

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D2098113	<b>(X3) Date Survey Completed</b>  09/17/2020
<b>Name of Provider or Supplier</b>  Center For Orthopaedic Reconstruction & Excellence	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 09/15/2020 through 09/17/2020. The findings were reviewed with the general supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 2 of 12 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2019 and 2020 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-15 (ii) 2020 First Event (aa) Blood Cell Identification ECI-01 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the general supervisor if the results had been documented as evaluated. The general supervisor reviewed the records and stated on 09/17/2020 at 02:45 pm the non-graded results had not been documented as reviewed.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p>

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, procedure manual, laboratory information system, manufacturer specifications, and interview with the general supervisor, the laboratory failed to demonstrate the performance specifications for new test methods; Findings include: (1) On the first day of the survey, the general supervisor stated to the surveyor arterial blood gas (PCO<sub>2</sub>, PO<sub>2</sub>, and pH) testing was performed on the Abbott iSTAT analyzer using the EG7+ cartridge; (2) On the second day of the survey, the general supervisor stated to the surveyor the new test system was available for patient arterial blood gas testing on 04/23/2020; (3) The surveyor reviewed the manufacturer's reportable range for the following: (a) PCO<sub>2</sub>: 15 - 90 mmHg (b) PO<sub>2</sub>: 50 - 450 mmHg (c) pH: 6.50 - 8.20 (4) On the third day of the survey, the surveyor reviewed the validation records for the analyzer with the following identified: (a) The reportable range had been verified as follows: (i) PCO<sub>2</sub>: 19 - 83 mmHg (ii) PO<sub>2</sub>: 59 - 434 mmHg (iii) pH: 6.50 - 7.8 (5) The surveyor reviewed the written procedure manual titled "iSTAT" and identified the following: (a) Section titled, "Expected Values" (i) The manufacturer's reportable range were documented as the the laboratory's reportable ranges and not the laboratory's verified reportable ranges. (6) The surveyor then observed in the laboratory's information system (Healthland Centriq), the manufacturer's reportable range was in use and not the laboratory's verified reportable ranges; (7) The surveyor then reviewed the validation records with the general supervisor. The general supervisor stated on 09/17/2020 at 02:50 pm the laboratory was using the manufacturer's reportable ranges, but they had not been verified as indicated above.

**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 nursing manager and the general supervisor, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 8 of 26 packed red blood cell units. Findings

include: (1) On the first day of the survey, the general supervisor 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 blood administration. The policy titled, "ADMINISTERING BLOOD AND BLOOD PRODUCTS" stated the following: (a) "D. Administration" (i) "3. Obtain vital signs prior to initiating the transfusion (baseline), 5 to 15 minutes of initiating the transfusion, every one hour until the transfusion is complete and after the transfusion. The rate of transfusion should be increased after 15 minutes to ensure the unit is administered within the 4-hour window." (3) The surveyor then reviewed records for 26 units of PRBCs (Packed Red Blood Cells) transfused between 02/01/2019 through 05/15/2019 and 01/03/2020 through 05/05/2020 for 26 patients, with the following identified: (a) Start time of the infusion (i) Patient #124833 - Transfused with 1 unit of PRBCs (unit #W091019141022) on 03/22/2019. There was no documentation indicating the start time of the infusion; (ii) Patient #133320 - Transfused with 1 unit of PRBCs (unit #W091020153684) on 03/15/2020. There was no documentation indicating the start time of the infusion. (b) Vital Signs 5 to 15 minutes after transfusion begins (i) Patient #97079 - Transfused with 1 unit of PRBCs (unit #W091019147985) on 04/03/2019 at 01:55 pm vitals taken at 12:19 (2 hours and 3 minutes after transfusion started) (c) Vital Signs every one hour until the transfusion is complete (i) Patient #120437 - Transfused with 1 unit of PRBCs (unit #W091019161236) on 05/05/2019 at 03:43 pm and ending at 07:18 pm vitals taken at 05:20 pm and 07:18 pm (1 hour and 58 minutes during the transfusion); (ii) Patient #133320 - Transfused with 1 unit of PRBCs (unit #W091020133846) on 03/15/2020 at 11:10 am and ending at 01:45 pm vitals taken at 12:25 pm and 14:05 pm (1 hour and 20 minutes during the transfusion); (iii) Patient #105804 - Transfused with 1 unit of PRBCs (unit #W091020179187) on 05/05/2020 at 05:23 am and ending at 07:30 am vitals taken at 06:01 am and 07:30 am (1 hour and 29 minutes during the transfusion). (d) Post-transfusion vital signs (i) Patient #123389 - Transfused with 1 unit of PRBCs (unit #W091018283863) on 02/01/2019. There was no evidence of post-transfusion vital signs documentation; (ii) Patient #125461 - Transfused with 1 unit of PRBCs (unit #W091019126900) on 03/18/2019. There was no evidence of post-transfusion vital signs documentation; (iii) Patient #124833 - Transfused with 1 unit of PRBCs (unit #W091019141022) on 03/22/2019. There was no evidence of post-transfusion vital signs documentation; (iv) Patient #133320 - Transfused with 1 unit of PRBCs (unit #W091020153684) on 03/15/2020. There was no evidence of post-transfusion vital signs documentation. (4) The above transfusion records were reviewed with the nursing manager on 09/17/2020 who stated at 02:30 pm the records were not complete as indicated above.