Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0689385	02/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lane Regional Medical Center	6300 Main Street, Zachary, 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 Validation Survey was performed at Lane Regional Medical Center, CLIA ID # 19D0689385 on February 10, 2020 through February 13, 2020. Lane Regional Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCES: 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 42 CFR 493.1421 CONDITION: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain the competency assessment supporting documentation for laboratory personnel for 2018. Findings: 1. Review of the laboratory's personnel records binder for 2018 revealed the laboratory did have a summary sheet to show assessments and documentation to support the competency assessments performed on testing personnel for 2017; however, the records did not have the supporting documentation for the 2018 competency assessments. 2. In interview on February 10, 2020 at 11:46 am, Personnel 2 stated the previous general supervisor maintained the competency records. Personnel 2 further stated the 2018 supporting documentation must have been destroyed instead of the 2017 documentation.
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: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Supervisor, Technical Consultant and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following: a) Personnel 2 serves as Technical Supervisor, Technical Consultant, and General Supervisor b) Personnel 3 serves as Technical Consultant and General Supervisor c) Personnel 5 serves as General Supervisor 2. Review of the laboratory's policy manual revealed the laboratory did not include competency assessment criteria or frequency of performance for personnel serving as Technical Supervisor, Technical Consultant and General Supervisor. 3. Review of personnel records revealed the laboratory did not perform competency assessments for personnel serving as Technical Supervisor, Technical Consultant and General Supervisor. 4. In interview on February 11, 2020 at 2:35 pm, Personnel 2 stated the laboratory did not have a policy for competency assessment for Technical Supervisor, Technical Consultant, and General Supervisor. Personnel 2 confirmed competency assessments were not performed for the identified personnel. II. Based on record review and interview with personnel, the laboratory failed to follow procedures for testing personnel competency assessments. Findings: 1. Review of the laboratory's "Annual Evaluation of Competency" policy revealed "The laboratory evaluates the competency of its personnel on an annual basis. Technical Staff are evaluated twice within the 1st year and annually thereafter. Each employee has a competency log sheet and cover page. The log sheet includes each method and/or instrument competency. Each competency is based on the six CLIA mandated methods of evaluation. Each tech assessment is reviewed by the Lab Manager and Lab Director. Assessments can be done by the Chief Tech/General Supervisor". 2. Further review of the laboratory's competency assessment forms revealed the laboratory utilizes a spreadsheet as the form for assessments performed. 3. Review of personnel records for the 2019 revealed the laboratory documented assessments on a spreadsheet; however, the laboratory did not include a summary of the six (6) criteria of evaluation required and the supporting documentation. 4. In interview on February 10, 2020 at 11:46 am, Personnel 2 confirmed the laboratory did not have a summary of competency assessment or the supporting documentation for 2019.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Findings: 1. Review of the laboratory's "Non-Regulated Analytes" policy revealed "Non-regulated PT testing should be performed every six months. Documentation should be performed

	within the calendar month it is due. As testing is performed, the form will be updated to indicate the month in which the next event must take place". 2. Review of the laboratory's records revealed the laboratory did not verify the accuracy of the following test: Manual Eosinophil and Clotest. 3. In interview on February 11, 2020 at 1:30pm, Personnel 2 confirmed the laboratory did not verify Manual Eosinophil counts or Clotest twice annually or realize these were not covered in proficiency testing selections.
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, record review 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 Lactic Acid are separated within 15 minutes according to the manufacturer for eighteen (18) of one hundred ninety (190) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by manufacturer. Refer to D5311 II. 3. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for five (5) of one hundred eleven (111) patients reviewed. Refer to D5311 III. 4. The laboratory failed to ensure patients were analyzed within thirty (30) minutes of collection for Arterial Blood Gas (ABG) for thirteen (13) of three hundred ninety two (392) patients reviewed. Refer to D5311 IV. 5. The laboratory failed to ensure patients were analyzed within four (4) hours of collection according to the manufacturer for the Biofire Filmarray Respiratory Panel for two (2) of thirty-four (34) patients reviewed. Refer to D5311 V. 6. The laboratory failed to ensure patient samples for Ammonia testing are separated immediately and analyzed within 30 minutes according to the manufacturer for twenty (20) of seventy-seven (77) patients reviewed. Refer to D5311 VI. 7. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 8. The laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391.
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, record review and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid are separated within 15 minutes according to the manufacturer for eighteen (18) of one hundred ninety (190) patients reviewed. Findings: 1. Observation by surveyor on February 10, 2020 at 3:08 pm revealed the laboratory performed Lactic Acid testing on the following two (2) chemisry analyzers: a) Siemens Dimension Vista Chemistry analyzer b) Siemens Atellica CH analyzer 2. In interview on February 11, 2020 at 3:45 pm, Personnel 2 stated the laboratory performs Lactic Acid patient samples on both the Siemens Dimension Vista and Atellica CH analyzers. 3. Review of the Siemens Dimension Vista Lactic Acid package insert revealed "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes". 4. Review of the Siemens Atellica CH Lactic Acid package insert revealed "Collect blood from a stasis free vein and store it in an ice bath. Separate the plasma by centrifugation within 30 minutes. Assay the sample immediately". 5. Review of patient records for Lactic Acid from November 1, 2019 through January 31, 2020 revealed the laboratory did not receive the following eighteen (18) of one hundred ninety (190) patients within 15 minutes in order to separate as required by the manufacturer: a) November 6, 2019 - Patient number L0307245 was collected at 05:00 am and received at 05:53 am (exceeding the fifteen (15) minutes required by the manufacturer by thirty-eight (38) minutes) b) November 8, 2019 - Patient number L0221466 was collected at 02:15 am and received at 02:39 am (exceeding the fifteen (15) minutes required by the manufacturer by nine (9) minutes) c) November 12, 2019 - Patient number L0137261 was collected at 02:10 am and received at 02:52 am (exceeding the fifteen (15) minutes required by the manufacturer by twenty-seven (27) minutes) d) November 18, 2019 - Patient number L0260098 was collected at 14:18 pm and received at 14:58 pm (exceeding the fifteen (15) minutes required by the manufacturer by twenty-five (25) minutes) e) November 22, 2019 - Patient number L0022951 was collected at 12:25 pm and received at 14:00 pm (exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour twenty (20) minutes) f) November 28, 2019 - Patient number L0103613 was collected at 05:35 am and received at 06:23 am (exceeding the fifteen (15) minutes required by the manufacturer by thirty-three (33) minutes) g) November 29, 2019 - Patient number L0229728 was collected at 04:20 am and received at 04:47 am (exceeding the fifteen (15) minutes required by the manufacturer by twelve (12) minutes) h) December 3, 2019 - Patient number L0036369 was collected at 23:18 pm and received at December 4, 2019 at 00:38 am (exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour five (5) minutes) i) December 4, 2019 - Patient number L0198631 was collected at 04:07 am and received at 05:27 am (exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour five (5) minutes) j) December 11, 2019 - Patient number L0225169 was collected at 21:15 pm and received at 21:39 pm (exceeding the fifteen (15) minutes required by the manufacturer by nine (9) minutes) k) December 17, 2019 - Patient number L0104424 was collected at 22:16 pm and received at 22:40 pm (exceeding the fifteen (15) minutes required by the manufacturer by nine (9) minutes) l) December 18, 2019 - Patient number L0080360 was collected at 21:20 pm and received at 21:45 pm (exceeding the fifteen (15) minutes required by the manufacturer by ten (10) minutes) m) December 23, 2019 - Patient number L0141190 was collected at 16:46 pm and received at 17:16 pm (exceeding the fifteen (15) minutes required by the manufacturer by fifteen (15) minutes) n) January 2, 2020 - Patient number L0249411 was collected at 13:54 pm and received at 15:21 pm (exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour twelve (12) minutes) o) January 8, 2020 - Patient

number L0195900 was collected at 23:00 pm and received at 23:47 pm (exceeding the fifteen (15) minutes required by the manufacturer by thirty-two (32) minutes) p) January 9, 2020 - Patient number L0257411 was collected at 03:00 am and received at 03:24 am (exceeding the fifteen (15) minutes required by the manufacturer by nine (9) minutes) q) January 23, 2020 - Patient number L0093008 was collected at 18:38 pm and received at 19:20 pm (exceeding the fifteen (15) minutes required by the manufacturer by twenty-seven (27) minutes) r) January 27, 2020 - Patient number L0035718 was collected at 18:42 pm and received at 19:12 pm (exceeding the fifteen (15) minutes required by the manufacturer by fifteen (15) minutes) s) January 29, 2020 - Patient number L0183555 was collected at 00:40 am and received at 01:06 am (exceeding the fifteen (15) minutes required by the manufacturer by eleven (11) minutes) 6. In interview on February 11, 2020 at 3:45 pm, Personnel 2 stated patient samples were only performed on the Dimension Vista whenever the Atellica CH analyzer was in downtime at various time daily. Personnel 2 confirmed the identified samples were not received within the fifteen minutes required. 7. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 632 Lactic Acid tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples are separated within two (2) hours as required by manufacturer. Findings: 1. Obsevation by surveyor during laboratory tour on February 13, 2020 at 8:45 am revealed the laboratory utilizes the Siemens Atellica Chemistry analyzer for Creatinine (CREA) testing. 2. In interview on February 13, 2020, Personnel 2 stated the laboratory receives patient samples from outside facilities such as Home Health, Nursing Homes, and Doctor's offices. Personnel 2 further stated the patient samples from Home Health facilities are received uncentrifuged. 3. Review of the Siemens Atellica package inserts revealed under "Collecting the Samples" that "Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection". 4. Review of Home Health test requisitions for patient testing from February 2, 2020 through February 10, 2020 revealed the laboratory received patient samples for basic metabolic panel and comprehensive metabolic panel which includes Creatinine (CREA) for the following three (3) of eight (8) patients reviewed: a) Patient L0020304: one (1) SST BD vacutainer tube and one (1) red BD vacutainer tube collected on February 3, 2020 at 12:34 pm and received at 18:59 pm (exceeding the two (2) hours required by manufacturer by four (4) hours twenty five (25) minutes) b) Patient L0132848: one (1) SST BD vacutainer tube collected on February 3, 2020 at 12:34 pm and received at 15:44 pm (exceeding the two (2) hours required by manufacturer by one (1) hour ten (10) minutes) c) Patient L0304279: one (1) gold BD vacutainer tube collected on February 5, 2020 at 18:30 pm and received at 20:45 pm (exceeding the two (2) hours required by manufacturer by fifteen (15) minutes) 5. In interview on February 13, 2020 at 9:00 am, Personnel 2 confirmed the identified patient samples were received uncentrifuged exceeding the manufacturer's requirements. III. Based on observation, record review and interview with personnel, the laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for five (5) of one hundred eleven (111) patients reviewed. Findings: 1. Observation by surveyors during laboratory tour on February 10, 2020 at 1:41 pm revealed the laboratory utilizes the Siemens Sysmex CA 660 coagulation analyzer for Partial Thromboplastin Time (PTT) testing. 2. Review of the Sysmex CA 600 package insert under "Specimen Storage" revealed "APTT test within 4 hours of collection". 3. Review of patient records for PTT testing from January 1, 2020 through January 15, 2020 revealed the laboratory did not perform patient testing within four (4) hours of collection for the following five (5) of one hundred eleven (111) patients reviewed: a. Patient L0306492: collected on January 1, 2020 at 21:32 pm and received on January 2, 2020 at 02:06 am (exceeding the four (4)

hours required by the manufacturer by thirty four (34) minutes) b. Patient L0056587: collected on January 2, 2020 at 17:10 pm and received on January 2, 2020 at 22:22 pm (exceeding the four (4) hours required by the manufacturer by one (1) hour thirty two (32) minutes) c. Patient L0111514: collected on January 7, 2020 at 09:15 am and received on January 7, 2020 at 13:45 pm (exceeding the four (4) hours required by the manufacturer by thirty (30) minutes) d. Patient L0064871: collected on January 9, 2020 at 12:26 pm and received on January 9, 2020 at 17:27 pm (exceeding the four (4) hours required by the manufacturer by one (1) hour one (1) minute) e. Patient L0189501: collected on January 10, 2020 at 11:05 am and received on January 10, 2020 at 15:45 pm (exceeding the four (4) hours required by the manufacturer by forty (40) minutes) 4. In interview On February 12, 2020 at 2pm, Personnel 2 confirmed the above patients were not tested within 4 hours as required by the manufacturer. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs 3,048 PTT tests annually. IV. Based on observation, record review and interview with personnel, the laboratory failed to ensure patients were analyzed within thirty (30) minutes of collection for Arterial Blood Gas (ABG) for thirteen (13) of three hundred ninety two (392) patients reviewed. Findings: 1. Observation by surveyors during laboratory tour on February 10, 2020 at 1:30 pm revealed the laboratory utilizes the following analyzers for Arterial Blood Gas (ABG) testing: a. Siemens RapidLab 1264 analyzer b. Siemens RapidPoint 405 analyzer 2. Review of the Siemens Rapidlab 1200 and RapidPoint 405 package inserts under "Handling and Storing Samples" revealed "Analyze the sample as soon as possible to minimize oxygen consumption. Plastic syringes should not be iced, but kept at room temperature as long as the blood is analyzed within 30 minutes of collection". 3. Review of patient records for Arterial Blood Gas (ABG) testing from February 2019, July 2019 and December 2019 revealed the laboratory did not perform patient testing within thirty (30) minutes of collection for the following thirteen (13) of three hundred ninety two (392) patients reviewed: a. Patient L0023909: collected on February 12, 2019 at 14:20 pm and analyzed on February 12, 2019 at 16:37 pm (exceeding the thirty (30) minutes required by the manufacturer by one (1) hour forty six (46) minutes) b. Patient L0177449: collected on February 18, 2019 at 03:42 am and analyzed on February 18, 2019 at 04:24 am (exceeding the thirty (30) minutes required by the manufacturer by sixteen (16) minutes) c. Patient L0177449: collected on February 18, 2019 at 09:05 am and analyzed on February 18, 2019 at 10:00 am (exceeding the thirty (30) minutes required by the manufacturer by fifty (50) minutes) d. Patient L0206045: collected on February 25, 2019 at 13:23 pm and analyzed on February 25, 2019 at 14:00 pm (exceeding the thirty (30) minutes required by the manufacturer by ten (10) minutes) e. Patient L0109167: collected on February 27, 2019 at 05:45 am and analyzed on February 27, 2019 at 06:58 am (exceeding the thirty (30) minutes required by the manufacturer by four (4) hours fifty four (54) minutes) f. Patient L0078031: collected on February 27, 2019 at 20:26 pm and analyzed on February 27, 2019 at 21:58 pm (exceeding the thirty (30) minutes required by the manufacturer by one (1) hour three (3) minutes) g. Patient L0121828: collected on July 3, 2019 at 04:00 am and analyzed on July 3, 2019 at 04:41 am (exceeding the thirty (30) minutes required by the manufacturer by eleven (11) minutes) h. Patient L0267691: collected on July 5, 2019 at 01:40 am and analyzed on July 5, 2019 at 02:36 am (exceeding the thirty (30) minutes required by the manufacturer by thirty four (34) minutes) i. Patient L0277469: collected on July 19, 2019 at 05:45 am and analyzed on July 19, 2019 at 06:20 am (exceeding the thirty (30) minutes required by the manufacturer by five (5) minutes) j. Patient L0277469: collected on July 23, 2019 at 09:20 am and analyzed on July 23, 2019 at 10:06 am (exceeding the thirty (30) minutes required by the manufacturer by sixteen (16) minutes) k. Patient L0277469: collected on July 23, 2019 at 18:00 pm and analyzed

on July 23, 2019 at 18:37 pm (exceeding the thirty (30) minutes required by the manufacturer by seven (7) minutes) l. Patient L0074936: collected on December 1, 2019 at 05:00 am and analyzed on December 1, 2019 at 06:12 am (exceeding the thirty (30) minutes required by the manufacturer by forty two (42) minutes) m. Patient L0067657: collected on December 4, 2019 at 14:30 pm and analyzed on December 4, 2019 at 15:38 pm (exceeding the thirty (30) minutes required by the manufacturer by forty one (41) minutes) 4. In interview on February 12, 2020 at 15:00 pm, Personnel 2 confirmed the identified patients were not analyzed as required by the manufacturer. 5. Review of the Task 1 & 3 provided to surveyors revealed the laboratory performs 4,249 ABG tests annually. V. Based on observation, record review and interview with personnel, the laboratory failed to ensure patients were analyzed within four (4) hours of collection according to the manufacturer for the Biofire Filmarray Respiratory Panel for two (2) of thirty-four (34) patients reviewed. Findings: 1. Observation by surveyors during laboratory tour revealed the laboratory utilized the Biofire Filmarray analyzer for respiratory panel testing. 2. Review of the Biofire Filmarray Respiratory Panel package insert under "Transport and Storage" revealed "Specimens in VTM should be processed and tested as soon as possible. If storage is required, specimens in VTM can be held at room temperature (18-30 degrees Celsius) for up to 4 hours". 3. Review of patient records for the Biofire respiratory panel from June 2, 2019 through June 16, 2019 revealed the laboratory did not perform testing within four (4) hours as required by the manufacturer for the following two (2) of thirty four (34) patients reviewed: a. Patient L0303271: collected on June 5, 2019 at 10:57 am and received on June 6, 2019 at 03:46 am (exceeding the four (4) hours required by manufacturer by eleven (11) hours forty nine (49) minutes) b. Patient L0146074: collected on June 7, 2019 at 14:20 pm and received on June 7, 2019 at 19:57 pm (exceeding the four (4) hours required by manufacturer by one (1) hour thirty seven (37) minutes) 4. In interview on February 12, 2020 at 11am, Personnel 2 confirmed the above samples were not tested within 4 hours. Personnel 2 also stated the laboratory was not aware of the 4 hour stability limitation for the respiratory panel. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs 1,321 respiratory panels annually. VI. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Ammonia testing are separated immediately and analyzed within 30 minutes according to the manufacturer for twenty (20) of seventy-seven (77) patients reviewed. Findings: 1. Observation by surveyor on February 11, 2020 at 3:08 pm revealed the laboratory performs Ammonia testing on the Siemens Atellica CH analyzer and the Siemens Dimension Vista chemistry analyzer. 2. In interview on February 11, 2020 at 3:45 pm, Personnel 2 stated Ammonia patient samples are performed on both analyzers. 3. Review of the Siemens Atellica CH and Dimension Vista Lactic Acid package inserts revealed "The tube should be completely filled, stored tightly capped on ice and centrifuged without delay. Samples should be analyzed within 30 minutes of centrifugation". 4. Review of patient records for Ammonia from November 1, 2019 through January 31, 2020 revealed the laboratory did not separate and analyze patient samples within 30 minutes for the following twenty (20) of seventy-seven (77) patients reviewed: a) November 1, 2019: Patient L0255299 was collected at 04:00 am and received at 11:20 am - exceeding the thirty (30) minutes required by the manufacturer by six (6) hours fifty (50) minutes b) November 1, 2019: Patient L0203753 was collected at 06:00 am and received at 13:31 pm - exceeding the thirty (30) minutes required by the manufacturer by seven (7) hours one (1) minute c) November 5, 2019: Patient L0307211 was collected at 05:00 am and received at 09:24 am - exceeding the thirty (30) minutes required by the manufacturer by three (3) hours fifty-four (54) minutes d) November 6, 2019: Patient L0304093 was collected at 08:40 am and received at 11: 43 am - exceeding the thirty (30) minutes required by the manufacturer by two (2)

	hours thirty-three (33) minutes e) November 8, 2019: Patient L0045008 was collected at 05:00 am and received at 08:50 am - exceeding the thirty (30) minutes required by the manufacturer by three (3) hours twenty (20) minutes f) November 27, 2019: Patient L0118459 was collected at unknown time and received at 12:54 pm - exceeding the thirty (30) minutes required by the manufacturer by unable to determine g) December 2, 2019: Patient L0255299 was collected at 02:30 am and received 09:13 am - exceeding the thirty (30) minutes required by the manufacturer by six (6) hours thirteen (13) minutes h) December 3, 2019: Patient L0061524 was collected at 05:55 am and received 09:39 am - exceeding the thirty (30) minutes required by the manufacturer by three (3) hours fourteen (14) minutes i) December 4, 2019: Patient L0308028 was collected at 05:00 am and received 10:00 am - exceeding the thirty (30) minutes required by the manufacturer by four (4) hours thirty (30) minutes j) December 4, 2019: Patient L0304093 was collected at an unknown time and received at 12:19 pm - exceeding the thirty (30) minutes required by the manufacturer by unable to determine k) December 9, 2019: Patient L0165935 was collected at 06:00 am and received at 10:24 am - exceeding the thirty (30) minutes required by the manufacturer by three (3) hours fifty-four (54) minutes l) December 13, 2019: Patient L0264131 was collected at 12:34 pm and received at 13:11 pm - exceeding the thirty (30) minutes required by the manufacturer by seven (7) minutes m) December 21, 2019: Patient L0059761 was collected at 11:30 am and received at 12:08 pm - exceeding the thirty (30) minutes required by the manufacturer by eight (8) minutes n) December 26, 2019: Patient L0244159 was collected at 11:23 am and received at 12: 32 pm - exceeding the thirty (30) minutes required by the manufacturer by thirty-nine (39) minutes o) January 2, 2020: Patient L0043066 was collected at 14:44 pm and received at 17:36 pm - exceeding the thirty (30) minutes required by the manufacturer by two (2) hours twenty-two (22) minutes p) January 6, 2020: Patient L0255299 was collected at 03:00 am and received at 09:06 am - exceeding the thirty (30) minutes required by the manufacturer by five (5) hours thirty-six (36) minutes q) January 7, 2020: Patient L0043637 was collected at 04:18 am and received at 07:02 am - exceeding the thirty (30) minutes required by the manufacturer by two (2) hours fourteen (14) minutes r) January 7, 2020: Patient L0304093 was collected at 05:00 am and received at 08:07 am - exceeding the thirty (30) minutes required by the manufacturer by two (2) hours thirty-seven (37) minutes s) January 14, 2020: Patient L0058207 was collected at 11:10 am and received at 14:33 pm - exceeding the thirty (30) minutes required by the manufacturer by two (2) hours fifty-three (53) minutes t) January 17, 2020: Patient L0210703 was collected at 14:15 pm and received at 15:35 pm - exceeding the thirty (30) minutes required by the manufacturer by fifty (50) minutes u) January 31, 2020: Patient L0309387 was collected at 04:30 am and received at 07:15 am - exceeding the thirty (30) minutes required by the manufacturer by two (2) hours fifteen (15) minutes 5. In interview on February 11, 2020 at 03:45 pm, Personnel 2 confirmed the identified samples noted above were not separated and analyzed as required by the manufacturer. 6. Review of the task 1&3 form provided to surveyor revealed the laboratory performs 300 Ammonia test annually.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. In interview on February 11, 2020 at 3:08 pm, Personnel 2 stated the laboratory provides services to outside facilities such as Doctor's offices, Nursing Homes, and Home Healths. 2. Review of a random selection of the "Lane RMC Test Dictionary" for outside facilities versus the manufacturer assay instructions revealed the laboratory did not address the following examples (not meant to be an inclusive list): a) Glycohemoglobin (HGB A1C) Laboratory manual: Whole blood specimen; 1 mL volume; Lavender container; special instructions-mix well by inverting several times Siemens Atellica CH: Specimens may be stored for up to 48 hours at room temperature, for up to 7 days at 2-8 degrees celsius, or stored frozen for up to 21 months (with one freeze-thaw) at -70 degrees celsius b) B-Natriuetic Peptide (BNP) Laboratory manual: Plasma specimen; 2 mL volume; Green container-if performed at Lane; Lavender-if performed at Labcorp or Quest Siemens Atellica CH: Collect blood samples in EDTA collection tubes and mix gently; For optimal recovery of BNP values, it is suggested that uncentrifuged whole blood samples be tested within 24 hours; After centrifugation, store separated plasma samples at 2-8 degrees celsius until testing; It is suggested that plasma be tested within 24 hours c) Creatine Kinase (CK) Laboratory manual: Plasma or Serum specimen; 1 mL volume; Green, Gel, or SST separator tube Siemens Atellica CH: Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection; specimens should be stored up to 4 hours at 25 degrees celsius or for up to 5 days at 2-8 degrees celsius or stored frozen for up to 2 months at -20 degrees celsius d) Creatinine (CREA) Laboratory manual: Plasma or Serum specimen; 1 mL volume; Green, Gel, or SST separator tube Siemens Atellica CH: Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection; Separated serum and plasma specimens may be stored for up to 24 hours at room temperature (18-26 degrees celsius) or for up to 7 days at 2-8 degrees celsius or stored frozen for up to 3 months at -20 degrees celsius or colder. e) Ammonia (AMM) Laboratory manual: Plasma specimen; 2 mL volume; Green container; special instructions-place sample on ice, avoid hemolysis, do not remove top Siemens Atellica CH: Separated specimens may be stored for up to 2 hours at 2-8 degrees celsius. Tube should be completely filled, stored tightly capped on ice and centrifuged without delay. Samples should be analyzed within 30 minutes of centrifugation. f) Lactic Acid (LAC) Laboratory manual: Plasma specimen; 2 mL volume; Gray container; special instructions-transport on ice Siemens Atellica CH: Sodium Fluoride is the preferred anticoagulant; collect blood from a stasis-free vein and store it in an ice bath; Separate the plasma by centrifugation within 30 minutes. A delay in separation can lead to an increase in lactate values. Assay the sample immediately. g) Thyroid Stimulating Hormone (TSH) Laboratory manual: Plasma or Serum specimen; 1 mL volume; Green, Gel or Serum separator tube Siemens Atellica CH: Serum should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection; Separated specimens are stable for 24 hours at room temperature or 2 days at 2-8 degrees celsius 3. In interview on February 13, 2020 at 9:00 am, Personnel 2 confirmed the laboratory manual for outside facilities did not reflect the manufacturer's requirements.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review 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 Lactic Acid are separated within 15 minutes according to the manufacturer for eighteen (18) of one hundred ninety (190) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by manufacturer. Refer to D5311 II. 3. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for five (5) of one hundred eleven (111) patients reviewed. Refer to D5311 III. 4. The laboratory failed to ensure patients were analyzed within thirty (30) minutes of collection for Arterial Blood Gas (ABG) for thirteen (13) of three hundred ninety two (392) patients reviewed. Refer to D5311 IV. 5. The laboratory failed to ensure patients were analyzed within four (4) hours of collection according to the manufacturer for the Biofire Filmarray Respiratory Panel for two (2) of thirty-four (34) patients reviewed. Refer to D5311 V. 6. The laboratory failed to ensure patient samples for Ammonia testing are separated immediately and analyzed within 30 minutes according to the manufacturer for twenty (20) of seventy-seven (77) patients reviewed. Refer to D5311 VI. 7. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317.
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, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to use normal donors as required by manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean with each new lot of innovin. Refer to D5411. 3. The laboratory failed to have complete performance specification verification studies for the Siemens Atellica Chemistry analyzer. Refer to D5421. 4. The laboratory failed to perform quality control every week (seven days) as required by the Individualized Quality Control Plan (IQCP) for Arterial Blood Gas (ABG) testing. Refer to D5445 I. 5. The laboratory failed to perform monthly Quality Control (QC) as required by the laboratory's Individualized Quality Control Plan (IQCP) for Acteone testing. Refer to D5445 II. 6. The laboratory failed to perform monthly Quality Control as required by the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire Filmarray System. Refer to D5445 III. 7. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material.

	Refer to D5469. 8. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
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 record review and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not include detailed instructions for the following: a) Course of action to take when an instrument becomes inoperable and the steps to put instrument back into use b) Step-by-step detailed instructions for procedure performance of Platelet Poor Plasma study c) Reference range determination for Prothrombin/International Normalized Ratio (PT/INR) testing, to include detailed instructions, donor criteria, and frequency d) Manual INR checks to include procedure and frequency e) Quality Control: to include but not limited to: Establishment of means and ranges of quality control material; who is to monitor and how changes are to be made, data used for establishment/reestablishment, correct means and ranges available to testing personnel, acceptability criteria, frequency, and how to address flags on quality control material f) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria g) Corrective Action to take for quality control failures to include, but not limited to, specific actions to be taken, when patient assessment is necessary and how to assess such patients. h) Refrigerator temperature requirements for the storage of blood products and reagents i) Specimen stability and storage requirements according to manufacturer j) Biofire Filmarray System QC establishment k) Blood Bank emergency release to include the timeframe for followup compatibility testing l) Quality Assurance (QA) to include what markers in place and who is responsible to monitor 2. In interview on February 12, 2020 at 9:30 am, Personnel 2 confirmed the laboratory's policy manual did not include the identified policies.

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: Based on observation, record review and interview with personnel, the laboratory failed to use normal donors as required by manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean with each new lot of innovin. Findings: 1. Observation by surveyor during laboratory tour on February 10, 2020 at 1: 41 pm revealed the laboratory utilizes the Sysmex CA-660 analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the "Siemens Healthcare Diagnostics Sysmex CA-600 Series Verification of Reference Interval" insert revealed the following donor requirements: a) " Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) b) Donors should not take any medications, including aspirin c) Donors should span the adult age range. Note: A separate range should be established for pediatric populations) d) Testing should be performed over a period of several days and by different people if possible, to allow for day to day variation e) Samples should be drawn each testing day, following the established protocol for collection, storage and processing f) The test results from the donors should be analyzed statistically. Software that performs this calculation can be used." 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for normal donor criteria for the establishment of normal PT mean. 4. Review of the laboratory's coagulation records revealed the laboratory did not have documentation of donor questionnaires utilized to verify reference interval for the following lot of innovin: a) Innovin Lot 549729 Expiration 01/02/2021 5. In interview on February 12, 2020 at approximately 4pm, the Hematology supervisor confirmed the laboratory does not use the manufacturer requirements for normal donors of reference intervals. The hematology supervisor further stated the normal donors are chosen from patient testing that falls in the normal range but there is no documentation of donor criteria or donors included in normal mean PT. 6. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs 5,247 PT/INR 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, record review and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Siemens

	Atellica Chemistry analyzer. Findings: 1. Observation by surveyors during laboratory tour on February 10, 2020 at 1:48 pm revealed the laboratory utilizes the Siemens Atellica chemistry analyzer for the following analytes: B-natriuretic peptide (BNP), Troponin(TROP), Creatine Kinase-MB (CKMB), Digoxin (DIG), Human Chorionic Gonadotropin (HCG), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), Ferritin (FER), Folate (FOLA), Free Triiodothyonine (FT3), Free Thyroxine (FT4), Thyroxine (T4), Vitamin D, Hemoglobin A1C (A1C), Carbamazepine (CARB), Phenobarbital (PHNB), Phenytoin (PHNY), Tobramycin (TOBR), Valproic Acid (VALP), Iron (FE), Total Iron Binding Capacity (TIBC), C Reactive Protein (CRP), Pre-Albumin (PALB), Potassium (K+), Sodium (NA), Chloride (CL), Acetaminophen (ACET), Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Ammonia (AMM), Amylase (AMY), Aspartate Aminotransferase (AST), Calcium (CA), Cholesterol (CHOL), Creatine Kinase (CK), Carbon Dioxide (CO2), Creatinine (CREA), Direct Bilirubin (DBIL), High Density Lipoprotein (HDL), Ethanol (ETOH), Gentamycin (GENT), Glucose (GLUC), Phosphorus (PHOS), Lactic Acid (LA), Low Density Lipoprotein (LDL), Lipase (LIP), Magnesium (MG), Salicylate (SAL), Total Bilirubin (TBIL), Total Protein (TP), Triglycerides (TRIG), Uric Acid (UA), Blood Urea Nitrogen (BUN), Vancomycin, (VANC), Amphetamine (AMP), Benzodiazapine (BENZ), Cocaine (COC), Barbituates (BARB), Tetrahydrocannabinol (THC), Methamphetamine (METH), Opiates (OPI), Phencyclidine (PCP), Urine Chloride (U-CL), Urine Creatinine (U-CREA), Urine Potassium (U-K+), Urine Sodium (U-NA), Urine Protein (U-PROT), Urine Microalbumin (U-Microalb) 2. In interview on February 11, 2020 at 09:00 am, Personnel 7 stated the laboratory started patient testing in January 2019. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for verification of Performance Specifications. 4. Review of the laboratory's installation records for the Siemens Atellica chemistry analyzer revealed the laboratory performed the following studies: a. Accuracy - method comparison b. Simple Precision c. Reportable Range - Linearities d. Reference Range 5. Further review of the laboratory's installation records revealed the laboratory did not have documentation for the following studies: a. Complete precision to include day-to-day, run-to-run, within run, and operator variance for all analytes b. Complete precision to include simple precision, day-to-day, run-to-run, within run, and operator variance for urine Chloride, urine Creatinine, urine Sodium, urine Protein, amphetamines, Benzodiazapines, Cocaine, Barbituates, THC, Methamphetamines, Opiates, and PCP 6. In interview on February 11, 2020 at 9:00 am, Personnel 7 stated the Siemens field representative performed the precision studies during installation and that laboratory personnel did not participate with the studies. 7. In further interview on February 12, 2020 at 9:30 am, Personnel 2 confirmed that the laboratory did not have complete studies.
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:
I. Based on observation, record review and interview with personnel, the laboratory failed to perform quality control every week (seven days) as required by the Individualized Quality Control Plan (IQCP) for Arterial Blood Gas (ABG) testing. Findings: 1. Observation by surveyor during laboratory tour on February 10, 2020 at 1: 30 pm revealed the laboratory utilizes the following analyzers for Arterial Blood Gas (ABG) testing: a) Siemens RapidLab 1265 analyzer b) Siemens RapidPoint 405 analyzer 2. Review of the laboratory's IQCP for both analyzers revealed the laboratory performs two (2) levels of external quality control (QC) once per week. 3. Review of the laboratory's "Quality Control on 1265 and 405" policy revealed the laboratory performs QC as part of routine weekly maintenance. 4. Review of the laboratory's QC records for the Siemens RapidLab 1265 analyzer from July 2019 and December 2019 revealed the laboratory did not perform external QC as required for the following dates: a) QC performed on July 22, 2019 and then on August 5, 2019 (QC due on July 29, 2019) b) QC performed on November 25, 2019 and then on December 9, 2019 (QC due on December 2, 2019) 5. Review of the laboratory's QC records for the Siemens RapidPoint 405 analyzer from July 2019 revealed the laboratory did not perform external QC as required for the following dates: a) QC performed on July 22, 2019 and then again on August 6, 2019 (QC due on July 29, 2019) 6. Review of the laboratory's patient records on the Siemens RapidLab 1265 analyzer from July 29, 2019 through August 5, 2019 revealed the laboratory performed the following six (6) patients without QC being performed as required: a) Patient L0140396 performed on July 31, 2019 (exceeds the weekly IQCP requirement by three (3) days) b) Patient L0304671 performed on August 1, 2019 (exceeds the weekly IQCP requirement by four (4) days) c) Patient L0302204 performed on August 1, 2019 (exceeds the weekly IQCP requirement by four (4) days) d) Patient L0114324 performed on August 1, 2019 (exceeds the weekly IQCP requirement by four (4) days) e) Patient L0113852 performed on August 2, 2019 (exceeds the weekly IQCP requirement by five (5) days) f) Patient L0001024 performed on August 2, 2019 (exceeds the weekly IQCP requirement by five (5) days) 7. Review of the laboratory's patient records on the Siemens RapidLab 1265 analzyer from December 2, 2019 through December 9, 2019 revealed the laboratory performed the following twelve (12) patients without QC being performed as required: a) Patient L0018642 performed on December 2, 2019 (exceeds the weekly IQCP requirement by one (1) day) b) Patient L0307941 performed on December 3, 2019 (exceeds the weekly IQCP requirement by one (1) day) c) Patient L0307941 performed on December 3, 2019 (exceeds the weekly IQCP requirement by one (1) day) d) Patient L0307940 performed on December 4, 2019 (exceeds the weekly IQCP requirement by two (2) days) e) Patient L0018642 performed on December 4, 2019 (exceeds the weekly IQCP requirement by two (2) days) f) Patient L0178753 performed on December 4, 2019 (exceeds the weekly IQCP requirement by two (2) days) g) Patient L0098072 performed on December 4, 2019 (exceeds the weekly IQCP requirement by two (2) days) h) Patient L0018642 performed on December 5, 2019 (exceeds the weekly IQCP requirement by three (3) days) i) Patient L0072156 performed on December 7, 2019 (exceeds the weekly IQCP requirement by five (5) days) j) Patient L0002249 performed on December 8, 2019 (exceeds the weekly IQCP requirement by six (6) days) k) Patient L0002249 performed on December 8, 2019 (exceeds the weekly IQCP requirement by six (6) days) l) Patient L0308137 performed on December 8, 2019 (exceeds the weekly IQCP requirement by six (6) days) 8. Review of the laboratory's patient records on the Siemens RapidPoint 405 analzyer from July 29, 2019 through August 6, 2019 revealed the laboratory performed the following nineteen (19) patients without QC being performed as required: a) Patient L0160031 performed on July 29, 2019

(exceeds the weekly IQCP requirement by one (1) day) b) Patient L0160031 performed on July 30, 2019 (exceeds the weekly IQCP requirement by one (1) day) c) Patient L0160031 performed on July 30, 2019 (exceeds the weekly IQCP requirement by one (1) day) d) Patient L0120457 performed on July 30, 2019 (exceeds the weekly IQCP requirement by one (1) day) e) Patient L0051784 performed on July 30, 2019 (exceeds the weekly IQCP requirement by one (1) day) f) Patient L0304614 performed on July 31, 2019 (exceeds the weekly IQCP requirement by two (2) days) g) Patient L0304671 performed on July 31, 2019 (exceeds the weekly IQCP requirement by two (2) days) h) Patient L0140396 performed on July 31, 2019 (exceeds the weekly IQCP requirement by two (2) days) i) Patient L0123889 performed on July 31, 2019 (exceeds the weekly IQCP requirement by two (2) days) j) Patient L0304671 performed on August 1, 2019 (exceeds the weekly IQCP requirement by three (3) days) k) Patient L0113852 performed on August 2, 2019 (exceeds the weekly IQCP requirement by four (4) days) l) Patient L0304763 performed on August 3, 2019 (exceeds the weekly IQCP requirement by five (5) days) m) Patient L0304763 performed on August 3, 2019 (exceeds the weekly IQCP requirement by five (5) days) n) Patient L0123889 performed on August 3, 2019 (exceeds the weekly IQCP requirement by five (5) days) o) Patient L0102258 performed on August 3, 2019 (exceeds the weekly IQCP requirement by five (5) days) p) Patient L0102258 performed on August 3, 2019 (exceeds the weekly IQCP requirement by five (5) days) q) Patient L0304814 performed on August 5, 2019 (exceeds the weekly IQCP requirement by seven (7) days) r) Patient L0304814 performed on August 5, 2019 (exceeds the weekly IQCP requirement by seven (7) days) s) Patient L0125945 performed on August 5, 2019 (exceeds the weekly IQCP requirement by seven (7) days) 9. In interview on February 12, 2019 at 15:20 pm, Personnel 3 confirmed the weekly QC for the identified dates was not performed as required. II. Based on observation, record review and interview with personnel, the laboratory failed to perform monthly Quality Control (QC) as required by the laboratory's Individualized Quality Control Plan (IQCP) for Acteone testing. Findings: 1. Observation by surveyors on February 13, 2020 at 9:25 am revealed the laboratory utilizes the Aimtab Ketone tablets for Serum Acetone testing. 2. Review of the laboratory's IQCP for Serum Acetone revealed the laboratory performs Quality Control (QC) monthly and with new lot or shipment. 3. Review of the laboratory's policy for Serum Acetone testing revealed the laboratory performs QC once per month and once per shipment or new lot. 4. Review of the laboratory's QC records from July 2019 through December 2019 for Serum Acetone testing revealed the laboratory did not perform QC monthly as required for the following dates: a) QC performed on July 3, 2019 then on August 5, 2019 (QC due on August 3, 2019) b) QC performed on October 2, 2019 then on November 5, 2019 (QC due on November 2, 2019) 5. Review of patient records from July 3, 2019 through December 31,2019 for Serum Acetone testing revealed the laboratory did not perform monthly QC as required for the following five (5) of one hundred eighteen (118) patients reviewed: a) Patient L0070021 performed on August 3, 2019 (exceeds monthly IQCP requirement by one (1) day) b) Patient L0123889 performed on August 3, 2019 (exceeds monthly IQCP requirement by one (1) day) c) Patient L0090183 performed on August 4, 2019 (exceeds monthly IQCP requirement by one (1) day) d) Patient L0078169 performed on November 3, 2019 (exceeds monthly IQCP requirement by one (1) day) e) Patient L0058316 performed on November 4, 2019 (exceeds monthly IQCP requirement by two (2) days) 6. In interview on February 13, 2020 at 09:45 am, Personnel 2 stated he did not realize Acetone QC was not performed as required. Personnel 2 confirmed the identified patients were resulted without documentation of monthly Acetone QC. III. Based on observation, record review and interview with personnel, the laboratory failed to perform monthly Quality Control as required by the laboratory's

Individualized Quality Control Plan (IQCP) for the Biofire Filmarray System. Findings: 1. Observation by surveyors during the laboratory tour on February 10, 2020 at 1:00 pm revealed the laboratory utilizes the Biofire Filmarray System for the following panel testing: a) Biofire Filmarray Respiratory Panel b) Biofire Filmarray Blood Culture Identification (BCID) Panel c) Biofire Filmarray Gastrointestinal (GI) Panel 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire Filmarray panel testing revealed the laboratory performs Quality Control (QC) monthly on each panel. 3. Review of the laboratory's QC records from December 1, 2019 through November 30, 2019 for the Biofire Filmarray System revealed the laboratory did not perform monthly QC as required for the following dates: a) Biofire Filmarray Respiratory Panel: QC performed on May 1, 2019 then on June 17, 2019 (QC due on June 1, 2019) b) Biofire Filmarray BCID Panel: 1) QC performed on February 8, 2019 then on March 28, 2019 (QC due on March 8, 2019) 2) QC performed on May 1, 2019 then on June 28, 2019 (QC due on June 1, 2019) 3) QC performed on August 2, 2019 then on September 9, 2019 (QC due on September 2, 2019) c) Biofire Filmarray GI Panel: 1) QC performed on February 8, 2019 then on March 18, 2019 (QC due on March 8, 2019) 2) QC performed on May 1, 2019 then on June 6, 2019 (QC due on June 1, 2019) 3) QC performed on July 17, 2019 then on August 21, 2019 (QC due on August 17, 2019) 4. Review of patient records from June 2, 2019 through June 16, 2019 for the Biofire Filmarray Respiratory Panel revealed the laboratory did not perform monthly QC for the following thirty two (32) patients reviewed: a. Patient L0011835 b. Patient L0303187 c. Patient L0302613 d. Patient L0303162 e. Patient L0173000 f. Patient L0090691 g. Patient L0234459 h. Patient L0303252 i. Patient L0053716 j. Patient L0240015 k. Patient L0303271 l. Patient L0239293 m. Patient L0227042 n. Patient L0120336 o. Patient L0198598 p. Patient L0017391 q. Patient L0120985 r. Patient L0070286 s. Patient L0146074 t. Patient L0140477 u. Patient L0040512 v. Patient L0267505 w. Patient L0026555 x. Patient L0281389 y. Patient L0017391 z. Patient L0250059 aa. Patient L0010879 bb. Patient L0001024 cc. Patient L0044843 dd. Patient L0184883 ee. Patient L0303433 ff. Patient L0303539 5. Review of patient records December 1, 2018 through November 30, 2019 for the Biofire Filmarray BCID Panel revealed the laboratory did not perform monthly QC for the following sixty (60) patients reviewed: a) February 19, 2019 through March 27, 2019 (twenty eight (28) patients) 1) Patient L0179685 2) Patient L0280253 3) Patient L0262975 4) Patient L0112495 5) Patient L0145886 6) Patient L0162920 7) Patient L0016669 8) Patient L0113529 9) Patient L0250555 10) Patient L0276972 11) Patient L0268140 12) Patient L0078559 13) Patient L0016351 14) Patient L0236504 15) Patient L0025383 16) Patient L0145886 17) Patient L0090058 18) Patient L0048810 19) Patient L0238578 20) Patient L0283661 21) Patient L0206421 22) Patient L0153602 23) Patient L0011051 24) Patient L0013775 25) Patient L0027398 26) Patient L0197675 27) Patient L0280879 28) Patient L0283110 b) June 2, 2019 through June 27, 2019 (twenty nine (29) patients 1) Patient L0041127 2) Patient L0015534 3) Patient L0000160 4) Patient L0100025 5) Patient L0045173 6) Patient L0053716 7) Patient L0025299 8) Patient L0087706 9) Patient L0014220 10) Patient L0120985 11) Patient L0013867 12) Patient L0090691 13) Patient L0191366 14) Patient L0209863 15) Patient L0250059 16) Patient L0035854 17) Patient L0119966 18) Patient L0136665 19) Patient L0078735 20) Patient L0303684 21) Patient L0137730 22) Patient L0110771 23) Patient L0303736 24) Patient L0107051 25) Patient L0036891 26) Patient L0241937 27) Patient L0046898 28) Patient L0047714 29) Patient L0055410 c) September 3, 2019 through September 8, 2019 (three (3) patients) 1) Patient L0045411 2) Patient L0038609 3) Patient L0029302 6. Review of patient records December 1, 2018 through November 30, 2019 for the Biofire Filmarray GI Panel revealed the laboratory did not perform monthly QC for the following forty two (42) patients reviewed: a) February 9, 2019

	through March 17, 2019 (thirty four (34) patients) 1) Patient L0038215 2) Patient L0129724 3) Patient L0050978 4) Patient L0005210 5) Patient L0186526 6) Patient L0157955 7) Patient L0091027 8) Patient L0004138 9) Patient L0300556 10) Patient L0186450 11) Patient L0177449 12) Patient L0106404 13) Patient L0239319 14) Patient L0281743 15) Patient L0174582 16) Patient L0284473 17) Patient L0275969 18) Patient L0076182 19) Patient L0141270 20) Patient L0073670 21) Patient L0025383 22) Patient L0055410 23) Patient L0031407 24) Patient L0038192 25) Patient L0051498 26) Patient L0131891 27) Patient L0301159 28) Patient L0056437 29) Patient L0300060 30) Patient L0014632 31) Patient L0198824 32) Patient L0106404 33) Patient L0133989 34) Patient L0103799 b) June 2, 2019 through June 5, 2019 (six (6) patients) 1) Patient L0229728 2) Patient L0030748 3) Patient L0048348 4) Patient L0176570 5) Patient L0234459 6) Patient L0134506 c) August 18, 2019 through August 20, 2019 (two (2) patients) 1) Patient L0118050 2) Patient L0092278 7. In interview on February 12, 2020 at 2:00 pm, the laboratory manager stated the laboratory understood that the monthly quality control could be performed any time during the month, not that it needed to be the same day each month.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Findings: 1. Observation by surveyor during laboratory tour on February 12, 2020 at 11:10 am revealed the laboratory utilizes a Hemochron Jr Whole Blood Microcoagulation System with Accriva Direct Check Whole Blood Control for ACT testing for the following lots in use: a) Normal control - Lot E9DNL011 Expiration date 02/29/2020 b) Abnormal control - Lot D9DLA021 Expiration date 08/31/2020 2. Review of the Accriva Direct Check Whole Blood Control package insert under "Performance Characteristics" revealed "Accriva recommends that each institution establish its own expected range of response based on the mean +/-2 standard deviations of at least 20 repeated test results". 3. Review of the laboratory's QC records revealed the laboratory determined QC acceptibility based on the performance ranges and mean provided by the manufacturer. 4. In interview on February 12, 2020 at 02:00 pm, Personnel 10 confirmed the laboratory uses the ranges provided by the manufacturer and does not establish its own mean and ranges.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to use normal donors as required by manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean with each new lot of innovin. Refer to D5411. 3. The laboratory failed to have complete performance specification verification studies for the Siemens Atellica Chemistry analyzer. Refer to D5421. 4. The laboratory failed to perform quality control every week (seven days) as required by the Individualized Quality Control Plan (IQCP) for Arterial Blood Gas (ABG) testing. Refer to D5445 I. 5. The laboratory failed to perform monthly Quality Control (QC) as required by the laboratory's Individualized Quality Control Plan (IQCP) for Acteone testing. Refer to D5445 II. 6. The laboratory failed to perform monthly Quality Control as required by the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire Filmarray System. Refer to D5445 III. 7. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during laboratory tour on February 10, 2020 at 1: 10 pm revealed the laboratory utilizes the Siemens Atellica Chemistry analyzer for Urine Drug Screen (UDS) testing to include the following tests: Amphetamine (AMP), Benzodiazapines (BENZ), Cocaine (COC), Barbiturates (BARB), Tetrohydrocannabinol (THC), Methamphetamine (METH), Opiates (OPI), and Phencyclidine (PCP). 2. Review of the Siemens Atellica package inserts revealed "The assay provides only a preliminary test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug-of-abuse result, particularly

	when preliminary results are used". 3. Review of patient test reports from February 20, 2020 revealed that the UDS results were preliminary on patient reports. . 4. In interview on February 11, 2020, Personnel 2 confirmed the laboratory did not include the disclaimer on patient reports and that the UDS results were preliminary. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs 2,957 UDS tests annually.
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, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D6016. 4. The Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 6. The Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D6026. 7. The Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6029. 8. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 9. The Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D6031.
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 record review and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. 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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid are separated within 15 minutes according to the manufacturer for eighteen (18) of one hundred ninety (190) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by manufacturer. Refer to D5311 II. 3. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for five (5) of one hundred eleven (111) patients reviewed. Refer to D5311 III. 5. The laboratory failed to ensure patients were analyzed within thirty (30) minutes of collection for Arterial Blood Gas (ABG) for thirteen (13) of three hundred ninety two (392) patients reviewed. Refer to D5311 IV. 6. The laboratory failed to ensure patients were analyzed within four (4) hours of collection according to the manufacturer for the Biofire Filmarray Respiratory Panel for two (2) of thirty-four (34) patients reviewed. Refer to D5311 V. 7. The laboratory failed to ensure patient samples for Ammonia testing are separated immediately and analyzed within 30 minutes according to the manufacturer for twenty (20) of seventy-seven (77) patients reviewed. Refer to D5311 VI. 8. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 9. The laboratory failed to use normal donors as required by manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean with each new lot of innovin. Refer to D5411.
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 record review and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform quality control every week (seven days) as required by the Individualized Quality Control Plan (IQCP) for Arterial Blood Gas (ABG) testing. Refer to D5445 I. 2. The laboratory failed to perform monthly Quality Control (QC) as required by the laboratory's Individualized Quality Control Plan (IQCP) for Acteone testing. Refer to D5445 II. 3.

	The laboratory failed to perform monthly Quality Control as required by the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire Filmarray System. Refer to D5445 III. 4. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D5805.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met education requirements. Refer to D6065.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Technical Supervisor, Technical Consultant and General Supervisor were complete. Refer to D5209 I. 2. The laboratory failed to follow procedures for testing personnel competency assessments. Refer to D5209 II. 3. The laboratory failed to ensure four (4) of forty seven (47) testing personnel met the educational qualifications for performing moderate complexity testing. Refer to D6065.
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 record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and 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 record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants 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 the quality control program was established to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure performance of competency assessments for personnel performing moderate complexity testing. Refer to D6046.
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 observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid are separated within 15 minutes according to the manufacturer for eighteen (18) of one hundred ninety (190) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure patient samples are separated within two (2) hours as required by manufacturer. Refer to D5311 II. 3. The laboratory failed to perform patient samples for Partial Thromboplastin Time (PTT) testing within four (4) hours of collection as required by the manufacturer for five (5) of one hundred eleven (111) patients reviewed. Refer to D5311 III. 4. The laboratory failed to ensure patients were analyzed within thirty (30) minutes of collection for Arterial Blood Gas (ABG) for thirteen (13) of three hundred ninety two (392) patients reviewed. Refer to D5311 IV. 5. The laboratory failed to ensure patients were analyzed within four (4) hours of collection according to the manufacturer for the Biofire Filmarray Respiratory Panel for two (2) of thirty-four (34) patients reviewed. Refer to D5311 V. 6. The laboratory failed to ensure patient samples for Ammonia testing are separated immediately and analyzed within 30 minutes according to the manufacturer for twenty (20) of seventy-seven (77) patients reviewed. Refer to D5311 VI. 7. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 8. The laboratory failed to use normal donors as required by manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean with each new lot of innovin. Refer to D5411.
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, record review, and 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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform quality control every week (seven days) as required by the Individualized Quality Control Plan (IQCP) for Arterial Blood Gas (ABG) testing. Refer to D5445 I. 2. The laboratory failed to perform monthly Quality Control (QC) as required by the laboratory's Individualized Quality Control Plan (IQCP) for Acteone testing. Refer to D5445 II. 3. The laboratory failed to perform monthly Quality Control as required by the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire Filmarray System. Refer to D5445 III. 4. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure performance of competency assessments for personnel performing moderate complexity testing. Refer to D5209 II.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide

	documentation to ensure all testing personnel met education requirements. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure four (4) of forty seven (47) testing personnel met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records on February 10, 2020 revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for the following personnel: a) Cath Lab Testing Personnel 22 b) Cath Lab Testing Personel 23 c) Cath Lab Testing Personnel 25 d) ICU Lab Testing Personnel 47 2. In interview on February 13, 2020 at 10:02 am, Personnel 2 confirmed the laboratory did not maintain documentation of education for the identified personnel.