Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1036892	04/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Drumright Community Hospital, Llc	610 West Bypass, Drumright, 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 recertification survey was performed on 04/22/2021 and 04/23/2021. The findings were reviewed with the laboratory manager and testing person #2 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1215; D5024: Hematology 493.1402; D6000: Laboratory Director
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Blood Gas testing. Findings include: (1) 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 included both low and high values on each day of blood gas testing for 13 of 14 days. Refer to D5537; (2) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
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, and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the specialty of Hematology for Coagulation testing. Findings include: (1) The laboratory failed to ensure the verified reportable ranges were used by the laboratory for D-Dimer testing Refer to D5421; (2) 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 D-Dimer testing for 1 of 1 days; and 10 of 15 days of PT/INR (Prothrombin Time/International Normalized Ratio) testing. Refer to D5545; (3) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for 4 of 12 events. Findings include: FAILURES (1) On 04/22/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following failures: (a) Third 2020 Hematology Event (i) Blood Cell Identification - The laboratory failed the results for 1 of 5 samples (BCI-13); (b) First 2020 Coagulation Event (i) PT (Prothrombin Time) - The laboratory failed the results for 1 of 5 samples (CHP-03); (2) The surveyor could not locate evidence in the records proving the failures had been addressed; (3) The surveyor reviewed the records with testing person #1, and asked if corrective action had been taken and documented for the failures. Testing person #1 stated on 08/26/2021 at 01:03 pm corrective action had not been taken. BIASES (1) On 04/22/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2020 Chemistry Core Event (i) Amylase - 4 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -2.2 (bb) Sample CH-07 - SDI of -2.4 (cc) Sample CH-08 - SDI of -2.2 (dd) Sample CH-10 - SDI of -2.1 (ii) Glucose - 4 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.2 (bb) Sample CH-07 - SDI of 2.7 (cc) Sample CH-08 - SDI of 2.8 (dd) Sample CH-10 - SDI of 2.3 (b) First 2020 Hematology Event (i) Lymphocytes - 3 of 5 results exhibited a positive bias (aa) Sample PNT-01 - SDI of 2.4 (bb) Sample PNT-02 - SDI of 2.0 (cc) Sample PNT-05 - SDI of 2.2 (ii) MCHC (Mean Corpuscular Hemoglobin Concentration) - 3 of 5 results exhibited a positive bias (aa) Sample PNT-01 - SDI of 2.6 (bb) Sample PNT-02 - SDI of 2.0 (cc) Sample PNT-05 - SDI of 2.0 (iii) MCV (Mean Corpuscular Volume) - 4 of 5 results exhibited a positive bias (aa) Sample PNT-01 - SDI of 2.6 (bb) Sample PNT-02 - SDI of 3.7 (cc) Sample PNT-04 - SDI of 3.8 (dd) Sample PNT-05 - SDI of 3.8 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 04/22/2021 at 01:15 pm the biases had not been addressed.

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 laboratory manager, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 12 events. Findings include: (1) On 04/22/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 Third Event - Red Blood Cell Identification sample ECI-15. (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked the laboratory manager if the result had been documented as evaluated. The laboratory manager reviewed the records and stated on 04/22/2021 at 11:55 am the non-graded result had not been documented as reviewed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring routine Hematology, Chemistry, and Urinalysis testing. Findings include: (1) On 04/22/2021, the laboratory manager stated the following to the surveyor at 10:00 am: (a) The laboratory performed routine chemistry testing using the Beckman Coulter AU480 analyzer; (b) The laboratory performed routine CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (c) The laboratory performed urine sediment examinations; (d) Specimens were transported to the laboratory from an outside long term care facility. (2) On 04/23 /2021, the surveyor asked the laboratory manager if instructions (e.g., client service manual) had been written and provided to the client which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager stated on 04/23/2021 at 09:25 am specimen handling instructions had not been written and provided to the client.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure an analyzer was stored as required by the manufacturer for 2 of 2 months. Findings include: (1) On 04/22/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) on the Sysmex XP-300 analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from February 2021 through March 2021 and identified documented humidity readings were less than 30% for 2 of 2 months as follows: (a) February - 3 of 28 humidity readings were documented as less than 30% (days 1,2,5); (b) March - 20 of 31 humidity readings were documented as less than 30% (days 6,7,8,9,10,11,12,13,14,15,16,17,18,19,21,22,23,24,25,28). (4) The surveyor reviewed the records with the laboratory manager, who stated on 04/22 /2021 at 04:15 pm the humidity of the laboratory had been maintained below 30% as indicated above.
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, written procedure, and interview with the laboratory manager, the laboratory failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Findings include: SYSMEX XP-300 ANALYZER (1) On 04/22/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory began using the Sysmex XP-300 analyzer to perform CBC (Complete Blood Count) testing on 07/01/2020; (2) The surveyor reviewed performance specification records for the analyzer and identified the laboratory had demonstrated the following reportable range for the following: (a) Hemoglobin - 0 - 20.9 g/dL (3) The surveyor then reviewed the laboratory procedure manual and identified that the procedure defined the reportable range for the following: (a) Hemoglobin - 0.0 - 25.0 g/dL (4) The surveyor reviewed the findings with the laboratory manager who stated on 04/04/2021 at 02:30 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory as indicated above. ALERE TRIAGE (1) On 04/22/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory began using the Alere Triage analyzer to perform D-Dimer testing on 08/16/2019; (2) The surveyor reviewed performance specification records for the analyzer and identified the laboratory had demonstrated the following

	reportable range of 0 - 4520 mg/ml; (3) The surveyor then reviewed the laboratory procedure manual and identified that the procedure defined the reportable range as 0 - 5000 mg/ml; (4) The surveyor reviewed the findings with the laboratory manager who stated on 04/04/2021 at 02:40 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory as indicated above.
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 laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing 1 of 4 quarterly maintenance procedures. Findings include: (1) On 04/22 /2021 at 09:55 am, the laboratory manager stated to the surveyor that routine chemistry testing was performed on the Beckman Coulter AU480 analyzer; (2) On 04 /23/2021, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance electronic logs. The requirements for quarterly maintenance were as follows: (a) Inspect Deionized W. Filter (b) Inspect S. Probe Filter (c) Clean Air Filters (d) Replacing Pump Roller Tubes (3) The surveyor then reviewed maintenance records for 21 months (June 2019 through February 2021). There was no evidence the weekly maintenance had been performed: (a) Between 06/07/2019 and 02/16/202 (4) The surveyor reviewed the records with the laboratory manager, who stated on 04/23/2021 at 03:25 pm, the quarterly maintenance had not been documented as performed as required.
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 laboratory manager, the laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing for 12 of 14 days. Findings include: (1) On 04/22 /2021 at 10:25 am, the laboratory manager stated the following to the surveyor: (a) Blood Gas (pH, pCO2, pO2) testing was performed using the OPTI-CCA-TS analyzer; (b) Two levels of quality control (QC) testing were performed each 8 hours of patient testing. (2) On 04/23/2021, the surveyor reviewed QC and patient testing records for January 2020 through July 2020. The review showed that two levels of QC testing had not been performed each eight hours of patient testing on each day of patient testing for 12 of 14 days of patient testing reviewed as follows: (a) 01/01 /2020- Patient #10088 had been tested at 10:50 am and level 1 and level 3 QC had not been performed; (b) 01/11/2020 - Patient #12903 had been tested at 01:24 pm and

	level 1 and level 3 QC had not been performed; (c) 01/17/2020 - A patient #11626 had been tested at 01:06 pm and level 1 and level 2 QC had not been performed; (d) 01 /18/2020 - A patient #10683 had been tested at 01:32 pm and level 1 and level 2 QC had not been performed; (e) 01/21/2020 - A patient #12991 had been tested at 08:56 am and level 1 and level 3 QC had not been performed; (f) 01/23/2020- A patient #10410 had been tested at 09:16 am am and level 1 and level 3 QC had not been performed; (g) 02/06/2020 - A patient #13073 had been tested at 06:44 pm and level 1 and level 3 QC had not been performed; (h) 02/21/2020 - A patient #13494 had been tested at 12:29 pm and level 1 and level 2 QC had not been performed; (i) 02/29/2020 - A patient #13594 had been tested at 09:35 am and level 1 and level 2 QC had not been performed; (j) 03/19/2020 - A patient #10088 had been tested at 11:43 am and level 1 and level 2 QC had not been performed; (k) 03/16/2020- A patient #13488 had been tested at 03:05 pm and QC had not been performed; (l) 07/08/2020 - A patient #10871 had been tested at 08:26 am and QC had not been performed. (3) The surveyor reviewed the records with the laboratory manager, who stated on 04/23/2020 at 02:25 pm two levels of QC materials had not been performed each 8 hours of patient testing as indicated above.
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 laboratory manager, the laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing for 1 of 1 day of patient testing; and failed to perform two levels of quality control materials each eight hours of PT/INR for 10 of 15 days of patient testing. Findings include: D-DIMER TESTING (1) On 04/22/2021 at 10:55 am, the laboratory manager stated the following to the surveyor: (a) D-Dimer testing was performed using the Alere Triage analyzer; (b) Two levels of quality control (QC) testing were performed each 8 hours of patient testing. (2) On 04/23/2021, the surveyor reviewed QC and patient testing records from February 2021. The review showed that two levels of QC testing had not been performed each eight hours of patient testing on each day of patient testing for 1 of 1 days of patient testing reviewed as follows: (a) 02/21/2021- Patient #11684 had been tested at 10:33 pm and level 1 and level 3 QC had not been performed. (3) The surveyor reviewed the records with the laboratory manager, who stated on 04/23/2021 at 02:50 pm two levels of QC materials had not been performed each 8 hours of patient testing as indicated above. PT/INR TESTING (1) On 04/22/2021 at 10:47 am, the laboratory manager stated the following to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the Hemochron Signature Elite analyzer; (b) Two levels of quality control (QC) testing were performed each 8 hours of patient testing. (2) On 04/23/2021, the surveyor reviewed QC and patient testing records for January 2021 through February 2021. The review showed that two levels of QC testing had not been performed each eight hours of patient testing on each day of patient testing for 10 of 15 days of patient testing reviewed as follows: (a) 01/27/2021- Patient #10423 had been tested at 03:44 pm and level 1 and level 3 QC had not been performed; (b) 01/28/2021- Patient #10423 had been tested at 11:36 am and level 1

	and level 3 QC had not been performed; (c) 01/29/2021- A patient #10423 had been tested at 07:20 amand level 1 and level 2 QC had not been performed; (d) 01/30/2021- A patient #10423 had been tested at 08:13 am and level 1 and level 2 QC had not been performed; (e) 02/01/2021- A patient #10423 had been tested 07:55 am and level 1 and level 3 QC had not been performed; (f) 02/02/2021- A patient #10423 had been tested at 07:10 am and level 1 and level 3 QC had not been performed; (g) 02/03 /2021- A patient #10423 had been tested at 07:25 am and level 1 and level 3 QC had not been performed; (h) 02/05/2021- A patient #10423 had been tested at 07:05 am and level 1 and level 2 QC had not been performed; (i) 02/07/2021- A patient #10423 had been tested at 07:12 am and level 1 and level 2 QC had not been performed (j) 02 /25/2021- A patient #10423 had been tested at 07:04 am and level 1 and level 2 QC had not been performed. (3) The surveyor reviewed the records with the laboratory manager, who stated on 04/23/2021 at 03:10 pm two levels of QC materials had not been performed each 8 hours of patient testing as indicated above.
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, written procedures, manufacturer's instructions, and interview with the laboratory manager, 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 ensure an analyzer was stored as required by the manufacturer for 2 of 2 months. Refer to D5413; (b) The laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents; and failed to ensure the verified reportable ranges were used by the laboratory. Refer to D5421; (c) The laboratory failed to follow the manufacturer's instructions for performing 1 of 4 quarterly maintenance procedures. Refer to D5429; (d) The laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing for 13 of 14 days; and 1 of 1 days of D-Dimer testing; and 10 of 15 days of PT/INR (Prothrombin Time/International Normalized Ratio) testing. Refer to D5537; (e) The laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing for 1of 1 day of patient testing; and failed to perform two levels of quality control materials each eight hours of PT/INR for 10 of 15 days of patient testing. Refer to D5545.
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, written procedures, and interview with the laboratory manager, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure performance specification procedures for a new test system was adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (4) The laboratory director failed to ensure evaluations included all moderate complexity testing performed for 5 of 7 testing persons. Refer to 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 a review of records, written procedures and interview with the laboratory manager, the laboratory director failed to ensure performance specification procedures for a new test system was adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Refer to D5421.
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 laboratory manager, 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 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 blood gas testing for 13 of 14 days. Refer to D5537; (2) The laboratory director failed to ensure two levels of quality control materials each eight hours of D-dimer testing for 1of 1 day of patient testing; and failed to perform two levels of quality control materials each eight hours of PT/INR for 10 of 15 days of patient 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, written instructions, manufacturer's instructions, and interview with the laboratory manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 laboratory manager, the laboratory director failed to ensure evaluations included all moderate complexity testing performed for 5 of 7 testing persons. Findings include: (1) On 04/22/2021 at 09:50 am, the laboratory manager stated to the surveyor: (a) D-Dimer testing was performed in the laboratory using the Alere Triage Meter; (b) PT/INR (Prothrombin Time/International Normalized Ratio) was performed in the laboratory using the Hemochron Signature Elite. (2) The surveyor then reviewed 2019, 2020, and 2021 personnel records for 7 persons performing D-Dimer testing and PT/INR testing. The records showed that evaluations had been performed as follows: (a) Testing Person #1- The evaluation performed on 01/03/2020 did not include D-Dimer and PT/INR testing; (b) Testing Person #2 - The evaluation performed on 12/18/2020 did not include D-Dimer and PT /INR testing; (c) Testing Person #3 - The evaluation performed on 01/03/2020 did not include D-Dimer testing; The evaluation performed on 12/18/2020 did not include D-Dimer and PT/INR testing; (d) Testing Person #4 - The evaluations performed on 08/12/2019 and 01/03/2020 did not include D-Dimer testing; (e) Testing Person #5 - The evaluations performed on 08/12/2019 and 01/03 /2020 did not include D-Dimer testing; The evaluation performed on 12/18/2020 did not include D-Dimer testing and PT/INR testing; (f) Testing Person #6 - The evaluation performed on 09/24/2020 did not include D-Dimer testing and PT/INR

	testing. (3) The surveyor reviewed the findings with laboratory manager, who stated on 04/22/2021 at 11:48 am the above evaluations did not include the D-Dimer testing and/or PT/INR testing as indicated above.