Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0049226	**(X3) Date Survey Completed** 12/15/2023
Name of Provider or Supplier Glenwood Regional Medical Center Lab	**Street Address, City, State** 503 Mcmillian Road, West Monroe, LA	
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 Complaint survey was performed at GLENWOOD REGIONAL MEDICAL CENTER LABORATORY, CLIA # 19D0049226, on December 13, 2023 through December 15, 2023. GLENWOOD REGIONAL MEDICAL CENTER LABORATORY was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1100 CONDITION: Facility administration 42 CFR 493.1240 CONDITION: Preanalytic systems 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyors, review of laboratory records and interview with personnel, the facility failed to ensure that procedures were established to provide quality services. Findings: 1. The facility failed to ensure the ventilation tubing for the Siemens Dimension Vista 500 analzyer was connected to the laboratory ventilation

	system. Refer to D3001. 2. The facility failed to ensure sufficient laboratory reagents and supplies were maintained to perform the type and volume of testing on the laboratoy test menu. Refer to D3007.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the facility failed to ensure the ventilation tubing for the Siemens Dimension Vista 500 analzyer was connected to the laboratory ventilation system. Findings: 1. Direct observation by surveyor during the laboratory tour on December 14, 2023 revealed the laboratory utilizes the Siemens Dimension Vista 500 (Serial Number DV330985) analyzer for chemistry testing. 2. Further observation by the surveyor noted the ventilation tube attached to the Vista 500 (SN DV330985) was not properly attached to the laboratory ventilation system in the ceiling. 3. In interview on December 14, 2023 at 10:52 am, General Supervisor 3 confirmed the ventilation tubing was not properly attached to laboratory ventilation system.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the facility failed to ensure sufficient laboratory reagents and supplies were maintained to perform the type and volume of testing on the laboratoy test menu. Findings: 1. Observation during laboratory tour on December 13, 2023 at 9:30am revealed the laboratory utilized two Sysmex hematology analyzers for patient testing. Direct observation by surveyors identified one bottle remaining of CleanCell reagent required for daily maintenance of Sysmex analyzers. 2. Interview with the Hematology supervisor on December 13, 2023 at 10am confirmed only one CleanCell was remaining. The Hematology supervisor further stated the laboratory had been trying to order more CleanCell solution along with many other necessary supplies, and that the laboratory had borrowed from a sister facility. The laboratory planned to clean the instrument with a 5% bleach solution in the barcoded CleanCell tube until the manufacturer supply was received by the laboratory. 3. Observation by surveyors of supply receipt confirmed the laboratory received the necessary CleanCell solution on December 15, 2023. 4. Interview with the director of laboratory services and pathologist on December 14, 2023 at 11:00am revealed the laboratory has been unable to obtain necessary supplies for numerous laboratory services for nearly 6 months. When the laboratory cannot obtain the supplies necessary for patient testing due to stock and payment issues, the laboratory contacts other third party vendors or borrows from neighboring facilities. The director of laboratory services and pathologist stated the laboratory notifies administration and corporate in Dallas when there is a critical need for laboratory supplies but the payment issues are not always resolved, resulting

	in the laboratory being unable to perform testing required or referencing testing to another laboratory, delaying results. 5. Review of laboratory records from September 2023 - December 2023 revealed the following tests in which the laboratory was unable to obtain the supplies necessary for testing: culture media (all microbiology cultures resulting in send out for identification and sensitivity), Cepheid PCR reagents (Strep A, MRSA, COVID, COVID/Flu/RSV combo), Procalicitonin, Biomerieux organism ID panels, Verigene blood culture panels, Iron, Cortisol, Lipase, Abbott I-Stat cartridges, ACT, blood culture bottles, Radiometer, Sysmex Flourocell, Hemoglobin A1C, urine drug screen reagents, Urinalysis strips and all reagents, Mueller Hinton media, halogen lamps for chemistry instruments, Immucor blood bank quality control. 6. Review of task 1&3 form provided to surveyors revealed the laboratory performs the following annual test volumes for the identified testing supplies: a) Cepheid PCR: * Strep A - 594 tests * MRSA - 717 tests * Covid/Flu/RSV - 1315 tests b) Procalcitonin - 1606 tests c) BioMerieux ID panels - 4237 tests d) Verigene Blood Culture panels - 650 tests e) Iron - 653 tests f) Cortisol - 1254 tests g) ACT - 610 tests h) Blood Cultures - 11684 tests i) Hemoglobin A1C - 3944 tests j) Urine Drug Screens - 6292 tests k) Urinalysis dipsticks - 16007 tests 7. Further record review of quality control, quality assessment records and email communications revealed the laboratory utilized expired quality control material to include Anti-A, Anti-B, Anti-D, corQC and Complement Control Cells from October 13, 2023 - October 25, 2023 due to a credit hold with the manufacturer, Immucor. The laboratory notified administration and corporate by email daily from October 16 - 25, 2023 of the critical need and inability to obtain the quality control reagents from the manufacturer prior to their expiration.
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 observation by surveyors, review of laboratory policy, manufacturer's instructions, patient records and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing were centrifuged without delay of collection per the manufacturer's instructions for twenty four (24) of one hundred forty one (141) patients reviewed from September 2023 through October 2023. Refer to D5311 I. 2. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes per seventy nine (79) of two hundred six (206) patients reviewed from September 9, 2023 through October 10, 2023. Refer to 5311 II. 3. The laboratory failed to ensure quality assessment (QA) monitors identified issues within the preanalytic system. Refer to D5393.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on observation by surveyors, review of manufacturer's package insert and patient test logs, and interview with personnel, the laboratory failed to ensure patient samples for Ammonia testing were centrifuged without delay of collection per the manufacturer's instructions for twenty four (24) of one hundred forty one (141) patients reviewed from September 2023 through October 2023. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 10:02 am revealed the laboratory utilizes the Siemens Dimenstion Vista 500 analyzer for Ammonia testing. 2. Review of the Siemens Dimension Vista 500 package insert for Ammonia revealed tubes are to be "completely filled, stored tightly capped on ice and centrifuged without delay". 3. Review of the laboratory's patient test logs for Ammonia from September 2023 through October 2023 revealed the following twenty four (24) of one hundred forty one (141) patients were not centrifuged without delay from collection: a) PT 0903:C00071R: collected September 3, 2023 at 07:35 am and received September 3, 2023 at 08:20 am (centrifuged after a forty five (45) minute delay) b) PT 0903:C000104R: collected September 3, 2023 at 06:09 am and received September 3, 2023 at 06:56 am (centrifuged after a forty seven (47) minute delay) c) PT 0903:C00950S: collected September 3, 2023 at 19:14 pm and received September 3, 2023 at 19:48 pm (centrifuged after a thirty four (34) minute delay) d) PT 0906: C00883R: collected September 6, 2023 at 11:24 am and received September 6, 2023 at 12:10 am (centrifuged after a forty six (46) minute delay) e) PT 0916:C00160R: collected September 16, 2023 at 05:07 am and received September 16, 2023 at 06:21 am (centrifuged after a seventy four (74) minute delay) f) PT 0919:C01450S: collected September 19, 2023 at 20:25 pm and received September 19, 2023 at 20:58 pm (centrifuged after a thirty three (33) minute delay) g) PT 0922:C00453R: collected September 22, 2023 at 06:24 am and received September 22, 2023 at 07:10 am (centrifuged after a forty six (46) minute delay) h) PT 0923:C00297R: collected September 23, 2023 at 03:20 am and received September 23, 2023 at 04:00 am (centrifuged after a forty (40) minute delay) i) PT 0923:C00873S: collected September 23, 2023 at 16:52 pm and received September 23, 2023 at 17:49 pm (centrifuged after a fifty seven (57) minute delay) j) PT 0924:C00986S: collected September 24, 2023 at 20:02 pm and received September 24, 2023 at 20:37 pm (centrifuged after a thirty five (35) minute delay) k) PT 0925:C00906R: collected September 25, 2023 at 12:37 pm and received September 25, 2023 at 13:20 pm (centrifuged after a forty three (43) minute delay) l) PT 0925:C01476S: collected September 25, 2023 at 19:28 pm and received September 25, 2023 at 19:58 pm (centrifuged after a thirty (30) minute delay) m) PT 1003:C00814S: collected October 3, 2023 at 12:14 pm and received October 3, 2023 at 13:09 pm (centrifuged after a fifty five (55) minute delay) n) PT 1006:C00249R: collected October 6, 2023 at 03:17 am and received October 6, 2023 at 03:52 am (centrifuged after a thirty five (35) mintute delay) o) PT 1006:C01085S: collected October 6, 2023 at 19:20 pm and received October 6, 2023 at 19:52 pm (centrifuged after a thirty two (32) minute delay) p) PT 1007:C00153R: collected October 7, 2023 at 05:16 am and received October 7, 2023 at 05:53 am (centrifuged after a thirty seven (37) minute delay) q) PT 1008:C00585R: collected October 8, 2023 at 10:13am and received October 8, 2023

at 10:53 am (centrifuged after a forty three (43) minute delay) r) PT 1013:C00563R: collected October 13, 2023 at 8:58 am and received October 13, 2023 at 1209 pm (centrifuged after a one hundred ninety one (191) minute delay) s) PT 1013:C00816R: collected October 13, 2023 at 13:09 pm and received October 13, 2023 at 14:20 pm (centrifuged after a seventy one (71) minute delay) t) PT 1014:C00664R: collected October 14, 2023 at 12:01 pm and received October 14, 2023 at 13:17 pm (centrifuged after a seventy six (76) minute delay) u) PT 1016:C00619R: collected October 16, 2023 at 08:32 am and received October 16, 2023 at 10:03 am (centrifuged after a ninety one (91) minute delay) v) PT 1021:C00640S: collected October 21, 2023 at 11:40 am and received October 21, 2023 at 12:13 pm (centrifuged after a thirty three (33) minute delay) w) PT 1021:C00767S: collected October 21, 2023 at 16:19 pm and received October 21, 2023 at 16:57 pm (centrifuged after a thirty eight (38) minute delay) x) PT 1026:C00120R: collected October 26, 2023 at 04:58 am and received October 26, 2023 at 05:34 am (centrifuged after a thirty six (36) minute delay) 4. In interview on December 14, 2023 at 03:00 pm, General Supervisor 1 confirmed the identified patient samples were not centrifuged without delay for Ammonia testing per manufacturer. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 975 Ammonia tests annually. II. Based on observation by surveyors, review of manufacturer's package insert and patient test logs, and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes for seventy nine (79) of two hundred six (206) patients reviewed from September 9, 2023 through October 10, 2023. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 10:02 am revealed the laboratory utilizes the Siemens Dimension Vista 500 analyzer for Lactic Acid patient testing. 2. Review of the Siemens Dimension Vista 500 package insert for Lactic Acid revealed blood collection is to be "followed by immediate chilling of the specimen and separation of the cells within 15 minutes". 3. Review of the laboratory's patient test logs for Lactic Acid from September 9, 2023 through October 10, 2023 revealed the following seventy nine (79) of two hundred six (206) patients reviewed were not separated within fifteen (15) minutes of collection: a) PT 0929:C01083S: collected September 29, 2023 at 16:30 pm and received September 29, 2023 at 16:53 pm (exceeding the manufacturer requirements by eight (8) minutes) b) PT 0929:C01207S: collected September 29, 2023 at 19:08 pm and received September 29, 2023 at 19:31 pm (exceeding the manufacturer requirements by eight (8) minutes) c) PT 0929:C01266S: collected September 29, 2023 at 20:36 pm and received September 29, 2023 at 21:02 pm (exceeding the manufacturer requirements by eleven (11) minutes) d) PT 0929:C01357S: collected September 29, 2023 at 23:00 pm and received September 29, 2023 at 23:26 pm (exceeding the manufacturer requirements by eleven (11) minutes) e) PT 0930:C00475S: collected September 30, 2023 at 06:00 am and received September 30, 2023 at 06:26 am (exceeding the manufacturer requirements by eleven (11) minutes) f) PT 0930: C00488S: collected September 30, 2023 at 07:25 am and received September 30, 2023 at 07:48 am (exceeding the manufacturer requirements by eight (8) minutes) g) PT 0930:C00703S: collected September 30, 2023 at 12:20 pm and received September 30, 2023 at 12:53 pm (exceeding the manufacturer requirements by eighteen (18) minutes) h) PT 0930:C00722S: collected September 30, 2023 at 12:18 pm and received September 30, 2023 at 12:48 pm (exceeding the manufacturer requirements by fifteen (15) minutes) i) PT 0930:C00876S: collected September 30, 2023 at 14:50 pm and received September 30, 2023 at 15:44 pm (exceeding the manufacturer requirements by thirty nine (39) minutes) j) PT 0930:C00912S: collected September 30, 2023 at 15:00 pm and received September 30, 2023 at 15:34 pm (exceeding the manufacturer requirements by nineteen (19) minutes) k) PT 0930: C00955S: collected September 30, 2023 at 15:05 pm and received September 30, 2023 at 15:45 pm (exceeding the manufacturer requirements by twenty five (25) minutes) l) PT 0930:C01038S: collected September 30, 2023 at 17:23 pm and received September 30, 2023 at 17:49 pm (exceeding the manufacturer requirements by eleven (11) minutes) m) PT 1001:C00646T: collected October 1, 2023 at 12:56 pm and received October 1, 2023 at 13:19 pm (exceeding the manufacturer requirements by eight (8) minutes) n) PT1001:C00765S: collected October 1, 2023 at 14:35 pm and received October 1, 2023 at 15:02 pm (exceeding the manufacturer requirements by twelve (12) minutes) o) PT 1001:C00947S: collected October 1, 2023 at 19:09 pm and received October 1, 2023 at 19:39 pm (exceeding the manufacturer requirements by fifteen (15) minutes) p) PT 1002:C00297S: collected October 2, 2023 at 02:03 am and received October 2, 2023 at 02:44 am (exceeding the manufacturer requirements by twenty six (26) minutes) q) PT 1002:C00607S: collected October 2, 2023 at 08:40 am and received October 2, 2023 at 09:01 am (exceeding the manufacturer requirements by six (6) minutes) r) PT 1002:C00746S: collected October 2, 2023 at 12:30 pm and received October 2, 2023 at 12:51 pm (exceeding the manufacturer requirements by six (6) minutes) s) PT 1002:C00759S: collected October 2, 2023 at 11:10 am and received October 2, 2023 at 11:31 am (exceeding the manufacturer requirements by six (6) minutes) t) PT 1002:C00845R: collected October 2, 2023 at 13:45 pm and received October 2, 2023 at 15:41 pm (exceeding the manufacturer requirements by seventy four (74) minutes) u) PT 1002:C00854R: collected October 2, 2023 at 11:45 am and received October 2, 2023 at 12:30 pm (exceeding the manufacturer requirements by thirty (30) minutes) v) PT 1002:C01277S: collected October 2, 2023 at 18:00 pm and received October 2, 2023 at 18:27 pm (exceeding the manufacturer requirements by twelve (12) minutes) w) PT 1002:C01313S: collected October 2, 2023 at 17:35 pm and received October 2, 2023 at 18:41 pm (exceeding the manufacturer requirements by fifty one (51) minutes) x) PT 1002:C01346S: collected October 2, 2023 at 19:25 pm and received October 2, 2023 at 19:48 pm (exceeding the manufacturer requirements by eight (8) minutes) y) PT 1002:C01387S: collected October 2, 2023 at 19:52 pm and received October 2, 2023 at 20:12 pm (exceeding the manufacturer requirements by five (5) minutes) z) PT 1002:C01459S: collected October 2, 2023 at 20:43 pm and received October 2, 2023 at 21:44 pm (exceeding the manufacturer requirements by forty six (46) minutes) aa) PT 1003:C00807S: collected October 3, 2023 at 12:14 pm and received October 3, 2023 at 13:09 pm (exceeding the manufacturer requirements by forty (40) minutes) bb) PT 1003: C00945S: collected October 3, 2023 at 15:26 pm and received October 3, 2023 at 16: 02 pm (exceeding the manufacturer requirements by twenty one (21) minutes) cc) PT 1003:C01040S: collected October 3, 2023 at 16:30 pm and received October 3, 2023 at 17:06 pm (exceeding the manufacturer requirements by twenty one (21) minutes) dd) PT 1003:C01314S: collected October 3, 2023 at 21:36 pm and received October 3, 2023 at 22:24 pm (exceeding the manufacturer requirements by thirty three (33) minutes) ee) PT 1004:C00187R: collected October 4, 2023 at 04:30 am and received October 4, 2023 at 05:04 am (exceeding the manufacturer requirements by nineteen (19) minutes) ff) PT 1004:C00339S: collected October 4, 2023 at 05:23 am and received October 4, 2023 at 05:47 am (exceeding the manufacturer requirements by nine (9) minutes) gg) PT 1004:C00353T: collected October 4, 2023 at 04:15 am and received October 4, 2023 at 05:50 am (exceeding the manufacturer requirements by eighty (80) minutes) hh) PT 1004:C00712S: collected October 4, 2023 at 12:30 pm and received October 4, 2023 at 12:51 pm (exceeding the manufacturer requirements by six (6) minutes) ii) PT 1004:C01204S: collected October 4, 2023 at 23:06 pm and received October 4, 2023 at 23:38 pm (exceeding the manufacturer requirements by seventeen (17) minutes) jj) PT 1005:C00300S: collected October 5, 2023 at 02:43 am and received October 5, 2023 at 03:12 am (exceeding the manufacturer requirements by fourteen (14) minutes) kk) PT 1005:C00471S: collected October 5, 2023 at 05:09

am and received October 5, 2023 at 06:14 am (exceeding the manufacturer requirements by fifty (50) minutes) ll) PT 1005:C00759R: collected October 5, 2023 at 12:48 pm and received October 5, 2023 at 13:35 pm (exceeding the manufacturer requirements by thirty two (32) minutes) mm) PT 1005:C00902S: collected October 5, 2023 at 13:29 pm and received October 5, 2023 at 14:03 pm (exceeding the manufacturer requirements by nineteen (19) minutes) nn) PT 1005:C00914S: collected October 5, 2023 at 14:07 pm and received October 5, 2023 at 14:47 pm (exceeding the manufacturer requirements by twenty five (25) minutes) oo) PT 1005: C01221S: collected October 5, 2023 at 22:40 pm and received October 5, 2023 at 23: 07 pm (exceeding the manufacturer requirements by twelve (12) minutes) pp) PT 1005:C01227S: collected October 5, 2023 at 22:00 pm and received October 5, 2023 at 22:26 pm (exceeding the manufacturer requirements by eleven (11) minutes) qq) PT 1005:C01232S: collected October 5, 2023 at 21:58 pm and received October 5, 2023 at 22:27 pm (exceeding the manufacturer requirements by fourteen (14) minutes) rr) PT 1006:C00305S: collected October 6, 2023 at 01:07 am and received October 6, 2023 at 01:53 am (exceeding the manufacturer requirements by thirty one (31) minutes) ss) PT 1006:C00360S: collected October 6, 2023 at 03:17 am and received October 6, 2023 at 05:50 am (exceeding the manufacturer requirements by one hundred thirty eight (138) minutes) tt) PT 1006:C00497S: collected October 6, 2023 at 07:15 am and received October 6, 2023 at 07:40 am (exceeding the manufacturer requirements by ten (10) minutes) uu) PT 1006:C00879S: collected October 6, 2023 at 13:45 pm and received October 6, 2023 at 14:12 pm (exceeding the manufacturer requirements by twelve (12) minutes) vv) PT 1006:C00904S: collected October 6, 2023 at 16:29 pm and received October 6, 2023 at 16:57 pm (exceeding the manufacturer requirements by thirteen (13) minutes) ww) PT 1006: C00921S: collected October 6, 2023 at 14:40 pm and received October 6, 2023 at 15: 08 pm (exceeding the manufacturer requirements by thirteen (13) minutes) xx) PT 1006:C00936S: collected October 6, 2023 at 15:53 pm and received October 6, 2023 at 16:35 pm (exceeding the manufacturer requirements by twenty seven (27) minutes) yy) PT 1006:C01109S: collected October 6, 2023 at 17:44 pm and received October 6, 2023 at 18:45 pm (exceeding the manufacturer requirements by forty six (46) minutes) zz) PT 1006:C01266S: collected October 6, 2023 at 21:34 pm and received October 6, 2023 at 22:59 pm (exceeding the manufacturer requirements by seventy (70) minutes) aaa) PT 1007:C00238S: collected October 7, 2023 at 01:24 am and received October 7, 2023 at 02:49 am (exceeding the manufacturer requirements by seventy (70) minutes) bbb) PT 1007:C00550S: collected October 7, 2023 at 10:40 am and received October 7, 2023 at 11:14 am (exceeding the manufacturer requirements by nineteen (19) minutes) ccc) PT 1007:C00706S: collected October 7, 2023 at 11:00 am and received October 7, 2023 at 12:51 pm (exceeding the manufacturer requirements by ninety six (96) minutes) ddd) PT 1007:C00903S: collected October 7, 2023 at 17:33 pm and received October 7, 2023 at 17:57 pm (exceeding the manufacturer requirements by nine (9) minutes) eee) PT 1007:C00946S: collected October 7, 2023 at 18:47 pm and received October 7, 2023 at 19:12 pm (exceeding the manufacturer requirements by ten (10) minutes) fff) 1008:C00460S: collected October 8, 2023 at 07:25 am and received October 8, 2023 at 07:46 am (exceeding the manufacturer requirements by six (6) minutes) ggg) PT 1008:C00530S: collected October 8, 2023 at 09:52 am and received October 8, 2023 at 10:26 am (exceeding the manufacturer requirements by nineteen (19) minutes) hhh) PT 1008:C00599S: collected October 8, 2023 at 11:24 am and received October 8, 2023 at 11:52 am (exceeding the manufacturer requirements by thirteen (13) minutes) iii) PT 1008: C00656S: collected October 8, 2023 at 12:40 pm and received October 8, 2023 at 13: 08 pm (exceeding the manufacturer requirements by thirteen (13) minutes) jjj) PT 1008:C00658S: collected October 8, 2023 at 12:13 pm and received October 8, 2023

	at 12:43 pm (exceeding the manufacturer requirements by fifteen (15) minutes) kkk) PT 1008:C00677S: collected October 8, 2023 at 19:50 pm and received October 8, 2023 at 20:23 pm (exceeding the manufacturer requirements by eighteen (18) minutes) lll) PT 1008:C00711S: collected October 8, 2023 at 19:02 pm and received October 8, 2023 at 20:24 pm (exceeding the manufacturer requirements by sixty seven (67) minutes) mmm) PT 1008:C00717S: collected October 8, 2023 at 14:48 pm and received October 8, 2023 at 15:11 pm (exceeding the manufacturer requirements by eight (8) minutes) nnn) PT 1008:C00883S: collected October 8, 2023 at 21:16 pm and received October 8, 2023 at 21:55 pm (exceeding the manufacturer requirements by twenty four (24) minutes) ooo) PT 1008:C00920R: collected October 8, 2023 at 20:52 pm and received October 8, 2023 at 21:17 pm (exceeding the manufacturer requirements by ten (10) minutes) ppp) PT 1008:C00936S: collected October 8, 2023 at 19:15 pm and received October 8, 2023 at 19:36 pm (exceeding the manufacturer requirements by six (6) minutes) qqq) PT 1008:C01027S: collected October 8, 2023 at 23:46 pm and received October 8, 2023 at 00:09 am (exceeding the manufacturer requirements by eight (8) minutes) rrr) PT 1009:C00249S: collected October 9, 2023 at 01:45 am and received October 9, 2023 at 02:17 am (exceeding the manufacturer requirements by seventeen (17) minutes) sss) PT 1009:C00362S: collected October 9, 2023 at 04:41 am and received October 9, 2023 at 05:31 am (exceeding the manufacturer requirements by thirty five (35) minutes) ttt) PT 1009:C00482S: collected October 9, 2023 at 09:10 am and received October 9, 2023 at 09:43 am (exceeding the manufacturer requirements by eighteen (18) minutes) uuu) PT 1009: C00766R: collected October 9, 2023 at 11:10 am and received October 9, 2023 at 11: 37 am (exceeding the manufacturer requirements by twelve (12) minutes) vvv) PT 1009:C01042S: collected October 9, 2023 at 15:55 pm and received October 9, 2023 at 16:23 pm (exceeding the manufacturer requirements by thirteen (13) minutes) www) PT 1009:C01078S: collected October 9, 2023 at 16:33 pm and received October 9, 2023 at 16:58 pm (exceeding the manufacturer requirements by ten (10) minutes) xxx) PT 1009:C01133S: collected October 9, 2023 at 18:43 pm and received October 9, 2023 at 19:17 pm (exceeding the manufacturer requirements by nineteen (19) minutes) yyy) PT 1009:C01285S: collected October 9, 2023 at 20:56 pm and received October 9, 2023 at 21:36 pm (exceeding the manufacturer requirements by twenty five (25) minutes) zzz) PT 1009:C01413S: collected October 9, 2023 at 23:38 pm and received October 9, 2023 at 00:03 am (exceeding the manufacturer requirements by ten (10) minutes) 4. In interview on December 14, 2023 at 03:00 pm, General Supervisor 1 confirmed the identified patient samples were not separated within fifteen (15) minutes of collection for Lactic Acid testing per manufacturer. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 7263 Lactic Acid tests annually.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality assessment (QA) records and interview with personnel, the laboratory failed to ensure quality assessment (QA) monitors

	identified issues within the preanalytic system. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing were centrifuged without delay of collection per the manufacturer's instructions for twenty four (24) of one hundred forty one (141) patients reviewed from September 2023 through October 2023. Refer to D5311 I. 2. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes per seventy nine (79) of two hundred six (206) patients reviewed from September 9, 2023 through October 10, 2023. Refer to 5311 II.
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 observation by surveyors, review of laboratory policies and records as well as interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5403. 2. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation for sixty seven (67) of one hundred forty one (141) patients reviewed. Refer to D5411 I. 3. The laboratory failed to analyze patient samples for Ionized Calcium within ten (10) minutes of collection per manufacturer requirements for twenty one (21) of twenty two (22) patients reviewed. Refer to D5411 II. 4. The laboratory failed to validate subsequent new lots of heparin reagent as required by the manufacturer for one (1) of two (2) lots reviewed. Refer to D5411 III. 5. The laboratory failed to verify the performance specifications for Factor Xa testing on the Siemens CA2500 coagulation analyzer. Refer to D5421. 6. The laboratory failed to ensure the weekly maintenance on two (2) Siemens Dimension Vista 500 analyzers was performed as required by the manufacturer. Refer to D5429. 7. The laboratory failed to perform quality control (QC) for Gram Negative Blood Culture (BC-GN) patient testing per policy for three (3) of five (5) months reviewed in 2023. Refer to D5445. 8. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a procedure for new lot of reagent verification for Anti-Xa testing. Findings: 1. Observation by surveyors on December 13, 2023 at 10:30 am during the laboratory tour revealed the laboratory utilizes the Sysmex CS-2500 coagulation analyzer for anti-Xa patient testing. 2. Review of the manufacturer's instructions for "Determining the Heparin Therapeutic Range by Ex-Vivo Method" revealed detailed instructions for Cumulative Summation method - "comparison of the unfractionated heparin sensitivity of a new lot of reagent with an existing validated lot of reagent" to "control for (and prevent) drift with multple changes over time." 3. Review of the laboratory's polcies revealed the laboratory did not have a written procedures for new lot of heparin kit to include; but not limited to Cumulative Summation or compare new reagent to existing lots prior to patient test. 4. In interview on December 15, 2023 at 9am, the hematology supervisor confirmed the laboratory did not have written procedures for new lot of heparin reagent kits.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: I. Based on observation by surveyors, review of manufacturer's package insert and patient test logs and interview with personnel, the laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation as required by the manufacturer for sixty seven (67) of one hundred forty one (141) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 10:02 am revealed the laboratory utilizes the Siemens Dimension Vista 500 analyzer for Ammonia patient testing. 2. Review of the Siemens Dimension Vista 500 package insert for Ammonia revealed "samples are to be analzyed within 30 minutes of centrifugation". 3. Review of the laboratory's patient test logs from September 2023 through October 2023 revealed the laboratory did not perform patient samples for Ammonia testing within thirty (30) minutes of centrifugation per manufacturer's requirements for the following sixty seven (67) of one hundred forty one (141) patients reviewed: a) PT 0901:C00237R: received September 1, 2023 at 05:44 am and resulted September 1, 2023 at 06:30 am (exceeding the manufacturer's requirements of 30 minutes by sixteen (16) minutes) b) PT 0901:C00439S: received September 1, 2023 at 06:00 am and resulted September 1, 2023 at 06:35 am (exceeding the manufacturer's requirements of 30 minutes by five

(5) minutes) c) PT 0901:C01268S: received September 1, 2023 at 21:41 pm and resulted September 1, 2023 at 22:22 pm (exceeding the manufacturer's requirements of 30 minutes by eleven (11) minutes) d) PT 0903:C00071R: received September 3, 2023 at 08:20 am and resulted September 3, 2023 at 08:56 am (exceeding the manufacturer's requirements of 30 minutes by six (6) minutes) e) PT 0903:C00191R: received September 3, 2023 at 05:22 am and resulted September 3, 2023 at 06:23 am (exceeding the manufacturer's requirements of 30 minutes by thirty one (31) minutes) f) PT 0903:C00221S: received September 3, 2023 at 01:25 am and resulted September 3, 2023 at 02:10 am (exceeding the manufacturer's requirements of 30 minutes by fifteen (15) minutes) g) PT 0903:C00959S: received September 3, 2023 at 19:48 pm and resulted September 3, 2023 at 20:32 pm (exceeding the manufacturer's requirements of 30 minutes by fourteen (14) minutes) h) PT 0904:C00088R: received September 4, 2023 at 03:12 am and resulted September 4, 2023 at 03:56 am (exceeding the manufacturer's requirements of 30 minutes by fourteen (14) minutes) i) PT 0904:C00386S: received September 4, 2023 at 04:33 am and resulted September 4, 2023 at 05:08 am (exceeding the manufacturer's requirements of 30 minutes by five (5) minutes) j) PT 0907:C00151R: received September 7, 2023 at 03:18 am and resulted September 7, 2023 at 03:50 am (exceeding the manufacturer's requirements of 30 minutes by two (2) minutes) k) PT 0907:C01004R: received September 7, 2023 at 13:57 pm and resulted September 7, 2023 at 15:09 pm (exceeding the manufacturer's requirements of 30 minutes by forty two (42) minutes) l) PT 0908: C00109R: received September 8, 2023 at 04:41 am and resulted September 8, 2023 at 05:19 am (exceeding the manufacturer's requirements of 30 minutes by eight (8) minutes) m) PT 0908:C01092S: received September 8, 2023 at 16:37 pm and resulted September 8, 2023 at 17:33 pm (exceeding manufacturer's requirements of 30 minutes by twenty six (26) minutes) n) PT 0910:C01067S: received September 10, 2023 at 22: 53 pm and resulted September 10, 2023 at 23:24 pm (exceeding manufacturer's requirements of 30 minutes by one (1) minute) o) PT 0912:C01462S: received September 12, 2023 at 23:05 pm and resulted September 12, 2023 at 23:44 pm (exceeding manufacturer's requirements of 30 minutes by nine (9) minutes) p) PT 0913:C01135R: received September 13, 2023 at 17:10 pm and resulted September 13, 2023 at 18:47 pm (exceeding manufacturer's requirements of 30 minutes by sixty seven (67) minutes) q) PT 0915:C00425S: received September 15, 2023 at 05:09 am and resulted September 15, 2023 at 06:07 am (exceeding manufacturer's requirements of 30 minutes by twenty eight (28) minutes) r) PT 0916:C00160R: received September 16, 2023 at 06:21 am and resulted September 16, 2023 at 06:52 am (exceeding manufacturer's requirements of 30 minutes by one (1) minute) s) PT 0918: C01275S: received September 18, 2023 at 21:16 pm and resulted September 18, 2023 at 22:01 pm (exceeding manufacturer's requirements of 30 minutes by fifteen (15) minutes) t) PT 0919:C00802S: received September 19, 2023 at 11:07 am and resulted September 19, 2023 at 11:43 am (exceeding manufacturer's requirements of 30 minutes by six (6) minutes) u) PT 0919:C01430S: received September 19, 2023 at 21: 16 pm and resulted September 19, 2023 at 21:48 pm (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) v) PT 0919:C01450S: received September 19, 2023 at 20:58 pm and resulted September 19, 2023 at 21:48 pm (exceeding manufacturer's requirements of 30 minutes by twenty (20) minutes) w) PT 0920:C00216R: received September 20, 2023 at 05:22 am and resulted September 20, 2023 at 06:04 am (exceeding manufacturer's requirements of 30 minutes by twelve (12) minutes) x) PT 0922:C00673S: received September 22, 2023 at 11:09 am and resulted September 22, 2023 at 11:40 am (exceeding manufacturer's requirements of 30 minutes by one (1) minute) y) PT 0923:C00873S: received September 23, 2023 at 17:49 pm and resulted September 23, 2023 at 18:29 pm (exceeding manufacturer's requirements of 30 minutes by ten (10) minutes) z) PT 0923:C01021S: received

September 23, 2023 at 20:09 pm and resulted September 23, 2023 at 20:59 pm (exceeding manufacturer's requirements of 30 minutes by twenty (20) minutes) aa) PT 0925:C00286S: received September 25, 2023 at 02:43 am and resulted September 25, 2023 at 03:55 am (exceeding manufacturer's requirements of 30 minutes by forty two (42) minutes) bb) PT 0902:C00640R: received September 25, 2023 at 08:18 am and resulted September 25, 2023 at 08:59 am (exceeding manufacturer's requirements of 30 minutes by eleven (11) minutes) cc) PT 0925:C00986S: received September 25, 2023 at 15:08 pm and resulted September 25, 2023 at 15:40 pm (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) dd) PT 0926: C00220R: received September 26, 2023 at 04:06 am and resulted September 26, 2023 at 05:03 am (exceeding manufacturer's requirements of 30 minutes by twenty seven (27) minutes) ee) PT 0926:C00941R: received September 26, 2023 at 14:47 pm and resulted September 26, 2023 at 15:38 pm (exceeding manufacturer's requirements of 30 minutes by twenty one (21) minutes) ff) PT 0926:C01000S: received September 26, 2023 at 16:58 pm and resulted September 26, 2023 at 17:29 pm (exceeding manufacturer's requirements of 30 minutes by one (1) minute) gg) PT 0927:C00833R: received September 27, 2023 at 12:12 pm and resulted September 27, 2023 at 13:21 pm (exceeding manufacturer's requirements of 30 minutes by thirty nine (39) minutes) hh) PT 0928:C00816R: received September 28, 2023 at 12:06 pm and resulted September 28, 2023 at 12:37 pm (exceeding manufacturer's requirements of 30 minutes by one (1) minute) ii) PT 0930:C00798R: received September 30, 2023 at 14: 10 pm and resulted September 30, 2023 at 14:42 pm (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) jj) PT 1001:C00395R: received October 1, 2023 at 04:23 am and resulted October 1, 2023 at 05:00 am (exceeding manufacturer's requirements of 30 minutes by seven (7) minutes) kk) PT 1002: C00372S: received October 2, 2023 at 04:44 am and resulted October 2, 2023 at 06:25 am (exceeding manufacturer's requirements of 30 minutes by seventy one (71) minutes) ll) PT 1002:C00680S: received October 2, 2023 at 12:51 pm and resulted October 2, 2023 at 13:23 pm (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) mm) PT 1002:C00721S: received October 2, 2023 at 11:48 am and resulted October 2, 2023 at 12:29 pm (exceeding manufacturer's requirements of 30 minutes by eleven (11) minutes) nn) PT 1002:C01255S: received October 2, 2023 at 19:03 pm and resulted October 2, 2023 at 20:14 pm (exceeding manufacturer's requirements of 30 minutes by forty one (41) minutes) oo) PT 1002:C01452S: received October 2, 2023 at 22:51 pm and resulted October 2, 2023 at 23:53 pm (exceeding manufacturer's requirements of 30 minutes by thirty two (32) minutes) pp) PT 1003:C00128R: received October 3, 2023 at 05:04 am and resulted October 3, 2023 at 06:29 am (exceeding manufacturer's requirements of 30 minutes by fifty five (55) minutes) qq) PT 1004:C01160S: received October 4, 2023 at 21:24 pm and resulted October 4, 2023 at 22:16 pm (exceeding manufacturer's requirements of 30 minutes by twenty two (22) minutes) rr) PT 1005:C01222S: received October 5, 2023 at 21:44 pm and resulted October 5, 2023 at 22:15 pm (exceeding manufacturer's requirements of 30 minutes by one (1) minute) ss) PT 1006:C00249R: received October 6, 2023 at 03:52 am and resulted October 6, 2023 at 04:27 am (exceeding manufacturer's requirements of 30 minutes by five (5) minutes) tt) PT 1006:C01085S: received October 6, 2023 at 19:52 pm and resulted October 6, 2023 at 20:31 pm (exceeding manufacturer's requirements of 30 minutes by nine (9) minutes) uu) PT 1013:C00321S: received October 13, 2023 at 03:28 am and resulted October 13, 2023 at 04:05 am (exceeding manufacturer's requirements of 30 minutes by three (3) minutes) vv) PT 1015:C00916S: received October 15, 2023 at 20:18 pm and resulted October 15, 2023 at 20:53 pm (exceeding manufacturer's requirements of 30 minutes by five (5) minutes) ww) PT 1016:C00975R: received October 16, 2023 at 13:39 pm and resulted October 16, 2023 at 15:24 pm (exceeding manufacturer's requirements of

30 minutes by seventy five (75) minutes) xx) PT 1016:C01364S: received October 16, 2023 at 21:36 pm and resulted October 16, 2023 at 22:18 pm (exceeding manufacturer's requirements of 30 minutes by twelve (12) minutes) yy) PT 1018: C00270R: received October 18, 2023 at 02:02 am and resulted October 18, 2023 at 03: 02 am (exceeding manufacturer's requirements of 30 minutes by thirty (30) minutes) zz) PT 1018:C00744R: received October 18, 2023 at 10:38 am and resulted October 18, 2023 at 11:32 am (exceeding manufacturer's requirements of 30 minutes by twenty four (24) minutes) aaa) PT 1018:C01436: received October 18, 2023 at 23:44 pm and resulted October 19, 2023 at 00:23 am (exceeding manufacturer's requirements of 30 minutes by nine (9) minutes) bbb) PT 1019:C00699S: received October 19, 2023 at 10:57 am and resulted October 19, 2023 at 11:46 am (exceeding manufacturer's requirements of 30 minutes by nineteen (19) minutes) ccc) PT 1021: C00140R: received October 21, 2023 at 05:35 am and resulted October 21, 2023 at 06: 12 am (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) ddd) PT 1021:C00640S: received October 21, 2023 at 12:13 pm and resulted October 21, 2023 at 13:08 pm (exceeding manufacturer's requirements of 30 minutes by twenty two (22) minutes) eee) PT 1022:C00861S: received October 22, 2023 at 18:58 pm and resulted October 22, 2023 at 19:39 pm (exceeding manufacturer's requirements of 30 minutes by eleven (11) minutes) fff) PT 1025:C00695R: received October 25, 2023 at 12:08 pm and resulted October 25, 2023 at 12:44 pm (exceeding manufacturer's requirements of 30 minutes by six (6) minutes) ggg) PT 1028: C00964S: received October 28, 2023 at 21:30 pm and resulted October 28, 2023 at 22: 04 pm (exceeding manufacturer's requirements of 30 minutes by four (4) minutes) hhh) PT 1028:C01027S: received October 28, 2023 at 22:45 pm and resulted October 29, 2023 at 00:29 am (exceeding manufacturer's requirements of 30 minutes by seventy four (74) minutes) iii) PT 1030:C00265S: received October 30, 2023 at 02:41 am and resulted October 30, 2023 at 03:50 am (exceeding manufacturer's requirements of 30 minutes by thirty nine (39) minutes) jjj) PT 1030:C00552R: received October 30, 2023 at 10:41 am and resulted October 30, 2023 at 11:12 am (exceeding manufacturer's requirements of 30 minutes by one (1) minutes) kkk) PT 1030:C00645S: received October 30, 2023 at 11:53 am and resulted October 30, 2023 at 12:30 pm (exceeding manufacturer's requirements of 30 minutes by seven (7) minutes) mmm) PT 1030:C00842S: received October 30, 2023 at 14:57 pm and resulted October 30, 2023 at 15:36 pm (exceeding manufacturer's requirements of 30 minutes by nine (9) minutes) nnn) PT 1031:C00206R: received October 31, 2023 at 04:18 am and resulted October 31, 2023 at 05:26 am (exceeding manufacturer's requirements of 30 minutes by thirty (30) minutes) ooo) PT 1031:C00333S: received October 31, 2023 at 03:19 am and resulted October 31, 2023 at 03:51 am (exceeding manufacturer's requirements of 30 minutes by two (2) minutes) ppp) PT 1031: C00954S: received October 31, 2023 at 17:33 pm and resulted October 31, 2023 at 18: 11 pm (exceeding manufacturer's requirements of 30 minutes by eight (8) minutes) 4. In interview on December 14, 2023 at 3:00 pm, General Supervisor confirmed the laboratory did not perform the identified patient samples for Ammonia testing as required by the manufacturer. 5. Review of the Task 1&3 form provided to surveyors revealed the laboratory performs 975 Ammonia tests annually. II. Based on observation by surveyors, review of manufacturer's operator manual, laboratory policy, patient test worksheets, and interview with personnel, the laboratory failed to analyze patient samples for Ionized Calcium within ten (10) minutes of collection per manufacturer requirements for twenty one (21) of twenty two (22) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 10:02 am utilizes the Abbott I-STAT analyzer with the CG8+ cartridge for Ionized Calcium patient testing. 2. Review of the Abbott I-STAT operator's manual for Ionized Calcium under "Test Timing" revealed "Within 10 minutes after

collection. Samples collected with anticoagulant for the measurement of pH, pCO2, pO2, TCO2, and Ionized Calcium". 3. Review of the laboratory policy for "Performing and Resulting I-STAT Test Using the EG7+ or CG8+ Cartridge" revealed "Samples for pH, pCO2, pO2, TCO2, and Ionized Calcium should be tested within 10 minutes of specimen collection". 4. Review of patient test worksheets for Ionized Calcium from September 2023 through November 2023 revealed the laboratory did not perform patient test samples for Ionized Calcium within 10 minutes of collection per manufacturer requirements for the following twenty one (21) of twenty two (22) patients reviewed: a) PT 0905:C01118S: sample collected September 5, 2023 at 16:41 pm and resulted September 5, 2023 at 19:47 pm (exceeding manufacturer requirements by one hundred seventy six (176) minutes) b) PT 0908: C00182R: sample collected September 8, 2023 at 06:00 am and resulted September 8, 2023 at 07:21 am (exceeding manufacturer requirements by seventy one (71) minutes) c) PT 0913:C01122R: sample collected September 13, 2023 at 16:22 pm and resulted September 13, 2023 at 18:50 pm (exceeding manufacturer requirements by one hundred thirty eight (138) minutes) d) PT 0913:C01239R: sample collected September 13, 2023 at 21:35 pm and resulted September 13, 2023 at 21:57 pm (exceeding manufacturer requirements by twelve (12) minutes) e) PT 0918:C01457S: sample collected September 18, 2023 at 22:45 pm and resulted September 18, 2023 at 23:49 pm (exceeding manufacturer requirements by fifty four (54) minutes) f) PT 0919:C00791R: sample collected September 19, 2023 at 10:15 am and resulted September 19, 2023 at 10:45 am (exceeding manufacturer requirements by twenty (20) minutes) g) PT 0920:C00458R: sample collected September 20, 2023 at 07:18 am and resulted September 20, 2023 at 07:36 am (exceeding manufacturer requirements by eight (8) minutes) h) PT 1006:C00524R: sample collected October 6, 2023 at 07:42 am and resulted October 6, 2023 at 08:12 am (exceeding manufacturer requirements by twenty (20) minutes) i) PT 1007:C00179R: sample collected October 7, 2023 at 07:12 am and resulted October 7, 2023 at 08:41 am (exceeding manufacturer requirements by seventy nine (79) minutes) j) PT 1008:C00267S: sample collected October 8, 2023 at 01:39 am and resulted October 8, 2023 at 02:56 am (exceeding manufacturer requirements by sixty seven (67) minutes) k) PT 1011: C00906R: sample collected October 11, 2023 at 12:42 pm and resulted October 11, 2023 at 13:43 pm (exceeding manufacturer requirements by fifty one (51) minutes) l) PT 1031:C00658S: sample collected October 31, 2023 at 11:37 am and resulted October 31, 2023 at 12:17 pm (exceeding manufacturer requirements by thirty (30) minutes) m) PT 1031:C00074R: sample collected October 31, 2023 at 04:30 am and resulted October 31, 2023 at 06:01 am (exceeding manufacturer requirements by eighty one (81) minutes) n) PT 1102:C00391S: sample collected November 2, 2023 at 06:44 am and resulted November 2, 2023 at 08:08 am (exceeding manufacturer requirements by seventy four (74) minutes) o) PT 1106:C00935R: sample collected November 6, 2023 at 13:30 pm and resulted November 6, 2023 at 14:57 pm (exceeding manufacturer requirements by sixty eight (68) minutes) p) PT 1117: C00510R: sample collected November 17, 2023 at 09:58 am and resulted November 17, 2023 at 11:30 am (exceeding manufacturer requirements by eighty two (82) minutes) q) PT 1117:C01104S: sample collected November 17, 2023 at 20:20 pm and resulted November 17, 2023 at 21:06 pm (exceeding manufacturer requirements by thirty six (36) minutes) r) PT 1119:C00540R: sample collected November 19, 2023 at 11:00 am and resulted November 19, 2023 at 11:47 am (exceeding manufacturer requirements by thirty seven (37) minutes) s) PT 1120:C00907R: sample collected November 20, 2023 at 13:15 pm and resulted November 20, 2023 at 13:58 pm (exceeding manufacturer requirements by thirty three (33) minutes) t) PT 1121: C00019R: sample collected November 21, 2023 at 03:32 am and resulted November 21, 2023 at 04:47 am (exceeding manufacturer requirements by sixty five (65)

	minutes) u) PT 1129:C00674S: sample collected November 29, 2023 at 11:02 am and resulted November 29, 2023 at 11:18 am (exceeding manufacturer requirements by six (6) minutes) 5. In interview on December 15, 2023 at 09:30 am, General Supervisor 1 confirmed the laboratory did not perform Ionized Calcium patient testing per manufacturer for the identified patients. 6. Review of the Task 1&3 form provided to surveyors revealed the laboratory performs 129 Ionized Calcium tests annually. III. Based on observation by surveyors, review of manufacturer instructions, laboratory quality control records, and interview with personnel, the laboratory failed to validate subsequent new lots of heparin reagent as required by the manufacturer for one (1) of two (2) lots reviewed. Findings: 1. Observation by surveyors on December 13, 2023 at 10:30 am during the laboratory tour revealed the laboratory utilizes the Sysmex CS-2500 coagulation analyzer for anti-Xa patient testing. 2. Review of the manufacturer's instructions for "Determining the Heparin Therapeutic Range by Ex-Vivo Method" revealed detailed instructions for Cumulative Summation method - "comparison of the unfractionated heparin sensitivity of a new lot of reagent with an existing validated lot of reagent" to "control for (and prevent) drift with multple changes over time." 3. Review of the current lot of Innovance Heparin Kit (#529) revealed the laboratory did not perform a Cumulative Summation to validate the new lot of reagent prior to patient testing. 4. In interview on December 15, 2023 at 9am, the hematology supervisor confirmed that a comparison of the current and new lot of reagent was not performed prior to putting the new Heparin reagent in place for patient testing. The hematology supervisor further confirmed the laboratory did not include Heparin reagent or Anti-Xa in new lot rollover processes. 5. Review of the Task 1&3 form revealed the laboratory performs 894 Anti-Xa tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the manufacturer's instructions, laboratory performance specification records and interview with personnel, the laboratory failed to verify the performance specifications for Anti-Xa testing on the Siemens CA2500 coagulation analyzer. Findings: 1. Observation by surveyors on December 13, 2023 at 10:03 am during the laboratory tour revealed the laboratory utilizes the two (2)Siemens CA2500 coagulation analyzers for Anti-Xa patient testing. 2. Review of the manufacturer's instructions for "Determining the Heparin Therapeutic Range by Ex-Vivo Method": "Collect acceptable patient samples, ideally collecting citrated blood from 30-40 patients receiving unfractionated heparin therapy. The samples selected must have Heparin concentrations that span the entire therapeutic range." 3. Review of the laboratory's performance specification records revealed the laboratory performed a method comparison for anti-Xa with ten (10) samples obtained from CliniSys Associates Ltd samples which stated **For Research Use Only**. Further review of the Heparin Therapeutic Range revealed only 5 samples performed by the laboratory were included in the complete study of 177

	sample points. 4. Further review of the laboratory's performance specification records revealed the laboratory did not perform the following: a) Accuracy with acceptable patient samples as defined by the manufacturer b) Complete Precision to include run-to-run, day-to-day, within run and operator variance d) Reference Range e) Heparin Therapeutic Range performed by the laboratory with acceptable patient samples 5. In interview on December 15, 2023 at 9am, the hematology supervisor stated the laboratory followed the instructions provided from the corporate office when anti-Xa was brought in house. The hematology supervisor further confirmed that corporate had determined the Heparin Therapeutic range using data from across the system, but was not sure how it was determined. The hematology supervisor stated the documentation provided was all the laboratory performed prior to patient testing. 6. Review of the Task 1&3 form revealed the laboratory performs 894 Anti-Xa tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 observation by surveyors, review of maintenance records and interview with personnel, the laboratory failed to ensure the weekly maintenance on two (2) Siemens Dimension Vista 500 analyzers was performed as required by the manufacturer. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 10:02 am revealed the laboratory utilizes the following analyzers for Chemistry testing: a) Siemens Dimension Vista 500 (Serial Number DV330985) b) Siemens Dimension Vista 500 (Serial Number DV330986) 2. Review of the Siemens Dimension Vista 500 maintenance records revealed the laboratory performs the following weekly maintenance: a) Clean Reagent Residue on Baseplate b) Inspect IMT Sample Port for Salt Crystals 3. Further review of the Siemens Dimension Vista 500 (Serial Number DV330985) maintenance records for 2023 revealed the laboratory did not perform weekly maintenance for the following six (6) of fifty two (52) weeks reviewed: a) Week of January 15, 2023 through January 21, 2023 b) Week of May 14, 2023 through May 20, 2023 c) Week of June 25, 2023 through July 1, 2023 d) Week of July 2, 2023 through July 8, 2023 e) Week of August 13, 2023 through August 19, 2023 f) Week of October 22, 2023 through October 28, 2023 4. Further review of the Siemens Dimension Vista 500 (Serial Number DV330986) maintenance records for 2023 revealed the laboratory did not perform weekly maintenance for the following five (5) of fifty two (52) weeks reviewed: a) Week of January 15, 2023 through January 21, 2023 b) Week of February 26, 2023 through March 4, 2023 c) Week of May 14, 2023 through May 20, 2023 d) Week of August 13, 2023 through August 19, 2023 e) Week of October 22, 2023 through October 28, 2023 5. In interview on December 15, 2023 at 10:30 am, General Supervisor confirmed the laboratory did not perform the identified maintenance.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records, patient logs and interview with personnel, the laboratory failed to perform quality control (QC) for Gram Negative Blood Culture (BC-GN) patient testing per policy for three (3) of five (5) months reviewed in 2023. Findings: 1. Observation by surveyors during the laboratory tour on December 13, 2023 at 9:30 am revealed the laboratory utilizes the Nanosphere Verigene SP analyzer for Gram Negative Blood Culture (BC-GN) patient testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) under "BC-GN External Control Plan" revealed "A minimum of one external positive and negative control must be performed per lot/shipment or at least every 30 days". 3. Review of the laboratory's quality control (QC) records revealed the laboratory did not perform external QC every thirty (30) days for the following three (3) of five (5) months in 2023: a) September 2023: QC due September 4, 2023; QC not performed until September 19, 2023 b) October 2023: QC due October 20, 2023; QC not performed until October 24, 2023 c) November 2023: QC due November 25, 2023; QC not performed until December 13, 2023 4. Further review of patient test logs revealed the laboratory reported the following twelve (12) of twenty six (26) patients for BC-GN without performance of external QC per IQCP: a) September 7, 2023: MR-GL30015013 b) September 8, 2023: MR-GL12670983 c) September 13, 2023: MR-GL30008405 d) October 20, 2023: MR-GL13968798 e) October 20, 2023: MR-GL30047137 f) October 23, 2023: MR-GL30048184 g) November 25, 2023: MR-GL30036655 h) November 28, 2023: MR-GL12708807 i) November 30, 2023: MR-GL12663973 j) November 30, 2023: MR-GL12725506 k) December 4, 2023: MR-GL12700119 l) December 7, 2023: MR-GL12529239 5. In interview on December 15, 2023 at 10:30 am, General Supervisor 1 confirmed the laboratory did not perform external QC for BC-GN per the laboratory's IQCP. 6. Review of the Task 1&3 provided to surveyors revealed the laboratory performs 650 BC-GN tests annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5403. 2. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation for sixty seven

	(67) of one hundred forty one (141) patients reviewed. Refer to D5411 I. 3. The laboratory failed to analyze patient samples for Ionized Calcium within ten (10) minutes of collection per manufacturer requirements for twenty one (21) of twenty two (22) patients reviewed. Refer to D5411 II. 4. The laboratory failed to validate subsequent new lots of heparin reagent as required by the manufacturer for one (1) of two (2) lots reviewed. Refer to D5411 III. 5. The laboratory failed to verify the performance specifications for Factor Xa testing on the Siemens CA2500 coagulation analyzer. Refer to D5421. 6. The laboratory failed to ensure the weekly maintenance on two (2) Siemens Dimension Vista 500 analyzers was performed as required by the manufacturer. Refer to D5429. 7. The laboratory failed to perform quality control (QC) for Gram Negative Blood Culture (BC-GN) patient testing per policy for three (3) of five (5) months reviewed in 2023. Refer to D5445.
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 observation by surveyors, review of laboratory policies and records as well as interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the environmental conditions for the laboratory are appropriate for testing provided. Refer to 6010. 2. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 3. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 4. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6020. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records and interview with personnel, the Laboratory Director failed to ensure the environmental conditions for the laboratory are appropriate for testing provided. Findings: 1. The laboratory failed to ensure the ventilation tubing for the Siemens Dimension Vista 500 analzyer was connected to the laboratory ventilation system. Refer to D3001.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing were centrifuged without delay of collection per the manufacturer's instructions for twenty four (24) of one hundred forty one (141) patients reviewed from September 2023 through October 2023. Refer to D5311 I. 2. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes per seventy nine (79) of two hundred six (206) patients reviewed from September 9, 2023 through October 10, 2023. Refer to 5311 II. 3. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation for sixty seven (67) of one hundred forty one (141) patients reviewed. Refer to D5411 I. 4. The laboratory failed to analyze patient samples for Ionized Calcium within ten (10) minutes of collection per manufacturer requirements for twenty one (21) of twenty two (22) patients reviewed. Refer to D5411 II. 5. The laboratory failed to validate subsequent new lots of heparin reagent as required by the manufacturer for one (1) of two (2) lots reviewed. Refer to D5411 III. 6. The laboratory failed to ensure the weekly maintenance on two (2) Siemens Dimension Vista 500 analyzers was performed as required by the manufacturer. Refer to D5429.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to ensure quality assessment (QA) monitors identified issues within the preanalytic system. Refer to D5393. 2. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6042.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Ammonia testing were centrifuged without delay of collection per the manufacturer's instructions for twenty four (24) of one hundred forty one (141) patients reviewed from September 2023 through October 2023. Refer to D5311 I. 2. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes per seventy nine (79) of two hundred six (206) patients reviewed from September 9, 2023 through October 10, 2023. Refer to 5311 II. 3. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation for sixty seven (67) of one hundred forty one (141) patients reviewed. Refer to D5411 I. 4. The laboratory failed to analyze patient samples for Ionized Calcium within ten (10) minutes of collection per manufacturer requirements for twenty one (21) of twenty two (22) patients reviewed. Refer to D5411 II. 5. The laboratory failed to validate subsequent new lots of heparin reagent as required by the manufacturer for one (1) of two (2) lots reviewed. Refer to D5411 III. 6. The laboratory failed to ensure the weekly maintenance on two (2) Siemens Dimension Vista 500 analyzers was performed as required by the manufacturer. Refer to D5429.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy and performance studies as well as interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and interview with personnel, the Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5445.