Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659838	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Throckmorton County Memorial Hospital	802 North Minter Avenue Box 729, Throckmorton, TX	

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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D2017 - 42 C.F.R. 493.807 Condition: Reinstatement of laboratories performing non-waived testing D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Proficiency Institute (API), the laboratory did not successfully participate in the specialty of Hematology for the analytes Red Blood Cells (RBC) in 3 of 4 events between 2016 and 2017. The findings included: 1. Based on review of the CMS-155 proficiency testing report and API records, the laboratory scores for Red Blood Cell count (RBC) were as follows: 2016 - First event: 0 percent 2016 - Third event: 40 percent 2017 -First event: 20 percent Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance. Refer to D2130. 2. In an interview at 11:28 hours o 8/15/2018 in the break room, the Laboratory Director confirmed the scores listed above were accurate.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Proficiency Institute (API), the laboratory did not successfully participate in the specialty of Hematology for the analytes Red Blood Cells (RBC) in 3 of 4 events between 2016 and 2017. The findings included: 1. Based on review of the CMS-155 proficiency testing report and API records, the laboratory scores for Red Blood Cell count (RBC) were as follows: 2016 - First event: 0 percent 2016 - Third event: 40 percent 2017 -First event: 20 percent Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance. Refer to D2130. 2. In an interview at 11:28 hours o 8/15/2018 in the break room, the Laboratory Director confirmed the scores listed above were accurate.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by:

	Based on a review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Proficiency Institute (API), the laboratory did not successfully participate in the specialty of Hematology for the analytes Red Blood Cells (RBC) in 3 of 4 events between 2016 and 2017. The findings included: 1. Based on review of the CMS-155 proficiency testing report and API records, the laboratory scores for Red Blood Cell count (RBC) were as follows: 2016 - First event: 0 percent 2016 - Third event: 40 percent 2017 -First event: 20 percent Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance. 2. In an interview at 11:28 hours o 8/15/2018 in the break room, the Laboratory Director confirmed the scores listed above were accurate.
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 review of the Vitros 350 verification study, laboratory procedures, and interview with facility personnel, the laboratory failed to verify patient normal ranges from the manufacturer, published literature, or establish reference ranges for the laboratory's patient population for 6 of 6 analytes reviewed on August 15, 2018. The findings included: 1. Based on a review of the Vitros 350 Chemistry System verification study, the accuracy, precision, and reportable range studies were approved by the laboratory director on 10/15/2016. On page 4 of the Ortho Clinical Diagnostics Glossary, the document states: " Reference Interval (Normal Range) Some regulations required that reference interval for each analyte be verified before results are reported out on the instrument. This is interpreted to mean that the normal range for endogenous analytes be validated. Due the difficulty in obtained specimens, validation of reference intervals for therapeutic drugs and some other analytes is not required. Validation is not recommended for assays that have been assigned medical decision limits for healthy patients (i.e. Cholesterol, HDL, LDL, Triglyceride, HgbA1c). Normal ranges are typically established from a study which calculated the central 95 percent of results measured on specimens obtained from healthy persons (minimum of 120 persons). The validation study assumes that this range is correct for the lab's population. Using a minimum of 20 specimens, the validation study proposes that the reference interval is consistent for the samples tested. Each laboratory is responsible for validating published reference intervals for their population." 2. Based on a random review of analyte instructions for use documents: The expected value for Alkaline Phosphatase (ALKP) is listed as 38 - 126 U/L. The expected value for Alanine Aminotransferase (ALT) is listed as 13 - 69 U/L for adults, 9 - 52 U/L for Females, and 21 - 72 U/L for Males. The expected value for Aspartate Aminotransferase (AST) is listed as 15 - 46 for adults, 14 -36 for Females, and 17 - 59 U/L for Males. The expected value for Blood Urea Nitrogen (BUN) is listed as 9 - 20 mg/dL for Males, and 7 - 17 mg/dL for Females. The expected values for Creatinine

	(Crea) are listed as 0.8 -1.5 mg/dL for Males and 0.7 -1.2 mg/dL for Females. The expected values for Glucose for fasting adults is listed as 74 - 106 mg/dL. 3. Based on a random review of two patient reports, the laboratory was currently using the following reference ranges: Alkaline Phosphatase -42 - 128 u/L ALT - 10 - 60 U/L for both male and female patients AST - 10 - 42 U/L for both male and female patients BUN - 7 -18 mg/dL for both male and female patients Creatinine -0.6 - 1.3 mg/dL for both male and female patients Glucose - 70 - 105 mg/dL 4. In an interview at 14:45 hours on 8/15/2018 in the break room, when asked for the origin of the reference values currently in use on patient reports, the Laboratory Director stated that she thought the reference ranges would have come from the manufacturer's instructions for use.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Vitros chemistry analyzer operator's manual, calibration records, calibration verification records, and interview with the Laboratory Director, the laboratory failed to calibrate Creatinine Kinase (CK), Blood Urea Nitrogen (BUN) and alanine aminotransferase (ALT) at least every 6 month or perform calibration verification procedures with a low, mid, and high value every 6 months between September 2016 and August 2018. The findings included: 1. The laboratory must perform calibration verification procedures with at least a minimal (zero) value, a mid-point value, and a maximum value near the upper limit at least once every 6 months unless the laboratory performs a calibration protocol using three (3) or more levels of calibration that include a low, a mid, and high value at least every 6 months. 2. Based on review of the operator's manual for the Vitros chemistry analyzer, on page 6-1, under Calibrating, the document states: "You should calibrate when: Required by government regulations. In the United States, the VITROS 250/350 Chemistry System must have calibration verified or be recalibrated at least every six months." 3. Based on review of calibration records for 2016, 2017, and 2018: The analyte CK was calibrated on the following dates: 1/19/2018 12/14/2017 4/13/2017 9/8/2016 Between

	the date of the survey and 1/19/2018, the elapsed time without a calibration or calibration verification procedures was 6 months and 27 days, excluding the end date. Between 4/13/2017 and 12/14/2017, the elapsed time without a calibration or calibration verification procedures was 8 months and 1 day, excluding the end date. Between 09/08/2016 and 4/13/2017, the elapsed time without a calibration or calibration verification procedures was 7 months and 5 days, excluding the end date. The analyte BUN was calibrated on the following dates: 3/5/2018 1/12/2018 2/27 /2017 9/6/2016 Between 2/27/2017and 1/12/2018, the elapsed time without a calibration or calibration verification procedures was 7 months and 5 days, excluding the end date. The analyte ALT was calibrated on the following dates: 6/22/2018 9/14 /2017 3/22/2017 9/6/2016 Between 9/14/2017 and 6/22/2018, the elapsed time without a calibration or calibration verification procedures was 9 months and 8 days, excluding the end date. 4. In an interview at 17:04 hours on 8/15/2018 in the laboratory, the Laboratory Director confirmed the accuracy of the calibration dates and stated the laboratory performed calibration verification procedures for electrolytes every six (6) months, but did not routinely perform calibration verification procedures for analytes that had not been calibrated at least every six (6) months.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, laboratory policies and procedures, and interview with the Laboratory Director, the laboratory failed to monitor the accuracy and precision of control materials over time for 2 of 2 lot numbers used to assess the performance of the Alere D-dimer test in 2017. The findings included: 1. Based on a review of quality control records for the Alere D-dimer test system, the following two lots of control materials were evaluated to detect immediate error in 2017: Lot: 3271 Expiration 9/28/2017 Lot: 3269 Expiration: 9/9/2017 2. Based on review of the laboratory's quality control procedures and quality control records, the two lots of D-dimer control were not evaluated over time to assess accuracy and precision. 3. In an interview at 11:01 hours on 8/15/2018 in the break room, the Laboratory Director confirmed that controls were evaluated each day of patient testing to detect immediate error but were not evaluated over time for accuracy and precision of the test method.
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 review of quality control records, patient test records, and interview with facility personnel, the laboratory failed to perform two control materials of different concentrations each day of patient testing for 14 of 15 days between June 5, 2017 and July 25, 2017. The findings included: 1. Based on review of quality control records, two levels of quality control materials were tested and within acceptable limits on 6/27 /2017. 2. Based on patient testing records, patient specimens were analyzed on the following dates between June 5, 2017 and July 25, 2017: 6/5/2017 -1 patient tested. No quality control performed. 6/8/2017-1 patient tested. No quality control performed. 6/10/2017-1 patient tested. No quality control performed. 6/12/2017-1 patient tested. No quality control performed. 6/22/2017-1 patient tested. No quality control performed. 6/24/2017-1 patient tested. No quality control performed. 6/27 /2017-1 patient tested. No quality control performed. 6/28/2017 - 2 patients tested 6/29 /2017-1 patient tested. No quality control performed. 7/2/2017-1 patient tested. No quality control performed. 7/12/2017-1 patient tested. No quality control performed. 7 /13/2017-1 patient tested. No quality control performed. 7/17/2017-1 patient tested. No quality control performed. 7/18/2017-1 patient tested. No quality control performed. 7/25/2017-1 patient tested. No quality control performed. 3. Based on review of the Alere D-dimer Test Product Insert (PN:26164en Rev. E, 2017/10), under Quality Control Considerations, the document states the following: "Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures." 4. In an interview at 11:01 hours on 8/15/2018 in the break room, the Laboratory Director confirmed the laboratory had not established an Individualized Quality Control Plan (IQCP) to modify the frequency of quality control testing from each day of patient testing to the manufacturer's suggested each new lot or shipment of test materials, or every 30 days.
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 the blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 1 of 1 day on August 10, 2018. The findings included: 1. Based on review of the Opti-CCA-TS blood gas analyzer operator's manual, on page 23, the document states the following: "Quality Control testing frequency Each facility should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency they operate under. Opti Medical Systems recommends that the SRC measurements should be confirmed within the acceptable ranges on both the high (level 3) and the low (Level 1) at least

	once each day of OPTI operation. On initial use of each lot of sensor cassettes and at 1 month intervals thereafter, validation should be performed by analytes of OPTI check or OPTI check plus." 2. Based on review of function check and quality control records: SRC module function checks were performed on 8/10/2018 between 08:06 hours and 08:11 hours. The last OPTI CCA-TS liquid controls were performed and within limits on July 3, 2018. 3. Based on review of patient records, testing was performed on a specimen from patient 10010391 on 8/10/2018. The laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 1 of 1 day on August 10, 2018. 4. In an interview with the Laboratory Director on 8/15 /2018 at 13:57 hours in the break room, the Laboratory Director stated the laboratory had not implemented an Individualized Quality Control Plan to modify the frequency of testing liquid controls at least one level every 8 hours of patient testing to include both a low and high control each day of patient testing to the frequency in the operator's manual of each lot of sensor cassettes and at 1 month intervals thereafter, validation should be performed by analytes of OPTI check or OPTI check plus. Based on review of patient records, only one patient had been tested between January 1, 2018 and the date of the survey, August 15, 2018.
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 review of the laboratory's quality control records, patient records, verification study records, and interview with facility personnel, the laboratory failed to establish and follow quality assessment procedures capable of identifying, monitoring, and correcting problems in analytic systems. The laboratory's quality assessment activities failed to identify, monitor, and correct the following: Based on review of the Vitros 350 verification study, laboratory procedures, and interview with facility personnel, the laboratory failed to verify patient normal ranges from the manufacturer, published literature, or establish reference ranges for the laboratory's patient population for 6 of 6 analytes reviewed on August 15, 2018. Refer to D5421. Based on review of the Vitros chemistry analyzer operator's manual, calibration records, calibration verification records, and interview with the Laboratory Director, the laboratory failed to calibrate Creatinine Kinase (CK), Blood Urea Nitrogen (BUN) and alanine aminotransferase (ALT) at least every 6 month or perform calibration verification procedures with a low, mid, and high value every 6 months between September 2016 and August 2018. Refer to D5439. Based on review of quality control records, laboratory policies and procedures, and interview with the Laboratory Director, the laboratory failed to monitor the accuracy and precision of control materials over time for 2 of 2 lot numbers used to assess the performance of the Alere D-dimer test in 2017. Refer to D5441. Based on review of quality control records, patient test records, and interview with facility personnel, the laboratory failed to perform two control materials of different concentrations each day of patient testing for 14 of 15 days between June 5, 2017 and July 25, 2017. Refer to D5447. Based on a review of the blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the laboratory failed to test one

	sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 1 of 1 day on August 10, 2018. Refer to D5537. In an interview at 17:10 hours on 8/15/2018 in the break room, when asked how the laboratory conducted quality assessment procedures, the Laboratory Director stated the laboratory used a monthly checklist.
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 review of the Cell-Dyn Emerald verification study, random review of patient records, and interview with the Laboratory Director, the laboratory failed to use pertinent reference intervals (normal values) for analytes reported in a complete blood count (CBC). The findings included: 1. Based on review of the Abbott Cell-Dyn Emerald verification study, the instrument was approved for use by the laboratory director on 11/05/2012 -approximately 5 years and 9 months prior to the date of the survey. 2. Based on review of the Abbott Cell-Dyn Emerald operator's manual, on page 4-16, the document states the following: "These ranges do not represent globally applicable reference intervals, but reflect combined reference ranges tested in the validation study. Each laboratory should establish/verify its own reference intervals." A listing of a few of the analytes and the associated reference intervals from table 4.15 from page 4-16: White blood cell count (WBC) Sex: M/F N = 270 Range: 4.70 -10.30 thousand per microliter (K/uL) Red blood cell count Sex: M /F N =270 Range: 4.03 - 5.46 million per microliter (M/uL) Hemoglobin Sex: M/F N = 270 Range: 12.40 - 16.90 grams per deciliter (g/dL) Platelet count Sex: M/F N = 270 Range: 165 - 385 thousand per microliter (K/uL) 3. A random review of patient reports indicated the following reference ranges were in use by the laboratory: WBC: 4.1 -10.9 K/uL RBC: 4.2 -6.3 M/uL Hemoglobin: 12.0 - 18.0 g/dL Platelet: 140 - 440 K/uL 4. In an interview at 14:52 hours on 8/15/2018 in the break room, when asked about the origins of the complete blood count reference ranges currently in use by the laboratory, the Laboratory Director stated that she assumed the reference ranges would match the manufacturer's reference range and that the laboratory had not established their own ranges or verified ranges from published literature to her knowledge. Key N=270: This is the sample size of the study performed by Abbott
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 laboratory proficiency testing performance, quality control records, verification study records, and interview with facility personnel, the Laboratory Director failed to provide overall management and direction of the laboratory services. Refer to D6013. D6016, and D6020.

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 review of the Vitros 350 verification study, laboratory procedures, and interview with facility personnel, the Laboratory Director failed to ensure patient normal ranges from the manufacturer, published literature were verified or established reference ranges for the laboratory's patient population for 6 of 6 analytes reviewed on August 15, 2018. Refer to D5421.
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 proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Proficiency Institute (API), the Laboratory Director failed to ensure that the laboratory successfully participated in the specialty of Hematology for the analytes Red Blood Cells (RBC) in 3 of 4 events between 2016 and 2017. Refer to D2130.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control records, patient records, and confirmed in interview with the laboratory director, the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services. The findings included: Based on review of quality control records, laboratory policies

	and procedures, and interview with the Laboratory Director, the Laboratory Director failed to ensure quality control procedures were established to monitor the accuracy and precision of control materials over time for 2 of 2 lot numbers used to assess the performance of the Alere D-dimer test in 2017. Refer to D5441. Based on review of quality control records, patient test records, and interview with facility personnel, the Laboratory Director failed to ensure the laboratory performed two control materials of different concentrations each day of patient testing for 14 of 15 days between June 5, 2017 and July 25, 2017. Refer to D5447. Based on a review of the blood gas analyzer operator's manual, quality control records, patient test records, and interview with facility personnel, the Laboratory Director failed to ensure the laboratory tested one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values each day of patient testing for 1 of 1 day on August 10, 2018. Refer to D5537.