review of the patient test reports 10 of 1457 in the month of February 2026, the following patients were past the 30-minute time frame. a. patient# 2033175 date collection and time: 02/25/2026 13:50, date and time received in laboratory: 02/26/2026 04:46, 14 hours 26 minutes past the time frame. b. patient #2030678 date collection and time: 02/06/2026 16:28, date and time received in laboratory: 02/06/2026 22:36, 5 hours 38 minutes past the time frame. c. patient #2003001 02/01/2026 11:17, date and time received in laboratory: 02/01/2026 14:42, 2 hours 55 minutes past the time frame. d. patient #2003001 date collection and

	time: 02/01/2026 11:18, date and time received in laboratory: 02/01/2026 14:42, 2 hours 54 minutes past the time frame. e. patient #2031750 date collection and time: 02/14/2026 03:00, date and time received in laboratory: 02/14/2026 04:53, 1 hour 23 minutes past the time frame. f. patient #2032845 date collection and time: 02/18/2026 16:42, date and time received in laboratory: 02/18/2026 18:16, 1 hour 4 minutes past the time frame. g. patient #2033071 date collection and time: 02/25/2026 12:06, date and time received in laboratory: 02/25/2026 13:25, 49 minutes past the time frame. h. patient # 2031449 date collection and time: 02/10/2026 06:57, date and time received in laboratory: 02/10/2026 08:11, 44 minutes past the time frame. i. patient # 2032560 date collection and time: 02/16/2026 14:43, date and time received in laboratory: 02/16/2026 15:33, 20 minutes past the time frame. j. patient # 2020887 date collection and time: 02/26/2026 07:02, date and time received in laboratory: 02/26/2026 07:48, 16 minutes past the time frame. 3. During an interview with Testing Person #35 (CMS 209, "POC Resp") on 5-20-2026 at 1500, testing person # 35 confirmed that they were over the 30-minute time frame and wasn't sure if the time stamps of collection and receive times were accurate. 4. The laboratory performs 19560 blood gases annually.
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: Based on review of the laboratory individual Quality Control Plan (IQCP), review of the laboratory's quality control records (QC), and interview with Technical Supervisor #1, the laboratory failed to follow their policy to perform inspections and to document physical defects upon receipt of new shipment of Becton Dickinson (BD) Bactec blood culture bottles for the last two years, as evidenced by: 1.In review of the laboratory's IQCP plan titled, "IQCP for Commercially Prepared CLSI-Exempt Media, stated, " Visual inspection of representative units of exempt media for physical defects or contamination immediately before inoculation with the primary specimen or cultivated microorganism. " 2.In review of the laboratory's QC records for blood culture bottles, BD Bactec plus Aerobic Lot #5362521 and BD Bactec lytic anaerobic lot# 5261472, the laboratory could not provide documentation for those lots as well as the last two years, that they visually inspected the bottles and recorded physical defects. 3.During an interview with Technical Supervisor #1 on 5-20-2026 at 1426 , the TS confirmed that they did not have documentation to show they performed visual inspections as required by their IQCP.
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 review of the laboratory's coagulation procedure, and interview with the Technical Consultant #1, the laboratory failed to have a step-by-step procedure on how to perform the Mean of the normal patient range (MNPT) study when the laboratory changes thromboplastin in the last two years for the Siemens CS-2500 coagulation analyzer, as evidenced by: 1. The laboratory could not provide to the surveyor a step by step procedure on how to perform the MNPT study for the Siemens CS-2500 coagulation analyzer. 2. The laboratory verified the geometric mean of 10.474 secs on 3-18-2026. 3. During an interview with Technical Consultant #1 on 5-20-2026 at 1305, TC confirmed that they did not have procedure on how to perform the MNPT each time the thromboplastin lot is changed to ensure patients were "normal."

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 review of manufacturer's instructions, direct observation, and interview with Technical Supervisor #1, the laboratory failed to label the new open container stability and expiration date of 2 of 2 Nerl waters found in the laboratory, as evidenced by: 1. In review of the manufacturer's instructions for the Nerl water stated, "Use within 30 days of opening." 2. In direct observation in Chemistry department on 5-20-2026 at 1406 the following nerl water box was not labeled with new open or expirations date: 1 box Lot #362987. 3. In direct observation in Blood Bank department 5-20-2026 at 1505 the following nerl water box was not labeled with new open or expiration date: 1 box lot #34140205. 4. During an interview with Technical Supervisor #1 on 5-20-2026 at 1506, the federal surveyor asked what were the open and new expiration dates for the two Nerl Waters, the Technical Supervisor #1 confirmed that new dates were not indicated on the box.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

	(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, maintenance logs, and interview with General Supervisor #1, the laboratory failed to document and perform daily maintenance on Unicl DXI chemistry analyzer as defined by the manufacturer for 5 of 5 months (3 months in 2025, 2 months in 2026) reviewed, as evidenced by: 1. In review of the manufacturer's instructions for daily maintenance for the Unicl DxI system stated, " Perform daily maintenance to prepare the instrument to process samples for the day. - Back up the system - Record the test count - Shake down the sold waste container -Run a clean routine. " 2. In review of the Daily Maintenance log from October 2025 to February 2026 the following days did not have daily maintenance record on the log (serial #901930), the laboratory is open everyday: a. October 2025: 15th,16th,17th,18th,19th ,20th, 21st b.November 2025: 1st, 2nd, 3rd, 4th, 10th, 12th,13th,14th, 15th,16th,17th,18th,19th,20th,21st, 22nd, 23rd, 26th, 27th, 28th, 29th, 30th. c.December 2025: 1st, 2nd, 6th,7th,8th, 9th,10th,11th,12th,13th,14th, 15th,16th, 25th,26th,27th, 28th, 29th, 30th d. January 2026: 4th,5th,6th,7th,8th,9th, 10th,11th,12th,13th, 20th,21st, 22nd, 23nd, 24th, 25th, 26th,27th f. February 2026: 4th, 5th, 6th,7th, 8th,18th,19th,20th, 21st 22nd, 23nd, 24th. 3. In an interview with General Supervisor #1 on 5-21-2026 at 0905, the GS confirmed that the daily maintenance had not been done within those dates.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's patient test records, laboratory's policies, manufacturer's instructions, and interview with laboratory staff, the Laboratory Director failed to meet the requirements for the overall management and direction of the laboratory, as evidenced by. 1. The Laboratory Director failed to meet the requirements for the overall quality of preanalytic and analytic systems for chemistry. See D6007
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test records, laboratory's policies, manufacturer's instructions, and interview with laboratory staff, the Laboratory Director failed to meet the requirements for the overall quality of preanalytic and

analytic systems for chemistry, as evidenced by: 1. The laboratory failed to follow its laboratory policy and manufacturer's instructions (Unicel DXI chemistry analyzer) for specimen collection and handling with the 30-minute analysis time frame for 15 of 64 ammonia specimens tested. See D5311-I 2. The laboratory failed to follow its laboratory policy and manufacturer's instructions (RapidPoint 500e system for specimen collection and handling with the 30 minute testing time frame for 10 of 1457 blood gas specimens tested. See D5311-II 3. The laboratory failed to document and perform daily maintenance on Unicel DXI chemistry analyzer as defined by the manufacturer for 5 of 5 months (3 months in 2025, 2 months in 2026). See D5429