Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470358	02/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oklahoma Blood Institute Sylvan N Goldman Center	1001 N Lincoln Boulevard, Oklahoma City, 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	A complaint survey was performed (State Complaint OK 00051556). The findings were reviewed with the vice-president of bio-development & QM, and the compliance officer at the conclusion of the survey. The laboratory was found out of compliance with following CLIA regulations: 1. 493.801; D2000: Enrollment and Testing of Samples 2. 493.1441; D6076: Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the vice-president of bio-development & QM, compliance officer, OBI special project manager reference laboratory, and the OBI quality assessment director, the headquarters laboratory failed to enroll in proficiency testing for each sub-center laboratory certificate during 2015 and 2016. Findings include: The OBI headquarters laboratory engaged in proficiency testing referral during 2015 and 2016. Refer to D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency

testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on a review of records, policies and procedures, and interview with the vice-president of bio-development & QM, compliance officer, OBI special project manager reference laboratory, and the OBI quality assessment director, the OBI headquarters laboratory engaged in proficiency testing referral during 2015 and 2016. Findings include: (1) At the beginning of the survey, the surveyors interviewed the vice-president of bio-development & QM and the compliance officer (09:30 am) and asked them to explain the testing performed and the locations of the OBI (Oklahoma Blood Institute) centers. The vice-president of bio-development & QM and the compliance officer stated to the surveyors ABO Group typing, Rh (D) typing, Unexpected Antibody Detection, Antibody Identification, and Compatibility testing were performed at each of the following locations: (a) OBI headquarters (37D0470358) located in Oklahoma City, OK (b) Tulsa sub-center (37D0931105) located in Tulsa, OK (c) Ft. Smith sub-center (04D0469265) located in Ft. Smith, AR (d) Little Rock sub-center (04D2096885) located in Little Rock, AR (became operational November 2015) (2) The surveyors requested the proficiency testing (PT) policies for 2015 through 2018 from the compliance officer (11:10 am). The policy, titled "Proficiency Testing Program" (DOC: OBI-QM-SOP-0612) had been revised/reviewed since the 12 /22/14 policy as follows: (a) Revision 9 - Effective 12/22/14 (b) Revision 10 - Effective 06/01/15 (c) Revision 11 - Effective 04/11/16 (d) Revision 12 - Effective 12 /12/16 (this is when the new policy was in effect stating that each CLIA number must enroll in PT separately) (e) Revision 13 - Effective 10/02/17 (f) Revision 14 - Effective 01/15/18 (current policy) (3) The surveyors asked the OBI special project manager reference laboratory (11:40 am) to explain the process of ordering and performing PT during 2015, 2016, 2017, and to date in 2018. The OBI special project manager reference laboratory stated the following to the surveyors: (a) During 2015 - Transfusion Medicine PT events J-A, J-B, and J-C ordered through CAP (College of American Pathologists) under the OBI headquarters CLIA number (37D0470358): (i) Each shipment from CAP (containing 3 test kits) was shipped to the headquarters location (each test kit consisted of a sealed styrofoam package which contained PT samples, and PT paperwork such as report forms, attestation forms, etc.). The OBI headquarters then distributed the unopened styrofoam test kits as follows: (aa) Kit #1 - Remained at the OBI headquarters (bb) Kit #2 - Delivered to the Tulsa sub-center by OBI courier (cc) Kit #3 - Delivered to the Ft. Smith sub-center by OBI courier (ii) The samples from each test kit were tested at each location, with result forms and attestations completed at each site. The completed paperwork (hard copies) were delivered by OBI courier back to the OBI headquarters in a red folder from each

	location; (iii) The OBI special project manager reference laboratory electronically entered all PT results for each of the test kits as they were received in the Oklahoma City office from each sub-center. After the final set of results were received from a sub-center, the results were electronically submitted to CAP; (iv) All hardcopies contained in the red folders for the headquarters and each sub-center location were maintained on-site at the OBI headquarters location; (v) Graded evaluations were emailed to the OBI special project manager reference laboratory from CAP; (vi) Corrective action was performed if necessary by each location; (vii) Results were reviewed and signed off by the laboratory director. (b) During 2016 - Transfusion Medicine PT events J-A, J-B, and J-C ordered through CAP under the OBI headquarters CLIA number (37D0470358): (i) Each shipment from CAP (containing 4 test kits) was shipped to the headquarters location (each test kit consisted of a sealed styrofoam package which contained PT samples, and PT paperwork such as report forms, attestation forms, etc.). The OBI headquarters then distributed the unopened styrofoam test kits as follows: (aa) Kit #1 - Remained at the OBI headquarters (bb) Kit #2 - Delivered to the Tulsa sub-center by OBI courier (cc) Kit #3 - Delivered to the Ft. Smith sub-center by OBI courier (dd) Kit #4 - Delivered to the Little Rock sub-center by OBI courier (ii) The samples from each test kit were tested at each location, with result forms and attestations completed at each site. The completed paperwork (hard copies) were delivered by OBI courier back to the OBI headquarters in a red folder from each location; (iii) The OBI special project manager reference laboratory electronically entered all PT results for each of the test kits as they were received in the Oklahoma City office from each sub-center. After the final set of results were received from a sub-center, the results were electronically submitted to CAP; (iv) All hardcopies contained in the red folders for the headquarters and each sub-center location were maintained on-site at the OBI headquarters location; (v) Graded evaluations were emailed to the OBI special project manager reference laboratory from CAP; (vi) Corrective action was performed if necessary by each location; (vii) Results were reviewed and signed off by the laboratory director. (c) During 2017 and to date in 2018 - Transfusion Medicine PT events J-A, J-B, and J-C ordered through CAP under each specific location CLIA number (per policy Revision 12 effective 12 /12/16): (i) The headquarters location and each of the three sub-centers received the PT samples directly from CAP specific for their CLIA number for each event; (ii) The headquarters and each sub-center tested the PT samples at their specific location, completed result forms and attestations, reviewed results, and submitted the results electronically from their specific location; (iii) The completed paperwork (hard copies) were then maintained at each specific location; (iv) Graded evaluations were sent to each specific location CLIA number from CAP; (v) Corrective action was performed if necessary by each location; (vi) Results were reviewed and signed off by the laboratory director. (4) The surveyors asked the OBI quality assessment director to explain the process of ordering and paying for PT. The OBI quality assessment director stated to the surveyors (01:34 pm) the OBI headquarters in Oklahoma City was, and continues to be, responsible for enrollment and ensuring payments were processed by the OBI finance department (in Oklahoma City) for the headquarters and sub-centers. In addition, the OBI quality assessment director stated the following: (a) During 2015 and 2016, PT was ordered for the headquarters and each sub-center under the headquarters CLIA number (ordered as separate kits contained in one order); (b) Beginning with the 2017 enrollment, PT was ordered for each facility CLIA number and mailed directly from CAP to each location independently. (5) Based on the provided information, it was determined the OBI headquarters engaged in proficiency testing referral during 2015 and 2016.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the vice-president of bio-development & QM, compliance officer, OBI special project manager reference laboratory, and the OBI quality assessment director, the laboratory director failed to provide overall management and direction. Findings include: The laboratory director failed to ensure proficiency testing samples were tested as required under subpart H of this part. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure 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, policies and procedures, and interview with the vice-president of bio-development & QM, compliance officer, OBI special project manager reference laboratory, and the OBI quality assessment director, the laboratory director failed to ensure proficiency testing samples were tested as required under subpart H of this part. Findings include: The OBI headquarters laboratory engaged in proficiency testing referral during 2015 and 2016. Refer to D2013.