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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D2130236 | (X3) Date Survey Completed 08/02/2018 |
| Name of Provider or Supplier Sayre Community Hospital | Street Address, City, State 911 Hospital Drive, Sayre, OK | |
| 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 | The survey was performed on 07/30/18-08/02/18. Immediate Jeopardy was determined during the survey due to issues identified with Erythrocyte Sedimentation Rate (ESR) testing, using the Diesse Mini-Cube test system, that was not approved by the FDA. The laboratory voluntarily ceased patient testing, which abated the Immediate Jeopardy situation. The findings were reviewed with the chief executive officer, chief operating officer, chief clinical officer, clinical laboratory operations officer, and laboratory supervisor during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director, Moderate Complexity Testing 493.1409; D6033: Technical Consultant 493.1441; D6076: Laboratory Director, High Complexity Testing NOTE: The laboratory discontinued Blood Bank testing on 06/01/18, therefore, changing the status to a moderate complexity laboratory. The laboratory changed the laboratory director effective 07/23/18 to an individual qualifying as a moderate complexity laboratory director under 493.1405 (b) (5). |
| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> |

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to sign proficiency testing attestation statements. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified attestation statements had either not been signed by the laboratory director, or signed by persons who did not qualify as a technical consultant (if delegated in writing for moderate complexity testing) or technical supervisor (if delegated in writing for high complexity Immunoematology testing) ; (2) The following was identified for 9 of 13 events reviewed: (a) Second 2017 Immunoematology Event - The attestation form had been signed by the previous laboratory supervisor (this person had earned an Associate Degree in Science, and therefore, did not qualify as a Technical Supervisor for Blood Bank or Laboratory Director for high complexity testing - this person had terminated employment in December 2017); (b) Second 2017 Chemistry Miscellaneous Event - The attestation form had been signed by the previous laboratory supervisor (this person did not qualify as a Technical Consultant or a Laboratory Director for moderate complexity testing); (c) Third 2017 Immunoematology Event - The attestation form had not been signed by the laboratory director (a pathologist was the laboratory director and technical supervisor for blood bank during this event); (d) Third 2017 Chemistry Core Event - The attestation form had been signed by the previous laboratory supervisor; (e) Third 2017 Microbiology Event - The attestation form had been signed by the previous laboratory supervisor; (f) Third 2017 Hematology/Coagulation - The attestation form had been signed by the previous laboratory supervisor; (g) First 2018 Immunoematology Event - The attestation form had been signed by the current laboratory director /technical consultant (this person had earned a Bachelor of Science degree, and therefore, did not qualify as a Technical Supervisor for Immunoematology or Laboratory Director for high complexity testing); (h) First 2018 Chemistry Core Event - The attestation form had not been signed by the laboratory director; (i) First 2018 Microbiology Event - The attestation form had not been signed by the laboratory director. (4) The surveyor explained to the clinical laboratory operations officer and laboratory supervisor that proficiency testing attestation statements for moderate complexity testing must be signed by the laboratory director or technical consultant (if delegated) and for Immunoematology testing must be signed by the laboratory director or technical supervisor (if delegated). NOTE: The Interpretive Guidelines under D2015 state "For moderate complexity testing, in accordance with 493.1407(e) (4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of 493.1409. For high complexity testing, in accordance with 493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of 493.1447."

D5024

HEMATOLOGY
 CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
 Based on a review of records, manufacturer's instructions, procedure manual, FDA

database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing the Sysmex CA-620 analyzer. Refer to D5411; (2) The laboratory failed to demonstrate the performance specifications for the Alere Triage Meter Pro and the Sysmex XS 1000i; and failed to ensure the verified reportable ranges were used by the laboratory for the Sysmex CA-620. Refer to D5421; (3) The laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Refer to D5423; (4) The laboratory failed to follow the manufacturer's quality control specifications for ESR (Erythrocyte Sedimentation Rate) testing. Refer to D5479; (5) The laboratory failed to perform two levels of quality control testing each eight hours of D-dimer testing. Refer to D5545; (6) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791; (7) The laboratory failed to make appropriate reference ranges available for coagulation testing. Refer to D5807.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The review verified the laboratory did not address a result that was not graded by the proficiency testing program for 1 of 2 Chemistry Miscellaneous events as follows: (a) First 2018 Event (i) UDS Opiates - 1 of 3 results (Sample UDS-02) had not been evaluated by the proficiency testing program. Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their results. (2) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated the laboratory had not evaluated the result that was not graded by the proficiency testing program.

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 a review of records, procedure manual, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for Urine Microscopic testing. Refer to D5411; (2) The laboratory failed to demonstrate the performance specifications for the Clostridium difficile test kit and the Clinitek Advantus analyzer; and failed to ensure the verified reportable ranges were used by the laboratory for the EPOC test system and Siemens Dimension analyzer. Refer to D5421; (3) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (4) The laboratory failed to perform two levels of quality control testing each day of patient testing. Refer to D5447; (5) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (6) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing. Refer to D5537; (7) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.

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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to follow the manufacturer's instructions. Findings include:
SYSMEX CA-620 ANALYZER (1) On the second day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor the Sysmex CA-620 analyzer was put into use to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT ((Partial Thromboplastin Time) testing on 07/10/17; (2) The surveyor reviewed the manufacturer's instructions for establishing a normal reference interval (the manufacturer required the establishment of a reference interval with a new analyzer). The manufacturer referred the reader to CLSI C28-A3c for information about establishing a reference interval which stated, "As indicated in this document, the working group endorses its previous recommendation that the best means to establish a reference interval is to collect samples from a sufficient number of qualified reference individuals to yield a minimum of 120 samples for analysis, by nonparametric means, for each partition (eg, sex, age range)." In addition, the manufacturer required the following for establishing a normal reference interval: (a) "Donors must be from a healthy population (no known pathological conditions)"; (b) "Donors should not take any medications, including aspirin"; (c) "Donors with a reasonably even distribution of males and females should be included"; (d) "Donors should span the adult age range. (NOTE: A separate range should be established for pediatric populations)"; (e) "Calculate mean and 2 SD range"; (f) "MNPT for INR calculation must be the geometric mean". (3) The surveyor reviewed the

implementation records for the analyzer. The following was identified for PT and PTT: (a) The lot numbers that were in use when the analyzer was implemented (and currently in use) were: (i) PT Reagent - Siemens Dade Innovin lot #539397 (ii) PTT Reagent - Siemens Actin FSL lot #556902 (b) The normal reference intervals had been established for PT and PTT as follows: (i) 21 donors had been utilized for PT and 22 donors had been utilized for PTT (instead of the 120 donors as required for establishment studies for a new analyzer); (ii) There was no documentation of the health status, medication history, age, and gender of the donors. (4) The surveyor reviewed the records with the clinical laboratory operations officer who stated the following: (a) The laboratory did not perform the 120 sample study; (b) There was no documentation to prove the health status, medication history, age, and gender of the donors. (5) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) Patient #123 - PT/INR testing performed on 07/10/17 and 07/13/17 (b) Patient #124 - PT/INR testing performed on 07/18/17 (c) Patient #125 - PT/INR and PTT testing performed on 07/23/17 (d) Patient #126 - PT/INR and PTT testing performed on 07/31/17 (e) Patient #127 - PT/INR and PTT testing performed on 08/06/17 (f) Patient #128 - PT/INR testing performed on 08/10/17 (g) Patient #129 - PT/INR and PTT testing performed on 08/18/17 (h) Patient #130 - PT/INR and PTT testing performed on 08/26/17 (i) Patient #131 - PT/INR testing performed on 09/03/07 (j) Patient #132 - PT/INR and PTT testing performed on 09/10/17 (k) Patient #133 - PT/INR and PTT testing performed on 09/20/17 (l) Patient #134 - PT/INR testing performed on 09/27/17 (m) Patient #135 - PT/INR testing performed on 10/09/17 (n) Patient #136 - PT/INR testing performed on 10/12/17 (o) Patient #137 - PT/INR and PTT testing performed on 10/28/17 (p) Patient #138 - PT/INR testing performed on 11/09/17 (q) Patient #139 - PT/INR testing performed on 11/13/17 (r) Patient #140 - PT/INR and PTT testing performed on 11/28/17 (s) Patient #141 - PT/INR and PTT testing performed on 12/04/17 (t) Patient #142 - PT/INR testing performed on 12/19/17 (u) Patient #143 - PT/INR testing performed on 12/31/17 (v) Patient #144 - PT/INR testing performed on 01/07/18 (w) Patient #145 - PT/INR and PTT testing performed on 01/18/18 (x) Patient #146 - PT/INR testing performed on 01/25/18 (y) Patient #147 - PT/INR and PTT testing performed on 02/07/18 (z) Patient #148 - PT/INR testing performed on 02/12/18 (aa) Patient #149 - PT/INR and PTT testing performed on 02/21/18 (bb) Patient #150 - PT/INR testing performed on 03/04/18 (bb) Patient #115 - PT/INR and PTT testing performed on 03/12/18 (cc) Patient #151 - PT/INR testing performed on 03/19/18 (dd) Patient #152 - PT/INR and PTT testing performed on 03/28/18 (ee) Patient # 153 - PT/INR and PTT testing performed on 04/06/18 (ff) Patient #154 - PT/INR and PTT testing performed on 04/15/18 (gg) Patient #155 - PT/INR testing performed on 04/30/18 (hh) Patient #156 - PT/INR testing performed on 04/10/18 (ii) Patient #157 - PT/INR and PTT testing performed on 05/19/18 (jj) Patient #158 - PT/INR testing performed on 05/30/18 (kk) Patient #159 - PT/INR testing performed on 06/05/18 (ll) Patient #160 - PT/INR testing performed on 06/13/18 and 06/28/18 (mm) Patient #161 - PT/INR testing performed on 06/20/18 (nn) Patient #162 - PT/INR testing performed on 06/29/18 (oo) Patient #163 - PT/INR testing performed on 07/05/18 (pp) Patient #164 - PT/INR performed on 07/13/18 (qq) Patient #165 - PT/INR testing performed on 07/20/18 (rr) Patient #166 - PT/INR testing performed on 07/24/18 (ss) Patient #167 - PT/INR and PTT testing performed on 07/31/18 URINE MICROSCOPIC (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor urine microscopic testing was performed in the laboratory; (2) On the third day of the survey, the laboratory supervisor stated to the surveyor, the KOVA system was used for performing urine microscopies (which consisted of KOVA tubes to centrifuge the urine specimen, the KOVA slide which was a plastic slide with 10 separate chambers,

and the KOVA Petter which was used to drop the specimen into a chamber on the KOVA slide. The laboratory began using this system to perform patient testing on 07/10/17; (3) The surveyor reviewed the procedure titled, "Urinalysis Policy And Procedure" which stated, "Using the previously prepared centrifuge tube, place it in the urinalysis centrifuge and centrifuge for 4-7 minutes at 2500 rpm" (4) The surveyor then reviewed the manufacturer's instructions for the KOVA system and identified the laboratory was not following the instructions for centrifuging urine specimens. The instructions stated, "Centrifuge the KOVA tubes (each containing 12 ml of urine specimen) at a relative centrifugal force (rcf) of 400 for five minutes; approximately 1500 revolutions per minute (rpm) with a 6 inch radius rotor"; (5) The surveyor reviewed the findings with the laboratory supervisor, who stated the laboratory had routinely centrifuged the urine specimens at a speed of 2500 rpm and was not aware the manufacturer of the KOVA system required the urine specimens to be centrifuged at a speed of 1500 rpm; (6) The following were examples of patient urine microscopic testing performed: (a) Patient #170 - testing performed on 07/10/17 (b) Patient #171 - testing performed on 07/30/17 (c) Patient #172 - testing performed on 08/03/17 (d) Patient #173 - testing performed on 08/29/17 (e) Patient #174 - testing performed on 09/13/17 (f) Patient #175 - testing performed on 09/30/17 (g) Patient #176 - testing performed on 10/15/17 (h) Patient #177 - testing performed on 10/29/17 (i) Patient #178 - testing performed on 11/09/17 (j) Patient #179 - testing performed on 11/28/17 (k) Patient #180 - testing performed on 12/07/17 (l) Patient #181 - testing performed on 01/04/18 (m) Patient #182 - testing performed on 01/25/18 (n) Patient #183 - testing performed on 02/25/18 (o) Patient #184 - testing performed on 03/20/18 (p) Patient #185 - testing performed on 04/25/18 (q) Patient #186 - testing performed on 05/21/18 (r) Patient #187 - testing performed on 06/18/18 (s) Patient #188- testing performed on 07/16/18 (t) Patient #189 - testing performed on 08/01/18

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 a review of records, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Findings include: ALERE TRIAGE METER PRO (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor D-dimer testing was performed on the Alere Triage Meter Pro analyzer; (2) On the second day of the survey, the laboratory supervisor stated to the surveyor the laboratory began performing patient testing on 07/13/17 (the laboratory supervisor did not begin employment until 06/11/18); (3) The surveyor reviewed the validation records for the analyzer with the following identified: (a) There was no evidence the precision and reportable range had been demonstrated; (b) There was no evidence the reference range (normal range) had been verified. (4) The surveyor then reviewed the validation

records with the clinical laboratory operations officer and laboratory supervisor. Both stated they could not locate records to prove the precision and reportable range had been demonstrated and the reference range had been verified; (5) Refer to D5545 for examples of patient testing performed. SYSMEX CA-620 (1) On the second day of the survey, the clinical laboratory operations officer and laboratory supervisor stated the Sysmex CA-620 analyzer was put into use to perform PT (Prothrombin Time) and PTT ((Partial Thromboplastin Time) testing on 07/10/17; (2) The surveyor reviewed validation records for the analyzer and identified the reportable ranges had been verified by the laboratory as follows: (a) PT - 9.3-49.0 (b) PTT - 22.9-57.5 (3) The surveyor then requested documentation to verify the reportable ranges that were currently in use. The clinical laboratory operations officer provided the surveyor with a printout from the LIS (Laboratory Information System) which verified the laboratory was using reportable ranges that were wider than the verified ranges: (a) PT - -9999999.9999-66.0 (v) PTT - -9999999.9999-90.0 (4) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor. Both stated the laboratory was not using the reportable ranges that had been verified by the laboratory; (5) Refer to D5411 for examples of PT and PTT testing performed when the laboratory was not using the verified reportable ranges. SYSMEX XS-1000i (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor the Sysmex XS-1000i analyzer was used to perform patient CBC Complete Blood Count) testing (consisted of the analytes WBC (White Blood Cell), RBC (Red Blood Cell), Hemoglobin, Hematocrit, Platelet, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), and MCHC (Mean Corpuscular Hemoglobin Concentration) and automated 5 part differential (% and absolute Neutrophil, Lymphocyte, Eosinophil, and Basophil)); (2) On the third day of the survey, the laboratory supervisor stated to the surveyor the laboratory began patient testing on 07/10/17; (3) The surveyor reviewed the validation records for the analyzer with the following identified: (a) There was no evidence the precision and reportable ranges had been demonstrated for each analyte; (b) There was no evidence the reference ranges (normal range) had been verified for each analyte. (4) The surveyor then reviewed the validation records with the clinical laboratory operations officer and laboratory supervisor. Both stated they could not locate records to prove the precision and reportable ranges had been demonstrated and the reference ranges had been verified; (5) The following were examples of patient CBC testing performed: (a) Patient #272 - testing performed on 07/18/17 (b) Patient #273 - testing performed on 07/25/17 (c) Patient #274 - testing performed on 08/03/17 (d) Patient #275 - testing performed on 08/18/17 (e) Patient #276 - testing performed on 09/02/17 (f) Patient #277 - testing performed on 09/29/17 (g) Patient #278 - testing performed on 10/10/17 (h) Patient #279 - testing performed on 10/28/17 (i) Patient #280 - testing performed on 11/16/17 (j) Patient #281 - testing performed on 12/06/17 (k) Patient #282 - testing performed on 12/31/17 (l) Patient #283 - testing performed on 01/12/18 (m) Patient #284 - testing performed on 01/27/18 (n) Patient #285 - testing performed on 02/21/18 (o) Patient #286 - testing performed on 03/07/18 (p) Patient #287 - testing performed on 04/04/18 (q) Patient #288 - testing performed on 04/17/18 (r) Patient #289 - testing performed on 05/07/18 (s) Patient #290 - testing performed on 05/21/18 (t) Patient #291 - testing performed on 06/05/18 (u) Patient #292 - testing performed on 07/02/18 (v) Patient #293 - testing performed on 07/30/18 EPOC (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Blood Gas (pH, pCO₂, and PO₂) and Lactic Acid testing were performed using the EPOC test system; (2) On the second day of the survey, the laboratory supervisor stated to the surveyor the laboratory began performing patient testing on 07/10/17; (3) The surveyor reviewed the validation records for the analyzer and identified there was no evidence the reference

ranges had been verified; (4) In addition, the surveyor reviewed the validation records and the EPOC procedure manual and identified the reportable ranges that had been demonstrated by the laboratory did not match the reportable ranges listed in the procedure manual: (a) The laboratory had demonstrated the following reportable ranges: (i) pH - 6.663-7.863 (ii) pO₂ - 29.5-618.0 (iii) pCO₂ - 16.3-131.4 (iv) Lactic Acid - 0.48-17.60 (b) The procedure manual listed the reportable ranges as follows: (i) pH - 6.5-8.0 (ii) pO₂ - 27.0-680 (iii) pCO₂ - 15-145 (iv) Lactic Acid - 0.4-19.4 (5) Upon further review of the validation records, the surveyor identified the validation had not been completed and signed off by the laboratory before the laboratory began patient testing on 07/10/17. The validation had been performed from 07/09/17 through 07/19/17, and the records had been signed off as approved by the laboratory on 07/20/17; (6) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated the following: (a) The reference ranges had not been verified; (b) The procedure manual did not reflect the reportable ranges that had been demonstrated by the laboratory. It appeared the laboratory had used the manufacturer's reportable ranges instead of the ranges that had been demonstrated; (c) The validation had not been completed before the laboratory began patient testing. (7) The following were examples of patient testing performed: (a) Patient #86 - Blood Gas testing performed on 07/10/17 (b) Patient #87 - Blood Gas testing performed on 07/12/17 and 07/14/17 (c) Patient #88 - Blood Gas testing performed on 07/13/17 (d) Patient #89 - Lactic Acid testing performed on 07/15/17 (e) Patient #90 - Blood Gas testing performed on 07/16/17 (f) Patient #91 - Blood Gas testing performed on 07/17/17 (g) Patient #92 - Lactic Acid testing performed on 07/18/17 and Blood Gas testing performed on 08/24/17 (h) Patient #93 - Lactic Acid testing performed on 07/20/17 and 06/03/18 (i) Patient #94 - Blood Gas testing performed on 08/01/17 (j) Patient #95 - Lactic Acid testing performed on 08/07/17 (k) Patient #96 - Lactic Acid testing performed on 08/19/17 (l) Patient #97 - Lactic Acid testing performed on 12/02/17 (m) Patient #98 - Blood Gas testing performed on 12/24/17 and 12/28/17 (n) Patient #99 - Lactic Acid testing performed on 12/29/17 (o) Patient #100 - Lactic Acid testing performed on 02/07/18 (p) Patient #101 - Blood Gas and Lactic Acid testing performed on 02/10/18 (q) Patient #102 - Blood Gas testing performed on 02/21/18 (r) Patient #103 - Blood Gas testing performed on 02/27/18 (s) Patient #104 - Lactic Acid testing performed on 04/07/18 (t) Patient #105 - Lactic Acid testing performed on 04/17/18 and 07/06/18 (u) Patient #106 - Blood Gas testing performed on 04/21/18 and 04/22/18 (v) Patient #107 - Lactic Acid testing performed on 04/25/18 (w) Patient #108 - Blood Gas testing performed on 04/29/18 (x) Patient #109 - Lactic Acid testing performed on 04/26/18 (y) Patient #110 - Blood Gas testing performed on 06/05/18 (z) Patient #111 - Lactic Acid testing performed on 06/06/18 and Blood Gas testing performed on 07/24/18 (aa) Patient #112 - Lactic Acid testing performed on 06/10/18 (bb) Patient #113 - Lactic Acid testing performed on 06/21/18 (cc) Patient #114 - Blood Gas testing performed on 06/24/18 (dd) Patient #115 - Lactic Acid testing performed on 06/25/18 (ee) Patient #116 - Lactic Acid testing performed 06/29/18 (ff) Patient #117 - Lactic Acid testing performed 07/04/18 (gg) Patient #118 - Lactic Acid testing performed on 07/18/18 (hh) Patient #119 - Lactic Acid testing performed on 07/22/18 (ii) Patient #120 - Blood Gas testing performed 07/26/18

CLOSTRIDIUM DIFFICILE (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Clostridium difficile (C. diff) testing was performed using the Alere Techlab C. diff QuikChek Complete test kit; (2) On the second day of the survey, the laboratory supervisor stated to the surveyor the laboratory began patient testing on 07/10/17; (3) The surveyor then reviewed records and could not locate documentation to substantiate the performance specifications (i.e., accuracy, precision) had been demonstrated for the test kit before it had been put into use; (4) The surveyor asked the clinical laboratory operations

officer and laboratory supervisor if the performance specifications had been demonstrated for the test kit. Both stated the performance specifications had not been demonstrated for the test kit; (5) The following were examples of patient C. diff testing performed: (a) Patient #22 - testing performed on 07/26/17 (b) Patient #23 - testing performed on 01/02/18 (c) Patient #24 - testing performed on 01/21/18 (d) Patient #25 - testing performed on 01/30/18 (e) Patient #26 - testing performed on 01/31/18 and 04/03/18 (f) Patient 327 - testing performed on 02/22/18 (g) Patient #28 - testing performed on 03/20/18 (h) Patient #29 - testing performed on 03/26/18 (i) Patient #30 - testing performed on 03/27/18 (j) Patient #31 - testing performed on 04/17/18 (k) Patient #32 - testing performed on 05/16/18 (l) Patient #33 - testing performed on 05/17/18 (m) Patient #34 - testing performed on 06/29/18 (n) Patient #122 - testing performed on 07/15/18 CLINITEK ADVANTUS (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor the Siemens Clinitek Advantus analyzer was used Urinalysis testing (for the analysis of Leukocytes, Nitrites, Protein, Blood, Glucose, Ketones, Bilirubin, Urobilinogen, pH, Specific Gravity, and Creatinine in patient urine specimens); (2) On the third day of the survey, the laboratory supervisor stated to the surveyor the laboratory began patient testing on 07/10/17; (3) The surveyor reviewed the validation records for the analyzer with the following identified: (a) There was no evidence the precision and reportable ranges, as applicable, had been demonstrated for each constituent; (b) There was no evidence the reference ranges (normal range) had been verified for each constituent. (4) The surveyor then reviewed the validation records with the clinical laboratory operations officer and laboratory supervisor. Both stated they could not locate records to prove the precision and reportable ranges had been demonstrated and the reference ranges had been verified; (5) The following were examples of patient Urinalysis testing performed: (a) Patient #190 - testing performed on 07/11/17 (b) Patient #191 - testing performed on 07/23/17 (c) Patient #192 - testing performed on 08/07/17 (d) Patient #193 - testing performed on 08/28/17 (e) Patient #194 - testing performed on 09/10/17 (f) Patient #195 - testing performed on 09/26/17 (g) Patient #196 - testing performed on 10/16/17 (h) Patient #197 - testing performed on 11/09/17 (i) Patient #198 - testing performed on 11/26/17 (j) Patient #199 - testing performed on 12/03/17 (k) Patient #200 - testing performed on 12/29/17 (l) Patient #201 - testing performed on 01/03/18 (m) Patient #202 - testing performed on 01/25/18 (n) Patient #203 - testing performed on 02/10/18 (o) Patient #204 - testing performed on 03/13/18 (p) Patient #205 - testing performed on 04/01/18 (q) Patient #206 - testing performed on 04/20/18 (r) Patient #207 - testing performed on 05/21/18 (s) Patient #208 - testing performed on 06/21/18 (t) Patient #209 - testing performed on 07/07/18 (u) Patient #210 - testing performed on 07/19/18 (v) Patient #211 - testing performed on 08/01/18 SIEMENS DIMENSION EXL 200 (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor the Siemens Dimension EXL 200 analyzer was used to perform patient CMP* (Comprehensive Metabolic Panel) testing; (2) On the third day of the survey, the laboratory supervisor stated to the surveyor the laboratory began patient testing on 07/10/17; (3) The surveyor reviewed validation records for the analyzer and identified the reportable ranges had been verified by the laboratory as follows: (a) BUN (Blood Urea Nitrogen) - 5.97-44.51 (b) Calcium - 5.35-13.24 (c) Creatinine - 0.594-5.115 (d) Glucose - 51.8-235.7 (e) Chloride - 86.0-122.0 (f) CO₂ - 18.71-35.88 (g) Potassium - 2.7-7.4 (h) Sodium - 117.0-159.0 (i) Albumin - 2.58-4.48 (j) ALT (Alanine Aminotransferase) - 19.0-261.0 (k) AST (Aspartate Aminotransferase) - 20.2-344.03 (l) Alkaline Phosphatase - 58.0-246.0 (m) Total Bilirubin - 0-4.2 (n) Total Protein - 4.57-10.25 (4) The surveyor then requested a printout from the analyzer to verify the reportable ranges that had been programmed into the analyzer and were currently in use. The printout verified the laboratory was using reportable ranges that were wider

than the verified ranges: (a) BUN - 0-150 (b) Calcium - 5.0-15.0 (c) Creatinine - 0.15-20.00 (d) Glucose - 0-500 (e) Chloride - 50-200 (f) CO₂ - 5-45 (g) Potassium - 1-10 (h) Sodium - 50-200 (i) Albumin - 0.6-8.0 (j) ALT - 6-1000 (k) AST - 0-1000 (l) Alkaline Phosphatase - 10-1000 (m) Total Bilirubin - 0.1-25.0 (n) Total Protein - 2.0-12.0 (4) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor. Both stated the laboratory was using the manufacturer's default reportable ranges for the above analytes, instead of the reportable ranges that had been demonstrated by the laboratory; (5) The following were examples of patient CMP testing performed when the laboratory was not using the verified reportable ranges: (a) Patient #254 - testing performed on 07/10/17 (b) Patient #255 - testing performed on 07/26/17 (c) Patient #256 - testing performed on 08/05/17 (d) Patient #257 - testing performed on 08/25/17 (e) Patient #258 - testing performed on 09/08/17 (f) Patient #259 - testing performed on 09/22/17 (g) Patient #260 - testing performed on 10/25/17 (h) Patient #261 - testing performed on 11/21/17 (i) Patient #262 - testing performed on 12/19/17 (j) Patient #263 - testing performed on 01/19/18 (k) Patient #264 - testing performed on 02/23/18 (l) Patient #265 - testing performed on 03/22/18 (m) Patient #266 - testing performed on 04/15/18 (n) Patient #267 - testing performed on 05/15/18 (o) Patient #268 - testing performed on 06/07/18 (p) Patient #269 - testing performed on 06/19/18 (q) Patient #270 - testing performed on 06/29/18 (r) Patient #271 - testing performed on 07/29/18 *CMP - BUN (Blood Urea Nitrogen), Calcium, Creatinine, Glucose, Chloride, CO₂, Potassium, Sodium, Albumin, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, and Total Protein

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a review of records, FDA database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor ESR (Erythrocyte Sedimentation Rate) testing was performed using the DIESSE Mini-Cube analyzer; (2) On the third day of the survey, the laboratory supervisor stated the laboratory began patient testing on 07/11/17; (3) The surveyor had not encountered this test system previously and therefore, attempted to verify the classification of the test. Since classification of test systems are performed by the FDA (Food and Drug

Administration), the surveyor reviewed the FDA test classification database. The database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (4) The surveyor explained this to the clinical laboratory operations officer and laboratory supervisor. The laboratory supervisor contacted the distributing manufacturer of the test system to obtain the FDA 510K approval. The distributing manufacturer responded with an email that stated, "In regards to the testing complexity, we do not have anything in writing stating the Diesse Mini-Cube is moderately complex, however, all automated ESR testing analyzers are considered moderately complex"; (5) The surveyor then contacted the CMS Dallas Regional Office, who in turn, contacted the CMS Central Office FDA liaison for confirmation of the classification of the test system. The surveyor was unable to find confirmation that the FDA had automatically classified all automated ESR test systems as moderate complexity, and therefore, determined the test system was classified as high complexity, which required the performance specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values) be established; (6) The surveyor reviewed the implementation records for the analyzer. There was no evidence the precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values) had been established; (7) The surveyor reviewed the validation records with the clinical laboratory operations officer and laboratory supervisor. Both stated there were no records to prove the precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals had been established; (8) Following the survey, on 08/03/18, the surveyor received an email from the CMS Central Office FDA liaison confirming that, if the test was not listed on the FDA CLIA database, then it was a high complexity test and the FDA had not automatically classified all automated ESR test systems as moderate complexity; (9) The following were examples of patient ESR testing performed: (a) Patient #212 - testing performed on 07/11/17 (b) Patient #213 - testing performed on 07/14/17 (c) Patient #214 - testing performed on 07/17/17 (d) Patient #215 - testing performed on 07/31/17 (e) Patient #216 - testing performed on 08/0/17 (f) Patient #217 - testing performed on 08/15/17 (g) Patient #218 - testing performed on 08/30/17 (h) Patient #219 - testing performed on 09/06/17 (i) Patient #220 - testing performed on 09/14/17 (j) Patient #221 - testing performed on 09/22/17 (k) Patient #222 - testing performed on 10/03/17 (l) Patient #223 - testing performed on 10/20/17 (m) Patient #224 - testing performed on 10/30/17 (n) Patient #225 - testing performed on 11/09/17 (o) Patient #226 - testing performed on 11/27/17 (p) Patient #227 - testing performed on 12/04/17 (q) Patient #228 - testing performed on 12/22/17 (r) Patient #229 - testing performed on 01/03/18 (s) Patient #230 - testing performed on 01/18/18 (t) Patient #231 - testing performed on 01/30/18 (u) Patient #232 - testing performed on 02/07/18 (v) Patient #233 - testing performed on 02/09/18 (w) Patient #234 - testing performed on 02/23/18 (x) Patient #235 - testing performed on 03/02/18 (y) Patient #236 - testing performed on 03/14/18 (z) Patient #237 - testing performed on 03/24/18 (aa) Patient #238 - testing performed on 04/02/18 (bb) Patient #239 - testing performed on 04/16/18 (bb) Patient #240 - testing performed on 04/25/18 (cc) Patient #241 - testing performed on 05/09/18 (dd) Patient #242 - testing performed on 05/22/18 (ee) Patient #243 - testing performed on 06/04/18 (ff) Patient #244 - testing performed on 06/12/18 (gg) Patient #245 - testing performed on 06/18/18 (hh) Patient #246 - testing performed on 06/29/18 (ii) Patient #247 - testing performed on 07/06/18 (jj) Patient #248 - testing performed on 07/09/18 (kk) Patient #249 - testing performed on 07/10/18 (ll) Patient #250 - testing performed on 07/12/18 (mm) Patient #83 - testing performed on 07/13/18 (nn) Patient #251 - testing performed on 07/14/18 (oo) Patient #252 - testing performed on 07/17/18 (pp) Patient #253 - testing performed on 07/18

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 a review of records, manufacturer's instructions, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor CMP* (Comprehensive Metabolic Panel) testing was performed on the Siemens Dimension EXL 200 analyzer; (2) On the third day of the survey, the laboratory supervisor stated to the surveyor the laboratory began patient testing on 07/10/17; (3) The surveyor reviewed the manufacturer's maintenance instructions for the analyzer. One of the monthly maintenance requirements was to "Replace HM Pump Heads"; (4) Maintenance records were reviewed by the surveyor for 11 months (08/01/17 through 06/30/18). The Replace HM Pump Heads had not been documented as performed as follows: (a) Between 01/28/18 and 03/13/18 (b) Between 04/24/18 and 07/03/18 (5) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated there was no evidence the maintenance had been performed as required; (6) The following were examples of patient testing performed: (a) Patient #264 - testing performed on 02/23/18 (b) Patient #267 - testing performed on 05/15/18 (c) Patient #268 - testing performed on 06/07/18 (d) Patient #269 - testing performed on 06/19/18 (e) Patient #270 - testing performed on 06/29/18 *CMP - BUN (Blood Urea Nitrogen), Calcium, Creatinine, Glucose, Chloride, CO₂, Potassium, Sodium, Albumin, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, and Total Protein

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to perform two levels of quality control materials each day of patient testing. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Lactic Acid testing was performed using the EPOC test system; (2) On the second day of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory began performing patient testing on 07/10/17; (b) Two levels of quality control (QC) materials were performed with each new test kit

lot number and on a monthly basis; (c) Beginning in June 2018 (the laboratory supervisor began employment on 06/11/18), the laboratory began performing two levels of QC materials each day of patient testing. (3) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system prior to June 2018. The laboratory supervisor stated there was no documentation to prove an IQCP had not been developed. Therefore, the surveyor determined two levels of QC materials must be performed each day of patient testing; (4) The surveyor reviewed QC and patient testing records from 07/10/17 through the second day of the survey. The review indicated two levels of QC materials had not been performed 15 of 22 days of patient testing reviewed; (5) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated two levels of QC materials had not been performed each day of patient testing; (6) The following were examples of patient Lactic Acid testing when two levels of QC materials had not been tested: (a) Patient #89 - testing performed on 07/15/17 (b) Patient #92 - testing performed on 07/18/17 (c) Patient #93 - testing performed on 07/20/17 and 06/03/18 (d) Patient #95 - testing performed on 08/07/17 (e) Patient #96 - testing performed on 08/19/17 (f) Patient #97 - testing performed on 12/02/17 (g) Patient #99 - testing performed on 12/29/17 (h) Patient #100 - testing performed on 02/07/18 (i) Patient #101 - testing performed on 02/10/18 (j) Patient #105 - testing performed on 04/17/18 (k) Patient #107 - testing performed on 04/25/18 (l) Patient #109 - testing performed on 04/26/18 (m) Patient #111 - testing performed on 06/06/18 (n) Patient #112 - testing performed on 06/10/18

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to perform a negative and positive control each day of patient testing. Findings include: URINE DRUG SCREEN (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Urine Drug Screen testing was performed using the MedTox Profile II ER test system; (2) Later on the first day, the laboratory supervisor stated to the surveyor the laboratory began performing patient testing on 01/06/18 (the laboratory supervisor did not begin employment until 06/11/18). In addition, the laboratory supervisor stated to the surveyor negative and positive quality control (QC) materials were performed with each new test kit lot and on a weekly basis; (3) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor stated there was no documentation to prove an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC testing must be performed each day of patient testing; (4) The surveyor reviewed QC and patient testing records from January 2018 through the first day of the survey. The review indicated negative and positive QC testing had not been performed 21 of 28 days of patient testing reviewed; (5) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated negative

and positive QC materials had not been performed each day of patient testing; (6) The following were examples of patient Urine Drug Screen testing when QC testing had not been performed: (a) Patient #1 - testing performed on 01/06/18 (b) Patient #2 - testing performed on 01/14/18 (c) Patient #3 - testing performed on 01/23/18 (d) Patient #4 - testing performed on 02/03/18 (e) Patient #5 - testing performed on 02/08/18 (f) Patient #6 - testing performed on 02/25/18 (g) Patient #7 - testing performed on 03/02/18 (h) Patient #8 - testing performed on 03/17/18 (i) Patient #9 - testing performed on 03/28/18 (j) Patient 10 - testing performed on 04/14/18 (k) Patient #11 - testing performed on 04/20/18 (l) Patient #12 - testing performed on 05/02/18 (m) Patient #13 - testing performed on 05/05/18 (n) Patient #14 - testing performed on 05/17/18 (o) Patient #15 - testing performed on 05/27/18 (p) Patient #16 - testing performed on 06/13/18 (q) Patient #17 - testing performed on 06/28/18 (r) Patient #18 - testing performed on 07/03/18 (s) Patient #19 - testing performed on 07/10/18 (t) Patient #20 - testing performed on 07/25/18 (u) Patient #21 - testing performed on 07/28/18

CLOSTRIDIUM DIFFICILE (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Clostridium difficile (C. diff) testing was performed using the Alere Techlab C. diff QuikChek Complete test kit; (2) On the second day of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory began patient testing on 07/10/17; (b) The laboratory had been performing negative and positive QC testing with new lot numbers of test kits and had not developed an IQCP; (c) After the laboratory supervisor had been hired on 06/11/18, a new policy was developed to test negative and positive control materials each day of patient testing. (3) The surveyor reviewed QC and patient testing records from July 2017 through the second day of the survey. The review indicated negative and positive QC testing had not been performed 14 of 21 days of patient testing reviewed; (4) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated negative and positive QC materials had not been performed each day of patient testing prior to 06/11/18; (6) The following were examples of patient C. diff testing when QC testing had not been performed: (a) Patient #22 - testing performed on 07/26/17 (b) Patient #23 - testing performed on 01/02/18 (c) Patient #24 - testing performed on 01/21/18 (d) Patient #25 - testing performed on 01/30/18 (e) Patient #26 - testing performed on 01/31/18 and 04/03/18 (f) Patient 327 - testing performed on 02/22/18 (g) Patient #28 - testing performed on 03/20/18 (h) Patient #29 - testing performed on 03/26/18 (i) Patient #30 - testing performed on 03/27/18 (j) Patient #31 - testing performed on 04/17/18 (k) Patient #32 - testing performed on 05/16/18 (l) Patient #33 - testing performed on 05/17/18 (m) Patient #34 - testing performed on 06/29/18

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the third day of the survey, the clinical laboratory operations officer and laboratory supervisor stated the following to the surveyor: (a) The laboratory began using the

Diesse Mini-Cube analyzer to perform automated ESR (Erythrocyte Sedimentation Rate) testing on 07/11/17; (b) Streck ESR-Chex Plus control materials (level 1 and level 2) were performed each day of patient testing. (2) The surveyor reviewed the manufacturer's instructions for the control materials. They stated "Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits"; (3) The surveyor then reviewed quality control records for 3 lot numbers of control materials used from 07/11/17 through the third day of the survey. The records verified the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert: (a) Level 1 and level 2 (lot #251) - Used from 07/11/17 through 08/15/17; (b) Level 1 and level 2 (lot #315) - Used from 08/18/17 through 01/29/18 (c) Level 1 and level 2 (lot #403) - Put into use on 01/30/18 and was currently in use. (4) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor. Both stated the laboratory had not established their own means and limits of acceptability, but instead used the manufacturer's package insert limits; (5) Refer to D5423 for examples of patient ESR testing performed.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Blood Gas (pH, pCO₂, pO₂) testing was performed using the EPOC test system; (2) On the second day of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory began performing patient testing on 07/10/17; (b) Two levels of quality control (QC) testing were performed with each new test kit lot number and on a monthly basis; (c) Beginning in June 2018 (the laboratory supervisor began employment on 06/11/18), a new policy was developed to perform two levels of QC materials each eight hours of patient testing. (3) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system prior to June 2018. The laboratory supervisor stated there was no documentation to prove an IQCP had not been developed. Therefore, the surveyor determined one level of QC material must be performed each 8 hours of patient testing, using a combination of control materials that include both low and high values on each day of patient testing; (4) The surveyor reviewed QC and patient testing records from 07/10/17 through the second day of the survey. The review indicated one level of QC testing had not been performed each eight hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing for 17 of 22 days of patient testing reviewed; (5) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated two levels of QC materials had not been performed each day of patient testing prior to June 2018; (6) The following were examples of patient

Blood Gas testing QC materials had not been tested: (a) Patient #86 - testing performed on 07/10/17 (b) Patient #87 - testing performed on 07/12/17 and 07/14/17 (c) Patient #88 - testing performed on 07/13/17 (d) Patient #90 - testing performed on 07/16/17 (e) Patient #91 - testing performed on 07/17/17 (f) Patient #94 - testing performed on 08/01/17 (g) Patient #92 - testing performed on 08/24/17 (h) Patient #98 - testing performed on 12/24/17 and 12/28/17 (i) Patient #101 - testing performed on 02/10/18 (j) Patient #102 - testing performed on 02/21/18 (k) Patient #103 - testing performed on 02/27/18 (l) Patient #104 - testing performed on 04/21/18 and 04/22/18 (m) Patient #108 - testing performed on 04/29/18 (n) Patient #110 - testing performed on 06/05/18

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to perform two levels of quality control testing each eight hours of D-dimer testing. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor D-dimer testing was performed on the Alere Triage Meter Pro analyzer; (2) On the second day of the survey, the laboratory supervisor stated to the surveyor the laboratory began performing patient testing on 07/13/17 (the laboratory supervisor did not begin employment until 06/11/18). In addition, the laboratory supervisor stated to the surveyor two levels of quality control (QC) materials were performed every 30 days and with new lot numbers of test devices; (3) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor stated there was no documentation to prove an IQCP had not been developed. Therefore, the surveyor determined two levels of QC materials must be performed each eight hours of patient testing; (4) The surveyor reviewed QC and patient testing records for testing performed from July 2017 through the second day of the survey. The records verified two levels of QC testing had not been performed each eight hours of patient testing for 54 of 56 days of patient testing reviewed (QC had not been performed on the days of patient testing); (5) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor. Both stated two levels of QC materials had not been performed each day of patient testing; (6) The following were examples of patient D-dimer testing when QC testing had not been performed: (a) Patient #35 - testing performed on 07/13/17 (b) Patient #36 - testing performed on 07/15/17 (c) Patient #37 - testing performed on 08/03/17 (d) Patient #38 - testing performed on 08/05/17 (e) Patient #39 - testing performed on 08/06/17 (f) Patient #40 - testing performed on 8/11/17 (g) Patient #41 - testing performed on 08/13/17 (h) Patient #42 - testing performed on 08/14/17 (i) Patient #43 - testing performed on 08/18/17 (j) Patient #44 - testing performed on 08/21/17 (k) Patient #45 - testing performed on 08/22/17 (l) Patient #46 - testing performed on 08/25/17 (m) Patient #47 - testing performed on 08/28/17 (n) Patient #48 - testing performed on 08/30/17 (o) Patient #49 - testing performed on 09/03/17 (p) Patient #50 - testing performed on 09/08/17 (q) Patient #51 - testing performed on 09/12/17 (r) Patient #52 - testing performed on 09

/14/17 (s) Patient #53 - testing performed on 09/16/17 (t) Patient #54 - testing performed on 09/18/17 (u) Patient #55 - testing performed on 09/22/17 and 03/02/18 (v) Patient #56 - testing performed on 10/08/17 (w) Patient #57 - testing performed on 10/17/17 (x) Patient #58 - testing performed on 10/22/17 (y) Patient #59 - testing performed on 11/06/17 (z) Patient #60 - testing performed on 11/10/17 (aa) Patient #61 - testing performed on 11/12/17 (bb) Patient #62 - testing performed on 11/24/17 (cc) Patient #63 - testing performed on 11/29/17 (dd) Patient #64 - testing performed on 01/07/18 (ee) Patient #65 - testing performed on 01/15/18 (ff) Patient #66 - testing performed on 01/29/18 (gg) Patient #67 - testing performed on 02/06/18 (hh) Patient #68 - testing performed on 02/13/18 (ii) Patient #69 - testing performed on 03/20/18 (jj) Patient #70 - testing performed on 03/24/18 (kk) Patient #71 - testing performed on 04/02/18 (ll) Patient #72 - testing performed on 04/17/18 (mm) Patient #73 - testing performed on 04/23/18 (nn) Patient #74 - testing performed on 05/09/18 (oo) Patient #75 - testing performed on 05/19/18 (pp) Patient #76 - testing performed on 06/04/18 (qq) Patient #77 - testing performed on 06/07/18 (rr) Patient #78 - testing performed on 06/18/18 (ss) Patient #79 - testing performed on 06/25/18 (tt) Patient #80 - testing performed on 07/04/18 (uu) Patient #81 - testing performed on 07/07/18 (vv) Patient #82 - testing performed on 07/08/18 (ww) Patient #83 - testing performed on 07/13/18 (xx) Patient #84 - testing performed on 07/18/18 (yy) Patient #85 - testing performed on 07/25/18

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 a review of records, manufacturer's instructions, procedure manual, FDA database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions. Refer to D5411; (b) The laboratory failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421; (c) The laboratory failed to establish the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Refer to 5423; (d) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (e) The laboratory failed to perform two levels of quality control testing each day of patient testing. Refer to D5447; (f) The laboratory failed to perform a negative and positive control each day of patient testing. Refer to D5449; (g) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (h) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing. Refer to D5537; (i) The laboratory failed to

perform two levels of quality control testing each eight hours of D-dimer testing. Refer to D5545.

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 a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to ensure patient test reports included the name of the laboratory location. Findings include: (1) On the second day of the survey, the surveyor reviewed 7 patient test reports as follows: (a) Report #1 - Lactic Acid testing was performed with the results reported on 07/02/18; (b) Report #2 - Urine Drug Screen testing was performed with the results reported on 07/02/18; (c) Report #3 - D-dimer testing was performed with the results reported on 07/04/18; (d) Report #4 - CMP* (Comprehensive Metabolic Panel) testing was performed with the results reported on 07/14/18; (e) Report #5 - CBC (Complete Blood Count) testing was performed with the results reported on 07/14/18; (f) Report #6 - Clostridium difficile testing was performed with the results reported on 07/15/18; (g) Report #7 - Lipid Panel* testing was performed with the results reported on 07/16/18. (2) The surveyor identified that the name of the laboratory on the reports was "SRP-Sayre", which did not match the name on the Clia certificate. The name on the Clia certificate was "Sayre Community Hospital"; (3) The surveyor reviewed the reports with the clinical laboratory operations officer and laboratory supervisor. Both stated the name on the reports did not match the name on the Clia certificate. *CMP - BUN (Blood Urea Nitrogen), Calcium, Creatinine, Glucose, Chloride, CO₂, Potassium, Sodium, Albumin, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, and Total Protein *Lipid Panel - Cholesterol, HDL (High Density Lipoprotein), Triglycerides, and LDL (Low Density Lipoprotein)

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory failed to make appropriate reference ranges available. Findings include: BLOOD GAS TESTING (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor Arterial Blood Gas (pH, pCO₂, and PO₂) testing was performed using

the EPOC test system; (2) On the second day of the survey, the laboratory supervisor stated to the surveyor the laboratory began performing patient testing on 07/13/17); (3) The surveyor reviewed records of patient testing performed on the analyzer from 07/13/17 through the second day of the survey and identified a venous pH that had been performed on a patient on 07/30/18 and asked the clinical laboratory operations officer to print the report; (4) The surveyor reviewed the report for the venous pH performed on patient #121 on 07/30/18. The report did not include reference intervals for venous pH. The reference intervals on the report were for arterial pH; (5) The surveyor reviewed the report with clinical laboratory operations officer who stated the report did not include reference intervals for venous pH. PT AND PTT TESTING (1) On the second day of the survey, the clinical laboratory operations officer and laboratory supervisor stated the Sysmex CA-620 analyzer was put into use to perform PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing on 07/10/17; (2) The surveyor reviewed the implementation records for the analyzer. The following was identified for PT and PTT: (a) The lot numbers that were in use when the analyzer was implemented (and currently in use) were: (i) PT Reagent - Siemens Dade Innovin lot #539397 (ii) PTT Reagent - Siemens Actin FSL lot #556902 (3) The surveyor reviewed the implementation records and identified the following normal reference ranges had been established: (a) PT - 9.27-10.76 seconds (b) PTT - 23.42-30.06 seconds (4) The surveyor then reviewed the following patient PT and PTT reports: (a) Patient #168 - PT performed on 07/25/18 with a reference range of 9.9-11.5 seconds; (b) Patient #169 - PTT testing performed on 07/16/18 with a reference range of 17.4-37.4 seconds. (5) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor. Both stated the established normal reference ranges for PT and PTT were not included on the patient report.

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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications. Refer to D6003; (2) The laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Refer to D6004; (3) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (4) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (5) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (6) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (7) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (8) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to

D6026. (9) The laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Refer to D6029.

D6003

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical

Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications. Findings include: (1) The laboratory director failed to ensure proficiency testing attestation statements for moderate complexity testing had been signed by the laboratory director or an individual meeting the educational qualifications. Refer to D2015.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Findings include: (1) During the survey performed from 07/30/18 through 08/02/18, the surveyor reviewed records for moderate complexity testing performed in the laboratory, from the date the laboratory became operational on 07/10/17, through the fourth day of the survey. Examples of the records reviewed include: (a) Personnel records (b) Proficiency testing records (c) Quality control records (d) Calibration and calibration verification records (e) Installation records (f) Maintenance and function check records (g) Temperature and humidity records (2) There was no evidence in the records to demonstrate the involvement of the laboratory director until the current laboratory director began reviewing the records on 07/08/18. For example, there were no signatures, dates, notes, etc. documented in the records by the previous laboratory director; (3) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor and asked if documentation of the previous laboratory director involvement was available. Both stated they were not able to locate documentation.

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 a review of records, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory failed to demonstrate the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. 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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: **ATTESTATION STATEMENTS SIGNED AFTER SAMPLES TESTED** (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 3 of 13 events, the attestation statements had been signed approximately 2-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2018 Chemistry Miscellaneous Event - The samples had been tested on 05/07/18 and the attestation statement had not been signed by the current laboratory director until 07/29/18 (the current laboratory director was employed by the facility effective 07/23/18); (b) First 2018 Hematology/Coagulation Event - The samples had been tested on 03/27/18 and the attestation statement had not been signed by the laboratory director until 07/29/18; (c) Second 2018 Chemistry Core Event - The samples had been tested on 03/27/18 and the attestation statement had not been signed by the laboratory director until 07/08/18. (2) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor, and explained that the attestation statement must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens. **ATTESTATION STATEMENTS NOT SIGNED BY LABORATORY DIRECTOR OR DESIGNEE** (1) The laboratory director or a qualified designee failed to sign proficiency testing attestation statements. Refer to D2015.

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 a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure two levels of quality control materials had been performed each day of patient testing. Refer to D5447; (2) The laboratory director failed to ensure negative and positive control materials had been performed each day of patient testing. Refer to D5449; (3) The laboratory director failed to ensure one sample of control material had been performed each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing. Refer to D5537; (4) The laboratory director failed to ensure two levels of quality control materials had been performed each eight hours of D-dimer testing. Refer to D5545.

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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. 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 a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5807.

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 a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #3 - This person began performing patient testing when the laboratory opened on 07/10/17. Although a training checklist had been completed (dated 07/05/17), the testing person signed off as performing their own training. Therefore, the surveyor determined the laboratory director did not ensure the testing person had been initially trained to perform moderate complexity testing. (2) The surveyor reviewed the findings with the clinical laboratory operations officer and laboratory supervisor. Both stated there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.

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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations manager and laboratory supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure that verification procedures were adequate to determine the performance

characteristics. Refer to D6040; (3) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (4) The technical consultant failed to ensure evaluations included all moderate complexity testing performed. Refer to D6053.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: EVALUATIONS (1) On the first day of the survey, the surveyor reviewed personnel records for 2 persons performing moderate complexity testing since the laboratory began patient testing on 07/10/17. The records indicated the six month evaluations for 2 of 2 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 04/15/18 evaluation had been performed by testing person #3 (this person had earned an associate degree in science); (b) Testing Person #3 - The 05/08/18 evaluation had been performed by testing person #3 (this

person had signed off as performing their own evaluation). (2) The surveyor explained to the clinical laboratory operations officer and laboratory supervisor that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). PROFICIENCY TESTING ATTESTATION FORMS (1) The laboratory director or designee failed to sign proficiency testing attestation statements for moderate complexity testing. The attestation forms had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant. Refer to D5215.

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 a review of records, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the laboratory demonstrated the performance specifications for new test methods; and failed to ensure the verified reportable ranges were used by the laboratory. 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 a review of records, manufacturer's instructions, procedure manual, and interview with the clinical laboratory operations officer and laboratory supervisor, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The technical consultant failed to ensure maintenance procedures had been performed as required by the manufacturer. Refer to D5429; (3) The technical consultant failed to ensure two levels of quality control materials had been performed each day of patient testing. Refer to D5447; (4) The technical consultant failed to ensure the laboratory performed negative and positive control materials each day of patient testing. Refer to D5449; (5) The technical consultant failed to ensure the laboratory performed one sample of control material each 8 hours of patient blood gas testing

using a combination of control materials that include both low and high values on each day of testing. Refer to D5537; (6) The technical consultant failed to ensure the laboratory performed two levels of quality control materials each eight hours of D-dimer testing. Refer to D5545.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the technical consultant failed to ensure evaluations included all moderate complexity testing performed. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the following testing were performed in the laboratory: (a) Urine Microscopic testing (b) Clostridium difficile testing using the Alere Techlab C. diff Quick Check Complete test kit. (2) The surveyor then reviewed personnel records for 2 persons performing urine microscopic and Clostridium difficile testing in the laboratory (testing person #2 and testing person #3); (3) There was no evidence the six month evaluations, performed for the above persons (dated as 04/15/18 for testing person #2 and 05/08/18 for testing person #3), included an assessment of urine microscopic and Clostridium difficile testing; (4) The surveyor reviewed the findings with the laboratory operations officer and laboratory supervisor. Both agreed the above evaluations did not include urine microscopic and Clostridium difficile testing.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on a review of records, written policy, and interview with the clinical laboratory operations officer and laboratory supervisor, testing personnel failed to follow the laboratory's policy for performing patient testing. Findings include: (1) On the first day of the survey, the clinical laboratory operations officer and laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On the third day of the survey, the surveyor reviewed the policy titled, "Performing CBC's With Sysmex 1000i": (a) Under the heading "Manual Differential" it stated, "Start at one side of the smear and travel across the smear to the other side. Count each WBC as it enters the view on the microscope. Stop counting when 100 cells have been counted"; (b) Under the heading "Precautions And Limitations" it stated, "When reviewing patient data ensure the Hgb and Hct match. The Hct should be approximately 3 times the Hgb level. Failure to achieve this relationship may indicate a specimen problem such as lipemia or clots in the specimen. An MCHC greater than 35.5 indicates a problem with the specimen or the analyzer run. Check for lipemia by centrifuging the specimen or the presence of

abnormal proteins which would be seen as rouleaux on scan of a smear". (3) The surveyor randomly reviewed patient CBC reports for testing performed in October 2017, December 2017 and June 2018 and identified testing personnel had not followed the above policies for 2 patients: (a) Patient #294 (i) The patient specimen had been tested on 10/12/17 and met the laboratory criteria for performing a manual differential. The reported WBC (White Blood Cell) count from the manual differential testing did not equal 100, instead the WBC count from the manual differential was reported as 96; (b) Patient #295 (i) The patient specimen had been tested on 12/28/17 with the following results reported: (aa) WBC - 3.4 (bb) RBC (Red Blood Cell) - 0.2 (cc) Hemoglobin - 8.6 (dd) Hematocrit - 2.6 (ee) MCV (Mean Corpuscular Volume) - 108.3 (ff) MCH (Mean Corpuscular Hemoglobin) - 358.3 (gg) MCHC (Mean Corpuscular Hemoglobin Concentration) - 330.8 (hh) Platelets - 80.0 (ii) The surveyor determined the testing personal did not follow the policy due to: (aa) The Hemoglobin (abbreviated in the policy as "Hgb") and the Hematocrit (abbreviated in the policy as "Hct") did not match within the rule of 3 criteria. The Hemoglobin was reported as 8.6 and the Hematocrit was reported as 2.6 (for the results to be accurate as stated in the policy, with a Hemoglobin of 8.6, the Hematocrit should be approximately 3 times the Hemoglobin or approximately 25-26); (bb) The MCHC was reported as 330.8, and as stated in the policy, an MCHC greater than 35.5 could indicate a problem with the specimen or presence of abnormal proteins; (cc) The specimen had been retested nine times (1:58 pm, 2:01 pm, 2:07 pm, 2:09 pm, 2:31 pm, 3:10 pm, 3:14 pm, 3:17 pm, and 3:20 pm), with the results of the 1:58 pm run reported. (4) The surveyor reviewed the reports with the clinical laboratory operations officer and laboratory supervisor. Both stated testing personnel did not follow the laboratory policy for the two patients.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of records, manufacturer's instructions, FDA database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to provide overall management and direction for high complexity testing. Findings include: (1) The laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications; and failed to ensure the laboratory director was qualified for all testing performed. Refer to D6078; (2) The laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Refer to D6079; (3) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer to D6086; (4) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6087; (5) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6089; (6) The laboratory director failed to ensure that a quality assessment program had been established and maintained. Refer to D6094.

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications; and failed to ensure the laboratory director was qualified for all testing performed. Findings include: ATTESTATION FORMS (1) The laboratory director failed to ensure proficiency testing attestation statements for high complexity Immunohematology testing had been signed or had been signed by individuals who met the educational qualifications of a laboratory director. Refer to D2015. MINICUBE (1) On the first day of the survey, clinical laboratory operations officer and laboratory supervisor stated the following to the surveyor: (a) The previous laboratory director (from 07/10/17 through 07/24/18) was a pathologist and met the educational qualifications for a high complexity laboratory director as stated in 493.1445(b)(1)(i) (ii); (b) The laboratory discontinued Immunohematology testing on 06/01/18 and obtained a new laboratory director effective 07/23/18. The new laboratory director met the educational qualifications for a moderate complexity laboratory director as stated in 493.1405(b)(5)(i)(ii)(iii). (2) On the third day of the survey, the surveyor

identified the Diesse Mini-Cube analyzer, used to perform automated ESR (Erythrocyte Sedimentation Rate) testing, was not listed on the FDA test classification database and therefore, had not obtained 510K approval by the FDA. Due to this, the test system defaulted to the classification as high complexity (refer to D5423); (3) From 07/23/18 through the third day of the survey, the current laboratory director did not qualify as a high complexity laboratory director; (4) The clinical laboratory operations officer and laboratory supervisor were not aware the Diesse Mini-Cube was classified as high complexity testing and discontinued the testing as of 08/01/18. Refer to D5423 for examples of patient ESR testing performed.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, procedure manual, FDA database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to provide overall supervision and effective direction over the operation and administration of the laboratory. Findings include: (1) During the survey performed from 07/30/18 through 08/02/18, the surveyor reviewed records for high complexity testing performed in the laboratory from the date the laboratory became operational on 07/10/17 through the fourth day of the survey. Examples of the records reviewed include: (a) Personnel records (b) Proficiency testing records (c) Quality control records (d) Installation records (e) Maintenance and function check records (f) Temperature and humidity records (2) There was no evidence in the records to demonstrate the involvement of the laboratory director. For example, there were no signatures, dates, notes, etc. documented in the records by the laboratory director (note: the laboratory discontinued Immunohematology testing effective 06/01/18 and the Diesse Mini-Cube ESR (Erythrocyte Sedimentation Rate) analyzer effective 08/01/18, when it was identified the test system was not FDA approved and therefore, classified as high complexity); (3) The surveyor reviewed the records with the clinical laboratory operations officer and laboratory supervisor and asked if documentation of the laboratory director involvement for high complexity testing was available. Both stated they were not able to locate documentation.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 a review of records, FDA database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory failed to ensure the performance specifications of precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals had been established for an Erythrocyte Sedimentation Rate test system not cleared or approved by the FDA. Refer to D5423.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) The laboratory director or a qualified designee failed to sign proficiency testing attestation statements. Refer to D2015.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, procedure manual, FDA

database, information provided by the distributing manufacturer, correspondence with the CMS Central Office FDA liaison, and interview with the clinical laboratory operations officer and laboratory supervisor, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5791.