Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473199	02/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital - Cushing	1027 E Cherry Street, Cushing, 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 validation survey was performed on 02/03,03,04/2020. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director, laboratory manager, chief nursing officer, health information manager, quality coordinator, and compliance manager during an exit conference performed at the conclusion of the survey.
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 3 of 22 events. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2018 Chemistry Core Event (i) Albumin - 5 of 5 results exhibited a positive bias (aa) CH-01 - SDI of 2.0 (bb) CH-02 - SDI of 2.2 (cc) CH-03 - SDI of 2.1 (dd) CH-04 - SDI of 3.3 (ee) CH-05 - SDI of 3.0 (ii) Carbamazepine - 3 of 5 results exhibited a positive bias (aa) CH-03 - SDI of 9.2 (bb) CH-04 - SDI of 2.9 (cc) CH-05 - SDI of 4.6 (iii) Phenytoin - 3 of 5 results exhibited a negative bias (aa) CH-02 - SDI of -2.2 (bb) CH-03 - SDI of -2.0 (cc) CH-04 - SDI of -2.1 (b) Second 2018 Hematology Event (i) Monocyte- 3 of 5 results exhibited a negative bias (aa) XE-07 - SDI of -2.0 (bb) XE-09 - SDI of -2.0 (cc) XE-10 - SDI of -2.1 (c) Third 2018 Chemistry Core Event (i) Creatine Kinase - 3 of 5 results exhibited a negative bias (aa) CH-11 - SDI of -2.3 (bb) CH-12 - SDI of -2.0 (cc) CH-13 - SDI of -2.1 (2) Surveyor #2 further reviewed the records and could not locate

	documentation verifying the biases had been identified and addressed; (3) Surveyor #2 then reviewed the records with the laboratory manager, and asked if the biases had been addressed. The laboratory manager stated on 02/03/2020 01:00 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 22 events. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 Third Event (aa) Blood Cell Identification ECI-12 (bb) Blood Cell Identification ECI-15 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) Surveyor #2 asked the laboratory manager if the results had been documented as evaluated. The laboratory manager reviewed the records and stated on 02/03/2020 at 10:05 am the non-graded results had not been documented as reviewed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to follow their written manual differential policy. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyors CBC (Complete Blood Count) testing was performed using the Sysmex XN-1000 analyzer; (2) On the third day of the survey, surveyor #2 reviewed the policy titled "Flags for Slide Scan and Manual Differentials for Complete Blood Count". The policy stated: "As defined in Epic Beaker, technicians and technologists need to perform....a manual differential if any of the following criteria and/or flags presents:" 1. " Eosinophils - greater than 2.0 X 10^3/L" (3) Surveyor #2 then reviewed patient records between 01/26/2019 and 11/06/2019. There was no evidence a manual differential had been performed for 1 of 12 patients as follows: (a) Patient result on 04 /01/2019 at 11:13 am: (i) Eosinophilia - 2.95 X 10^3/L (4) Surveyor #2 reviewed the findings with the laboratory manager. The laboratory manager stated on 02/05/2020 at 04:00 pm a manual differential had not been performed as indicated above.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents; and failed to follow the manufacturer's instructions for verifying the accuracy check of the needle for Syphilis testing. Findings include: COAGULATION REAGENTS (1) On the first day of the survey, the laboratory manager stated to the surveyors the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On the fourth day of the survey, surveyor #2 observed the refrigerator where the testing reagents were maintained and identified the following reagents which appeared to be currently in use: (a) PT - HemosIL Recombiplastin 2G reagent, lot #N0789332 (b) PTT - HemosIL Synthasil APTT reagent, lot #N0980446 (3) The laboratory manager stated to surveyor #2 the above reagent lot numbers were currently in use, and had initially been put into use as follows: (a) HemosIL Recombiplastin 2G reagent - 05/01/19 (b) HemosIL Synthasil APTT reagent - 08/01 /19 (4) Surveyor #2 reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Establishing a Normal Reference Interval" (i) "Reference Interval should be established whenever there is a change in: * Instrumentation and/or methodology. * Lot number of reagent. * Sample collection procedures. * At least once a year." (ii) "Reference Intervals should be established for each assay the lab performs."; (iii) "Reference Intervals should be established over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators."; (iv) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (v) "Donors should span the adult age range. Pediatric ranges should be established separately."; (vi) "Donors should be equally divided between male/female."; (vii) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal reference interval in seconds and use along with the lot-specific ISI value in the INR setup calculation page". (b) Section titled "Comparison Study" (i) "Collect and handle specimens according to accepted laboratory practice for the assay being performed" (ii) "Include diseases/treatments known to affect the assay being performed" (iii) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible" (iv) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data" (v) "Evaluate the new instrument or reagent over clinically meaningful range including data below and above the expected reference range" (vi) "For a given specimen, analysis by the comparative and new methods or reagents

	should be accomplished within 1 hour of each other to avoid possible degradation of the samples" (vii) "Analyze each patient sample using the new method (or reagents) and the comparative method" (viii) "Examine the results after each run. If an isolated specimen's results for the new and comparative methods differ more than observed for other specimens, retest that specimen in duplicate on both methods. If the difference has been resolved use the repeat data" (ix) "Record data on the data sheets provided" (x) "The analysis of the comparison data can be as simple as a visual comparison, calculation of the difference (delta) between the two methods, or as involved as a regression analysis. The comparison will depend on the types of specimen, instruments and methodologies chosen. The more similarities among those items, the closer will be the comparison results" (5) Surveyor #2 reviewed the implementation records for Recombiplastin 2G reagent lot #N0789332 and APTT reagent lot #N0980446, with the following identified: (a) Recombiplastin 2G lot #N0789332 (i) Normal Reference Interval (aa) The donors were not equally divided between male /female. The laboratory had used 17 males and 13 females; (bb) There was no documentation of the health status and medication history of the donors. (ii) Quality Control Ranges (aa) Quality control ranges had not been established. (iii) Comparison Study (aa) There was no documentation the laboratory performed a comparison between the old and new lots of reagent using 40 specimens (20 normal and 20 outside of the laboratory normal reference interval). (b) APTT reagent lot #N0980446 (i) Normal Reference Interval (aa) The donors were not equally divided between male /female. The laboratory had used 17 males and 13 females; (bb) There was no documentation of the health status and medication history of the donors. (ii) Quality Control Ranges (aa) Quality control ranges had not been established. (iii) Comparison Study (aa) There was no documentation the laboratory performed a comparison between the old and new lots of reagent using 40 specimens (20 normal and 20 outside of the laboratory normal reference interval). (6) The findings were reviewed with the laboratory manager who stated on 02/03/2020 at 4:00 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above. SYPHILIS TESTING (1) On the first day of the survey, the laboratory manager stated the following to the surveyors: (a) Syphilis testing was performed using the RPR Card Test. (2) On the third day of the survey, surveyor #2 reviewed the manufacturer's instructions for verifying the accuracy check of the needle for Syphilis testing. The instructions stated, "The needle should deliver 60 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3mL syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5mL. The needle is considered satisfactory if 30 1 drops are obtained in 0.5mL."; (3) Surveyor #2 reviewed patient records for testing performed between 09/28/2018 and 11/22/2019. For 9 of 9 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the accuracy check of the needle. The findings for the 9 records were: (a) Patient testing was performed on 09/23/2018; (b) Patient testing was performed on 09/30/2018; (c) Patient testing was performed on 10 /06/2018; (d) Patient testing was performed on 11/01/2018; (e) Patient testing was performed on 03/19/2019; (f) Patient testing was performed on 08/06/2019; (g) Patient testing was performed on 08/09/2019; (h) Patient testing was performed on 11 /21/2019; (i) Patient testing was performed on 11/22/2019. (4) Surveyor #2 reviewed the records with the laboratory manager, who stated on 02/05/2020 at 11:30 am the accuracy check of the needle had not been documented as indicated above.
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 analyzers and materials were stored as required by the manufacturer. Findings include: LABORATORY HUMIDITY (1) On the first day of the survey, the laboratory manager stated the following to the surveyors: (a) Routine chemistry testing was performed on the Abbott Architect; (b) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XN-1000; (c) Routine coagulation testing was performed on the ACL Elite; (d) Routine urinalysis testing was performed on the Iris iCHEM 100. (2) The surveyors reviewed the operator manuals for the relative humidity requirements for all the analyzers: (a) Abbott Architect - 10 - 85% (b) Sysmex XN-1000 - 30 - 85% (c) ACL Elite - 12 - 85% (d) iCHEM 100 - 20 - 80% (3) The surveyors reviewed laboratory humidity records from January 2019 through December 2019. There was no evidence that the humidity, where the analyzers were maintained, had been monitored at an acceptable range of 20 - 80% to accommodate the analyzers; (4) The surveyors asked the laboratory manager if the humidity, where the analyzers were maintained, was being monitored. The laboratory manager stated on 02/03/2020 at 10: 00 am the humidity was not being monitored. BLOOD COLLECTION TUBE STORAGE (1) On the first day of the survey, the laboratory manager stated the following to the surveyors: (a) Blood collection tubes were stored in two laboratory draw rooms used for the following: (i) Routine Chemistry testing performed on the Abbott Architect; (ii) Routine CBC testing performed on the Sysmex XN-1000; (iii) Routine Coagulation testing performed on the ACL Elite; (2) The surveyors reviewed the manufacturer's environmental requirements for the blood collection tubes, which required a room temperature 4-25 degrees C (Celsius). The following were examples of blood collection tubes stored in the rooms: (i) BD Vacutainer K2 EDTA (20 tubes of lot# 9158919) (ii) BD Vacutainer Lithium Heparin (22 tubes of lot# 9260595) (iii) BD Vacutainer Sodium Fluoride Potassium Oxalate (50 tubes of lot# 9184964) (iv) BD Vacutainer SST (20 tubes of lot# 9311242) (3) The surveyors reviewed laboratory temperature records from January 2019 through December 2019. There was no evidence that the temperature, where the blood collection tubes were maintained, had been monitored at an acceptable range of 4-25 degrees C to accommodate the blood collection tubes; (4) The surveyors asked the laboratory manager if the room temperature, where the blood collection tubes were maintained, was being monitored. The laboratory manager stated on 02/03/2020 at 10:00 am the room temperature was not being monitored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to ensure materials had not exceeded their expiration date. Findings include: (1) On the first day of the survey, surveyor #1 observed the contents of the laboratory drawing room #2. The following expired materials were observed in the drawing room, which were available for use: (a) Four tubes of BD Vacutainer Buff Na Citrate 3.2%, lot #9036654, expiration date 11/30/2019. (2) Surveyor #1 showed the expired materials to the laboratory manager who stated on 02/03/2020 at 09:55 am the expired materials were available for use and stated they should have been discarded once they had expired.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. 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 perform function checks as defined by the manufacturer. Findings include: (1) On the second day of the survey, the laboratory manager stated the following to surveyors: (a) The MTS 0.5 milliliter (ml) dispenser was used to dispense MTS Diluent 2 Plus to make cell suspensions for ABO/Rh Typing; (b) The MTS 1.0 ml dispenser was used to dispense MTS Diluent 2 to make cell suspensions for Compatibility testing. (2) Surveyor #1 reviewed the manufacturer's requirements for the dispensers. The manufacturer required the following: (a) Periodic volume verification checks (b) Weekly cleaning (3) Surveyor #1 reviewed blood bank records between January 2019 and December 2019 and could not locate evidence the periodic volume verification checks had been performed; (4) Surveyor #1 then asked the laboratory manager if the volume verification checks had been performed for the dispenser; and if the laboratory had a policy to define how often the checks were to be performed (since the manufacturer did not define the meaning of periodic, the laboratory must define the frequency). The laboratory manager stated on 02/04/2020 at 11:00 am volume verification checks had not been performed on the dispenser in 2019; and the laboratory did not have a policy to define the frequency for performing the volume checks.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the

	laboratory failed to perform a negative and positive control each day of patient Streptococcus A testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors the laboratory performed Streptococcus A testing using the Quidel QuickVue+ test kit (a non-waived test kit); (2) Surveyor #2 reviewed records for patient testing performed from January 2019 through December 2019 and identified the following during 1 of the 12 months: (a) Negative and positive quality control testing had not been perform for 2 days of the review period: (a) Testing performed on 08/14/2019; (b) Testing performed on 08/15/2019. (3) Surveyor #2 reviewed the records with the laboratory manager, who stated on 02/03/2020 at 02: 00 pm the quality control testing had been performed, but had not been documented.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. 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 comply with 21 CFR 606.160(b)(3)(ii). The laboratory failed to visually inspect units of packed red blood cells immediately before distribution. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors, the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the third day of the survey, surveyor #2 reviewed patient blood bank records from 10/2019 through 12 /2019. For 4 of 17 units checked out by the laboratory, there was no evidence a visual inspection had been performed immediately before distribution; (3) The findings were discussed with the laboratory manager who stated on 02/05/2020 at 4:00 pm visual inspections were being performed, but not documented.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. 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, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On the second day of the survey, the laboratory manager stated the following to the surveyors: (a) Units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (b) Units of fresh frozen plasma, which were stored in the plasma freezer, were used for patient transfusions; (c) Alarm checks for the refrigerator and

	freezer were performed quarterly, by the laboratory. (2) Surveyor #2 reviewed alarm checks records from January 2019 through January 2020 with the following identified: (a) The refrigerator and freezer alarm checks had not been performed on a quarter basis as follows: (i) Refrigerator - The checks had not been performed between 02/18/19 and 07/24/19; (ii) Freezer - The checks had not been performed between 02/18/19 and 07/24/19. (3) Surveyor #2 reviewed the refrigerator and freezer alarm checks records with the laboratory manager, who stated on 02/04/2020 at 10:30 am the alarm checks had not been performed quarterly as required.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. 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 written policies and interview with the laboratory manager and quality assurance manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 5 of 17 packed red blood cell units. Findings include: (1) On the first day of the survey, the laboratory manager stated the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Administration" stated the following: (a) "Policy" (i) "The physician will obtain an informed consent and document the indication for the transfusion in the medical record." (b) "Section E. Administration" (i) "8. Obtain vital signs q 5 minutes X's 3 at least 15 minutes after the blood begins infusing and q 30 minutes until transfusion is done." (3) Surveyor #2 then reviewed records for 17 units of PRBCs (Packed Red Blood Cells) transfused between 05/2019 and 12/2019 for 7 patients, with the following identified: (a) Patient #0000116945 - Transfused with 1 unit of PRBC's (unit #W204919408357) on 05/30/2019. There was no documentation vitals had been taken every 5 minutes for the first 15 minutes; (b) Patient #0000151584 - Transfused with 2 units of PRBC's (unit #W200219662749 and unit #W200219670512) on 10/15 /2019. There was no documentation vitals had been taken every 5 minutes for the first 15 minutes; (c) Patient #0000084222 - Transfused with 2 units of PRBC's (unit #W200919245172 and unit #W200919251427) on 11/10/19. There was no documentation a consent had been obtained. (4) The above transfusion records were reviewed with the laboratory manager and quality assurance manager. Both stated on 02/05/2020 at 3:15 pm, the records were not complete as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 3 of 27 events. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2018 and 2019 proficiency testing records. It was identified for 3 of 22 events, the attestation statements had been signed approximately 1-2 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Hematology Third event of 2018 - The samples had been tested on 12/15/2018 and the attestation statement had not been signed by the laboratory director until 01/16 /2019; (b) Hematology Second event of 2019 - The samples had been tested on 08/11 /2019 and the attestation statement had not been signed by the laboratory director until 10/23/2019; (2) Surveyor #2 reviewed the findings with the laboratory manager and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
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 that a person performing moderate complexity testing had the appropriate training. Findings include: (1) On the first day of the survey, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #3 - This person was hired to perform patient testing on 05/20/2019. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 11/06/2019. (2) Surveyor #2 reviewed the findings with the laboratory manager, who stated on 02/03/2020 at 11:25 am, there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure evaluations included all moderate complexity testing performed. Refer to D6054.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include:

	(1) On the first day of the survey, surveyor #2 reviewed records for 4 persons performing moderate complexity testing in 2018 and 2019. The records verified the evaluations for 2 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 (i) The 09/05/2019 annual evaluation had been performed by testing person #1 (this person had earned a high school diploma and had a HEW (Health Education and Welfare) certification. (2) Surveyor #2 explained to the laboratory manager on 02 /03/2020 at 11:15 am that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 6 of 6 testing persons. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors ROM (Rupture of Membrane-detection of amniotic fluid in vaginal secretions) testing was performed using the ROM Plus kit in the laboratory: (2) Surveyor #2 then reviewed 2019 personnel records for 6 persons performing ROM analysis in the laboratory. The records verified that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 09/25/2019 (b) Testing Person #2 - Performed on 09/05/2019 (c) Testing Person #3 - Performed on 11/06/2019 (d) Testing Person #4 - Performed on 10/10/2019 (e) Testing Person #5 - Performed on 10/03/2019 (f) Testing Person #6 - Performed on 10 /03/2019 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of the ROM analysis; (4) Surveyor #2 reviewed the findings with the laboratory manager, who stated on 02/03/2020 at 11:20 am the above evaluations did not include the ROM analysis.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 that a person performing high complexity testing had the appropriate training. Findings include: (1) On the first day of the survey,

	surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #3 - This person was hired to perform patient testing on 05/20/2019. There was no documentation this person had been initially trained. A competency evaluation had not been documented as performed until 11/06/2019. (2) Surveyor #2 reviewed the findings with the laboratory manager, who stated on 02/03/2020 at 11:25 am, there was no additional documentation to prove the above person had been initially trained to perform high complexity testing.