Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2098113	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Center For Orthopaedic Reconstruction & Excellence	3029 W Main Street, Jenks, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The survey was performed on 07/24,25,26/18 The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the CEO and laboratory manager during an exit conference performed at the conclusion of the survey.
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 written policies and procedures, and interview with the laboratory manager, the laboratory failed to have a written procedure for Wet Prep analysis; and failed to follow a written policy. Findings include: WET PREP ANALYSIS (1) On the first day of the survey, the laboratory manager stated to the surveyor microscopic Wet Prep analysis was performed; (2) Later on the first day, the surveyor asked the laboratory manager for dates of patient Wet Prep analysis performed during 2018. The laboratory manager stated to the surveyor patient Wet Prep analysis had been performed on 01/31/18, 03/14/18, and 06/14/18; (3) The surveyor then reviewed procedure manuals, and was unable to locate a written procedure for performing Wet Prep analysis; (3) The surveyor asked the laboratory manager if a written procedure was available for Wet Prep analysis. The laboratory manager stated a procedure had not been written. NOT FOLLOWING WRITTEN POLICY (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) PT/INR and PTT testing were performed on the ACL Elite analyzer; (b) The laboratory had a policy to ensure the specimens tested on the

	analyzer were platelet poor. (2) On the second day of the survey, the surveyor reviewed the policy titled, "Centrifuge Calibration Verification for Platelet Poor Plasma" which stated, "Plasma used for coagulation studies must be platelet-poor. Centrifuge speed and duration must be established by the laboratory to ensure platelet counts are less than 10,000/uL. A minimum of 10 specimens should be validated every six months"; (3) The surveyor then reviewed records for 2017 and 2018 and identified the platelet-poor plasma checks had not been performed every six months as required by policy, instead, the checks had been performed on an annual basis. In addition, the laboratory had not tested a minimum of 10 specimens: (a) 05/05/17 - The platelet-poor plasma check had been performed using 5 specimens; (b) 05/18/18 - The platelet-poor plasma check had been performed using 5 specimens. (4) The surveyor reviewed the records and policy with the laboratory manager who stated the laboratory had not followed their written policy for ensuring platelet-poor plasma every six months using at least 10 specimens.
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 perform maintenance procedures as required by the manufacturers. Findings include: ACL ELITE ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the ACL Elite analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Bi-Weekly (i) Reboot the Analyzer (ii) Clean Rotor Holder and Optic Path (3) Maintenance records were reviewed by the surveyor for 18 months (January 2017 through June 2018). The bi-weekly maintenance of Reboot the Analyzer had not been documented as performed: (a) Prior to 03/01/17 (b) Between 03 /13/17 and 01/02/18 (c) Between 04/04/18 and 05/03/18 (d) Between 05/03/18 and 06 /05/18 (4) The surveyor reviewed the records with the laboratory manager who stated there was no evidence the above maintenance had been performed as required. BIOMERIEUX VIDAS ANALYZER (1) On the first day of the survey, the laboratory manager stated to the surveyor Troponin I testing was performed on the Biomerieux Vidas analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's requirements for maintenance, which were: (a) Weekly (i) SPR Block Clean (ii) Computer Shutdown (b) Monthly (i) Reagent StripTray Clean (ii) Strip Preparation Tray Clean (iii) Drip Trays Clean (iv) QCV Assay Perform (v) Printer Clean (3) The surveyor then reviewed maintenance records for 18 months (January 2017 through June 2018). There was no evidence the maintenance had been performed as follows: (a) Weekly (i) SPR Block Clean had not been documented as performed between: (aa) 10/27/17 and 11/10/17 (bb) 06/20/17 and 07 /14/17 (cc) 01/05/18 and 01/19/18 (dd) 05/18/18 and 06/01/18 (ee) 06/21/18 and 07/05 /18 (ii) Computer Shutdown had not been documented as performed between: (aa) 10 /27/17 and 11/10/17 (bb) 06/29/17 and 07/14/17 (cc) 05/18/18 and 06/01/18 (b) Monthly (i) Reagent Strip Tray Clean, Strip Preparation Tray Clean, Dip Trays Clean, and Clean Lens had not been documented as performed between 01/26/18 and 03/02

	/18; (ii) QCV Assay Perform had not been documented as performed during January 2017 and July 2017; (iii) Clean Lens had not been documented as performed during March 2017 and June 2017. (4) The surveyor reviewed the records with the laboratory manager, who stated there was no evidence the maintenance, as indicated above, had been performed as required.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, written polices, and interview with the laboratory manager, the laboratory failed to follow their function check protocol for ensuring their centrifuges were functioning properly. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the following centrifuges were used in the laboratory: (a) The Hettich Zentrifugen EBA 280 centrifuge was used to process coagulation specimens for PT/INR (Prothrombin Time/International Normalized Ratio and PTT (Partial Thromboplastin Time) testing at a speed of 3750 rpm (revolutions per minute) for 10 minutes; (b) The Hettich Zentrifugen EBA 270 centrifuge was used to process urine specimens for microscopic urine sediment analysis at a speed of 1500 rpm for 5 minutes; (c) The Ortho Workstation centrifuge was used to process blood bank specimens for ABO/Rh, Antibody Screen, and Compatibility testing at a speed of 1032 rpm for 10 minutes. (2) Later on the first day, the surveyor reviewed the policy titled, "Centrifuge Maintenance" which stated, "Twice yearly the centrifuge speed and timers should be checked to ensure proper functioning of the centrifuge"; (3) The surveyor reviewed the speed and timer checks for the centrifuges above and identified the checks had not been performed twice yearly as required by policy, instead, the checks had been performed on an annual basis: (a) Hettich Zentrifugen EBA 280 centrifuge (i) 05/01/17 - The speed had been checked at 3750 rpm and the timer had been checked at 10 minutes; (ii) 05/11/18 - The speed had been checked at 3750 rpm and the timer had been checked at 10 minutes. (b) Hettich Zentrifugen EBA 270 centrifuge (i) 05/01/17 - The speed had been checked at 1500 rpm and the timer had been checked at 5 minutes; (ii) 05/11/18 - The speed had been checked at 1500 rpm and the timer had been checked at 5 minutes. (c) Ortho Workstation centrifuge (i) 05/01/17 - The speed had been checked at 1032 rpm and the timer had been checked at 10 minutes; (ii) 05/11/18 - The speed had been checked at 1070 rpm and the timer had been checked at 10 minutes. The function check had been performed again on 05/29/18 to recheck the speed which was 1031 rpm and the timer was rechecked at 10 minutes. (4) The surveyor reviewed the records and policy with the laboratory manager who stated the laboratory had not followed their written policy for checking the speed and timers of the centrifuges twice annually.
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 and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the laboratory manager stated to the following to the surveyor: (a) Units of packed red blood cells, which were stored in the Helmer blood bank refrigerator, were used for patient transfusions; (b) Alarm checks for the refrigerator were performed on a quarterly basis. (2) Later on the first day, the surveyor reviewed refrigerator alarm check records from March 2016 through April 2018. It was identified the alarm checks had not been performed on a quarterly basis (every 3 months) as follows: (a) 2017 - Alarm checks had not been performed during the second quarter (not performed between 03 /24/17 and 07/14/17). (3) The surveyor reviewed the records with the laboratory manager who stated the refrigerator alarm checks had not been performed on a quarterly basis as indicated above.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, literature reference, and interview with the laboratory manager, the laboratory director failed to ensure manual differentials were being performed as required for accurate and reliable results. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC testing was performed using the Horiba ABX Micros 60 analyzer; (b) Manual differentials were performed as required by policy and /or the manufacturer's instructions (i.e., when automated differentials flags were obtained during analysis). (2) On the second day of the survey, the surveyor reviewed 14 patient records for manual differential testing performed during February 2017, June 2018, and July 2018. For 1 of the records, the reported white blood cell (WBC) count from the manual differential testing did not equal 100: (a) Report #1 - The testing was performed on 02//9/17, with a WBC count of 98 reported. (3) The surveyor then reviewed the procedure titled, "Manual Diff And Smear Review Criteria". The procedure did not specify the number of cells to count in a manual differential, however, it was standard laboratory practice to perform a manual WBC differential count of 100 cells; (4) The surveyor reviewed the report with the

	laboratory manager, who stated the manual differential did not equal 100. NOTE: The following is a reference obtained by the surveyor following the survey which verifies 100 cells should be counted in a manual differential: (a) The textbook, "Hematology Clinical Principals and Applications, Second Edition" by Bernadette F. Rodak (W.B. Saunders Company), states "The manual differential, however, should always be performed in a systematic manner. Once the correct area has been selected, a back-and-forth serpentine or "battlement" track pattern is preferred for minimizing distributional errors. One hundred WBCs are counted and classified through the use of push-down button counters or newer computer-interfaced touch-pads".
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 failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016, 2017 and 2018 proficiency testing records. It was identified for 12 of 14 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) Third 2016 Chemistry Group 2 Event - The sample testing had been completed on 12/08/16 and the attestation statement had not been signed by the laboratory director until 01/18 /17; (b) Third 2016 Hematology/Coagulation Event - The sample testing had been completed on 11/17/16 and the attestation statement had not been signed by the laboratory director until 01/18/17; (c) Third 2016 Immunohematology Event -The sample testing had been completed on 12/21/17 and the attestation statement had not been signed by the laboratory director until 01/18/17; (d) First 2017 Chemistry Core Event - The sample testing had been completed on 02/02/17 and the attestation statement had not been signed by the laboratory director until 04/19/17; (e) First 2017 Hematology/Coagulation Event - The sample testing had been completed on 03/24/17 and the attestation statement had not been signed by the laboratory director until 04/19 /17; (f) Second 2017 Chemistry Core Event - The sample testing had been completed on 06/01/17 and the attestation statement had not been signed by the laboratory director until 07/26/17; (g) Second 2017 Immunohematology Event - The sample testing had been completed on 08/14/17 and the attestation statement had not been signed by the laboratory director until 10/26/17; (h) Third 2017 Chemistry Core Event - The sample testing had been completed on 09/08/17 and the attestation statement had not been signed by the laboratory director until 10/26/17; (i) Third 2017 Hematology/Coagulation Event - The sample testing had been completed on 12/01/17 and the attestation statement had not been signed by the laboratory director until 01/23 /17; (j) Third 2017 Immunohematology Event - The sample testing had been completed on 12/12/17 and the attestation statement had not been signed by the laboratory director until 01/23/18; (k) First 2018 Chemistry Core Event - The sample

	testing had been completed on 02/07/18 and the attestation statement had not been signed by the laboratory director until 04/26/18; (l) First 2018 Hematology /Coagulation Event - The sample testing had been completed on 03/20/18 and the attestation statement had not been signed by the laboratory director until 04/26/18. (2) The surveyor 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.