Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698063	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Baylor St Luke's Medical Group	310 Gaslight Boulevard, Lufkin, 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	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant. D6063 - 42 C.F.R. 493.1412 Condition: Laboratories performing moderate complexity testing; testing personnel. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the CLIA/FDA database, review of the laboratory's records from 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments in 2020 for the non-regulated analyte D-Dimer performed on the Quidel Triage MeterPro (Serial Number: SN79125). The findings included: 1. A review of the laboratory's test menu submitted on October 27, 2021 revealed the laboratory

	performed D-Dimer testing using the Quidel Triage MeterPro. 2. Review of the CLIA /FDA database stated the following for D-Dimer testing using the Quidel Triage MeterPro: Document: #CR180370 Parent Document #: K042890 Effective Date: 06-29-2018 Complexity: Moderate 3. Review of laboratory records found no PT enrollment or twice annual accuracy assessments for 2020 for D-Dimer. 4. The laboratory was asked to provide documentation of performing twice annual accuracy assessments for D-Dimer in 2020. No documentation was provided. 5. An interview with the primary testing person on October 27, 2021 at 09:45 hours in the laboratory confirmed the findings. When asked if the D-Dimer test was waived or moderate, she stated, "It is waived." She went on to say that she thought it was waived because other tests on the same instrument are waived. Key: CLIA - Clinical Laboratory Improvement Amendments FDA - Food and Drug Administration
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 surveyor observations, review of manufacturer's instructions, review of quality control records, patient records, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to provide documentation of monitoring revised expiration dates (refer to D5415). 2. The laboratory failed to provide documentation of performing verification studies on the Quidel Triage MeterPro for moderate complexity D-Dimer testing (refer to D5421). 3. The laboratory failed to provide documentation of having a mechanism in place to detect immediate errors and errors over time (refer to D5441). 4. The laboratory failed to provide documentation of performing quality control testing prior to patient testing after a change of reagents on the Sysmex XN-300 hematology analyzer (refer to D5461). 5. The laboratory failed to provide documentation of verifying new lots of quality control reagents prior to placing them into use (refer to D5469).
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: II. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for three of three Quidel Triage MeterPro D-Dimer cartridges stored

	at room temperature. The findings included: 1. Surveyor observation on October 27, 2021 at 09:15 hours found three Quidel Triage MeterPro D-Dimer cartridges located in container next to the instrument. Lot #T12457 Manufacturer expiration date: 02-24-2022 No revised or open date documented 2. Review of the manufacturer's instructions for the Quidel Triage MeterPro D-Dimer cartridges under, "Storage and Handling Requirements" it stated, "Store the Test Devices in a refrigerator at 2C to 8C (35F to 46F). Once removed from refrigeration, the pouched Test Device is stable for up to 14 days at room temperature, but not beyond the expiration date printed on the pouch. With a soft, felt tip marker, gently write the date and time of removal from the refrigerator on the pouch and cross out the manufacturer expiration date printed on the pouch. Care must be taken to document the time the product is at room temperature. Once equilibrated to room temperature, do not return the Test Device to refrigeration ..." 3. The laboratory was asked to provide documentation of monitoring the revised expiration date of the cartridges. No documentation was provided. 4. An interview with the primary testing person on October 27, 2021 at 09:17 hours in the laboratory confirmed the findings. She was aware of the revised expiration date once at room temperature. She went on to say that the laboratory would utilize the cartridges prior to the 14 day expiration dates. 45469 I. Based on the surveyor's direct observation, review of the Bio-Rad Liquicheck Immunoassy Plus control instructions for use (IFU), and confirmed in interview, the laboratory failed to document revised expiration dates on opened QC bottles for three of three QC lot numbers in use. The findings included: 1. Tour of the laboratory facilities conducted 10/27/2021 at 09:30 hours, and subsequent surveyor's direct observation found unlabeled, thawed Bio-Rad Liquidcheck QC in the refrigerator with no open or revised expiration date documented. Bio-Rad Level 1 - Lot 85231 Exp: 2/28/2022 Bio-Rad Level 2 - Lot 85232 Exp: 2/28/2022 Bio-Rad Level 3 - Lot 85233 Exp: 2/28/2022 2. Review of Bio-Rad Liquicheck Immunoassay plus control IFU (Ref 360) section Storage and Stability, subsection Thawed Opened stated the following; "When thawed, opened, and stored tightly capped at 2 to 8(degrees) C, this product will be stable as follows: - All analytes: 14 days Except: - Estradoil: 5 days - Folate: 4 days" 3. Review of the CMS-116 Estimated Annual test volume, signed by the laboratory director 10/27 /2021, listed the annual test volume for the specialty of Chemistry as 24,475. 4. An interview with the primary testing personnel on 10/27/21 at 15:45 hours in the lab confirmed the above findings. The primary testing personnel stated they forgot to indicate the revised expiration date after opening. Key: CMS=Center of Medicare and Medicaid QC=Quality Control
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: II. Based on review of laboratory verification studies for D-Dimer performed on the Quidel Triage MeterPro, and confirmed in interview of facility personnel, the laboratory failed to have documentation of a complete verification study. The findings

	included: 1. A review of laboratory records found no verification studies for the Quidel Triage MeterPro used for D-Dimer testing. The laboratory failed to provide documentation of performing accuracy, precision, reportable range of the analyzer, and patient normal ranges. 2. The laboratory was asked to provide documentation of completing a verification study for D-Dimer. No documentation was provided. 3. An interview with the primary testing person on October 27, 2021 at 09:45 hours in the laboratory confirmed the findings. When asked if the D-Dimer test was waived or moderate, she stated, "It is waived." Later, at 11:30 hours in the conference room she provided a one page document that she stated was the correlation study but it did not have any raw data or information identifying where the information came from. 45469 I. Based on review of the laboratory's verification studies for the Sysmex XP300 hematology analyzer, review of patient test records and staff interview, the laboratory failed to have documentation of verifying patient normal ranges for 1 of 1 patient normal range used for testing CBCs (complete blood count). The findings included: 1. A review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for CBCs. 2. Review of patient records revealed the following listed CBC range was in use for males and females: WBC 3.1-13 Lymph % 15.0 - 55.0 Lymph absolute 0.5 - 6.0 MXD % 0.5 - 12.0 MXD absolute 0.1 - 0.8 Neut % 35.0 - 80 Neut absolute 0.04 - 1.4 RBC 3.2 - 7.0 HGB 10.5 - 18.0 HCT 33.0 - 60.0 MCV 80.0 - 100.0 MCH 26.0 - 34.0 MCHC 30.0 - 37-0 RDW 35.3 - 48.9 Platelets 100 - 500 MPV 6.0 - 12.0 3. Review of the annual test volume listed on the CMS-116 form submitted 10/26/2021 lists the laobratory's 'Total Estimated Annual Test Volume' for the Specialty 'hematology' as 7,920. 4. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 5. An interview with the technical consultant on 10/27/2021 at 16:30 hours in the laboratory confirmed the findings. Key: % - percent Lymph - Lymphocyte MXD - Mixed Cell Count Neut - Neutrophil RBC - red blood cell WBC - white blood cell HGB - hemoglobin HCT - hematocrit MCV - mean cell volume MCHC - mean corpuscular hemoglobin concentration RDW - red cell distribution width MPV - mean platelet volume
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: I. Based on review of laboratory quality control records from II. Based on review of the laboratory's quality control records from September 2020 to October 2021 for the Quidel Triage MeterPro (Serial Number 79125) used in testing for D-Dimer, review of manufacturer's instructions, and confirmed in interview with facility personnel, the laboratory failed to provide documentation of reviewing quality control over time for 13 of 13 months reviewed. The findings included: 1. Review of quality control

	records for the Quidel Triage MeterPro from September 2020 to October 2021 found no documentation of quality control over time that could identify errors over time. 2. Review of the laboratory's QC records for D-Dimer testing using the Quidel Triage MeterPro from September 2020 to October 2021 found the laboratory performed external QC testing as follows: 09-29-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 10-31-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 12-15-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 01-14-2021 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 02-02-2021 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 03-30-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 04-12-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 05-12-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 06-08-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 07-01-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 08-08-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 09-02-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 09-30-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 10-04-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 3. The laboratory was asked to provide documentation of monitoring D-Dimer quality records over time to identify errors over time. No documentation was provided. 3. An interview with the primary testing person on October 27, 2021 at 11:30 hours in the conference room confirmed the findings.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of laboratory patient test results, and confirmed in interview, the laboratory failed to document the performance of controls after a change in reagents on the Sysmex XP-300 hematology analyzer for three out of four days reviewed. Findings were: 1. A review of the facility's Hematology quality control (QC) records and event logs revealed no documentation that quality control had been performed when the following reagents were placed in use on the Sysmex XP-300 hematology analyzer. 12/23/2020 at 13:57 Cellpack Lot No Y0081 Exp 3/1 /22 5/18/2021 at 09:08 Cellpack Lot No Y0005 Exp 7/12/22 8/26/2021 at 12:46 Cellpack Lot No Y1041 Exp 10/14/22 2. A review of patent testing showed the following patients were tested after the Cellpack reagent was changed: Patient ID CBC Collection Date, Time, and Release Time 8550 12/23/2020 - 13:03- 13:31 9807 5 /18/2021 - 09:14 - 12:35 10728 8/26/2021 - 16:06 - 16:40 10729 8/26/2021 - 16:20 - 16:44 10730 8/26/2021 - 16:39 - 17:03 3. An interview with the primary testing person 10/27/21 at 10:50 hours in the laboratory confirmed the above findings.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's quality control records from December 2019 to February 2021 for the TOSOH chemistry analyzer used for TSH testing, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of verifying six of six new lot numbers of controls prior to placing them into use. The findings included: 1. Review of the laboratory's policy titled, "Quality Control Policy" approved by the laboratory director on July 10, 2019, it stated: "This procedure provides information for processing and monitoring Quality Control (QC) within the In and Out Clinic Laboratory. Quality Control is used to monitor the reliability of the instrument and reagents. The performance of analytical methods is monitored by analyzing specimens whose concentration are known then comparing the observed values with known values. The known values are represented by a range of acceptable values upper and lower limits for the control specimen (control limits) ..." 2. Review of quality control records from December 2019 to February 2021 for the TOSOH chemistry analyzer used by the laboratory to perform TSH testing found no documentation of verifying new lot numbers of controls for the following six of six lot numbers of controls prior to placing them into use: BioRad Immunoassay Plus Lot 85231 (expiration date: 02-28-2022) BioRad Immunoassay Plus Lot 85232 (expiration date: 02-28-2022) BioRad Immunoassay Plus Lot 85233 (expiration date: 02-28-2022) BioRad Immunoassay Plus Lot 40981 (expiration date 09-30-2020) BioRad Immunoassay Plus Lot 40982 (expiration date: 09-30-2020) BioRad Immunoassay plus Lot 40983 (expiration date: 09-30-2022) 3. The laboratory was asked to provide documentation of verifying new lots of control material prior to placing them into use No documentation was provided. 4. In an interview with the primary testing person on October 27, 2021 at 15:50 hours in the break room confirmed the findings. She stated that she does that for the Sysmex but did not know she needed to do it for the TOSOH. This confirmed the findings.
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 review of manufacturer's instructions, review of the laboratory's quality control (QC) records for D-Dimer performed on the Quidel Triage MeterPro from September 2020 to October 2021, random review of patient records, and confirmed in interview with facility personnel, the laboratory failed to provide documentation of performing quality control testing every 8 hours of patient testing for 13 of 13 months reviewed. The findings included: Note: The laboratory did not develop an IQCP for D-Dimer testing to reduce the frequency of quality control testing on the Quidel Triage MeterPro. Therefore, the laboratory must perform quality control testing every 8 hours of patient testing. 1. Review of the manufacturer's instructions for the Alere Triage MeterPro for D-Dimer stated, " ...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. Controls should be tested in the same manner as if testing patient specimens. When running patient specimens or external controls, if an analyte fails for any reason (built-in control failure or an external control out of range) no patient results will be reported. Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 2. The manufacturer's instructions are less stringent than the CLIA regulations at CFR 493, and the laboratory did not provide evidence of developing an IQCP plan. 3. Review of the laboratory's QC records for D-Dimer testing using the Quidel Triage MeterPro from September 2020 to October 2021 found the laboratory performed external QC testing as follows: 09-29-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 10-31-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 12-15-2020 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 01-14-2021 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 02-02-2021 Lot # C3652AN (exp. date: 05-01-2021) Lot # C3664AN (exp. date: 05-07-2021) 03-30-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 04-12-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 05-12-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 06-08-2021 Lot # C3659AN (exp. date: 08-27-2021) Lot # C3672AN (exp. date: 09-096-2021) 07-01-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 08-08-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 09-02-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 09-30-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 10-04-2021 Lot # C3768 (exp. date: 02-26-2022) Lot # C8791 (exp. date: 02-22-2022) 4. Random review of patient records revealed patient testing was performed the following days when no quality control testing was documented each 8 hours of patient testing: See patient alias list 5. The laboratory was asked to provide documentation of performing two levels of quality control testing each 8 hours of patient testing from September 2020 to October 2021 for D-Dimer or developing an IQCP to reduce the frequency of quality control testing. No documentation was provided. 6. An interview with the primary testing person on October 27, 2021 at 11: 30 hours in the conference room confirmed the findings. She stated the laboratory runs controls every 30 days. Key: IQCP - Individualized Quality Control Plan
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that

	ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex XN-300 hematology analyzer, instrument print outs, laboratory patient records, and confirmed in interview, the laboratory failed to ensure corrective actions were performed to address flags on CBC (complete blood count) results for 4 out of 6 CBC (complete blood count) patient results reviewed in October 2021. The findings included: 1. Review of the Sysmex XP-300 Instructions for Use (Code No. AU553517) chapter 8 'Display and Output of Analysis Results' subsection 'Description of the analysist result screens' gives the following: 'Meanings of signs displayed on the left of the analysis data are as follows:' Sign Explanation [!] Value is out of the linearity limit. [+] Result exceeds the upper patient limit. [-] Result exceeds the lower patent limit. [*] Result is unreliable. 'In 3 histograms (RBC, WBC, PLT), the volume distribution is shown graphically. Flags are indicated by one of the following. Flag Explanation [WL] Relative frequency of WBC-LD has exceeded the range. [WU] Relative frequency of WBC-UD has exceeded the range. [T1] T1 discriminator position cannot be determined. [T2] T2 discriminator position cannot be determined. [F1] Relative frequency of T1 has exceeded the range. [F2] Relative frequency of T1 or T2 has exceeded the range. [F3] Relative frequency of T2 has exceeded the range. [RL] Relative frequency of RBC-LD has exceeded the range. [RU] Relative frequency of RBC-UD has exceeded the range. [DW] Distribution width cannot be calculated. [MP] There are multiple peaks. [PL] Relative frequency of PLT-LD has exceeded the range. [PU] - Relative frequency of PLT-UD has exceeded the range. [AG] - The particle count equal or less than WBC-LD has exceeded the range. 2. Random review of the laboratory patient test records from October 2021 revealed the laboratory reported 4 of 6 CBC results with no documentation of the corrective action to resolve the system flags. Date Patient ID Flags 10/14/2021 11014051 AG* 10/28/2021 11027011 AG* 10/25/2021 11025125 WU, T1 10/22/2021 11022097 WU, F1, T2 3. The laboratory was asked to provide documentation of performing corrective actions to resolve the potential instrument or sample errors. No documentation was provided. 4. An interview with the primary testing personnel on 10/27/2021 at 1500 hours in the laboratory confirmed the above findings. She went on to say the laboratory does not have a written policy for how to handle flags on CBC results and that she would hand the provider a list of the flags.
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 random review of patient reports from January 2020 to October 2021, and confirmed in interview of facility personnel, the laboratory failed to include the

	correct facility address on 30 of 30 patient reports. The findings were: 1. A random review of patient reports from January 20, 2020 to October 2021 found the laboratory failed to include the correct testing facility address on 30 of 30 patient test reports. 2. The laboratory was asked to provide documentation of patient reports which included the laboratory's correct address. No documentation was provided. 3. An interview with the primary testing person on October 27, 2021 at 11:30 hours in the conference room found she was unaware the wrong address was on the patient reports and she would have to work with someone in IT. This confirmed the findings.
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 surveyor observations, review of manufacturer's instructions, laboratory records, patient results, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory (refer to D6013, D6014, D6020, and D6029).
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 laboratory records and staff interview, it was revealed the laboratory director failed to ensure verification studies were performed and complete prior to performing patient testing (refer to D5421).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex XN-300

	hematology analyzer, review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure laboratory personnel performed testing to ensure accurate and reliable results (refer to D5779).
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 laboratory quality control records and confirmed in interview with facility personnel, the laboratory director failed to ensure a quality control plan is established and maintained (refer to D5441, D5461, D5545, and D5469).
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 review of laboratory personnel records, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to ensure two of two testing personnel received training prior to patient testing for the Quidel Triage MeterPro for D-Dimer testing. The findings included: 1. Review of personnel records for Testing Personnel #1 and Testing Personnel #2 (as listed on Form CMS-209) found no documentation of training records for the Quidel Triage MeterPro when it implemented a new analyte, D-Dimer, in September 2020. 2. Review of patient test logs found the laboratory began patient testing for D-Dimer in September 2020 and that both Testing Personnel #1 and Testing Personnel #2 (as listed on Form CMS-209) perform patient testing for moderate complexity D-Dimer testing. 3. The laboratory was asked to provide documentation of training testing personnel on the D-Dimer prior to patient testing. No documentation was provided. 4. An interview with the primary testing person on October 27, 2021 at 11:30 hours in the conference room confirmed the findings. She stated she did not realize they needed training since they thought it was waived and done the same way as other analytes on the same analyzer.
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 surveyor observations, review of manufacturer's instructions, laboratory records, patient results, and confirmed in interview of facility personnel, the technical consultant failed to provide technical oversight of the laboratory (refer to D6039, D6040, D6042, and D6045).
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on review of the CLIA/FDA database, review of laboratory records and confirmed in interview of facility personnel, the technical consultant failed to select appropriate test methodology for clinical use. The findings included: 1. Review of the CLIA/FDA database stated the following for D-Dimer testing using the Quidel Triage MeterPro: Document: #CR180370 Parent Document #: K042890 Effective Date: 06-29-2018 Complexity: Moderate 2. The Technical Consultant failed to ensure the laboratory recognized that D-Dimer testing on the Quidel Triage MeterPro was a moderate complexity test. 3. An interview with the primary testing person on October 27, 2021 at 09:45 hours in the laboratory confirmed the findings. When asked if the D-Dimer test was waived or moderate, she stated, "It is waived." She went on to say that she thought it was waived because other tests on the same instrument are waived.
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 review of the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure verification studies were performed and complete prior to performing patient testing (refer to D5421).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of laboratory quality control records and confirmed in interview with facility personnel, the technical consultant failed to ensure the laboratory's quality control program required the laboratory to verify manufacturer means and ranges to assess control acceptability prior to placing new lot numbers into use (refer to D5469).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, instrument verification records, and confirmed in interview of facility personnel, the technical consultant failed to identify that 2 of 2 testing personnel did not have documentation of training prior to implementing a new moderate complexity test on the Quidel Triage MeterPro (refer to D6066).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview it was determined that one of three testing personnel failed to have documentation of education required to perform moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on review of the laboratory's personnel records and confirmed in interview of facility personnel found that one of three testing personnel failed to have documentation of education required to perform moderate complexity testing. The findings included: 1. Review of the laboratory's personnel records found Testing Person number 3 (as listed on Form CMS-209) did not have documentation of education for moderate complexity testing on file. 2. The laboratory was asked to provide education documents qualifying Testing Person number 3 to perform moderate complexity testing. No documentation was provided. 3. An interview with Testing Personnel #2 (as listed on Form CMS-209 on October 27, 2021 at 16:00 hours in the break room confirmed the findings. She stated they did not have a high school diploma for Testing Personnel #3. This confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, instrument verification records, and confirmed in interview of facility personnel, two of two testing personnel performing moderate complexity testing failed to have documentation of training prior to testing patients for the Quidel Triage MeterPro D-Dimer. The findings included: 1. The laboratory implemented moderate complexity D-Dimer testing using the Quidel Triage MeterPro in September 2020. 2. Review of personnel records for the two of two testing personnel performing testing on the analyzer failed to have documentation of training prior to patient testing that would qualify them to perform moderate complexity testing. 3. An interview with the primary testing person on October 27, 2021 at 09:45 hours in the laboratory confirmed the findings. When asked if the D-Dimer test was waived or moderate, she stated, "It is waived." She went on to say that she thought it was waived because other tests on the same instrument are waived.