Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469265	02/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oklahoma Blood Institute, Arkansas Blood Institute	5300 South U Street, Fort Smith, AR	

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 validation survey was performed on February 15, 2018 and February 23, 2018. The laboratory was found to be out of compliance with the following CLIA regulations: CFR 493.801: D2000 CONDITION: Enrollment and Testing of Samples CFR 493.1441: D6076 CONDITION: High Complexity 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: Through review of proficiency testing documentation, laboratory policies and procedures, and interview it was determined that the Oklahoma Blood Institute Arkansas laboratory (04D0469265) failed to enroll in a proficiency testing program for each specialty/subspecialty for which it is certified, as required in Subpart I. Findings include: (1) The laboratory failed to enroll in proficiency testing and perform testing under its own CLIA certificate number for 2015 and 2016, and the laboratory engaged in nter-laboratory communication and collaboration in the performance of proficiency testing during 2015 and 2016. Refer to D2011.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Through review of the CASPER 155 report, review of policies and procedure, and review of proficiency testing records it was determined that the laboratory failed to enroll in a proficiency testing program for the services it provides, test proficiency testing samples and report results under its own CLIA certificate number in 2015 and 2016, and the laboratory engaged in inter-laboratory communication and collaboration in the performance of proficiency testing during 2015, 2016. Findings follow: 1. The laboratory failed to enroll in proficiency testing for the years of 2015 and 2016. (a) At the start of the validation survey on 2/15/18 at approximately 0830 the review of the CASPER 155 report revealed that no proficiency testing scores were posted for Oklahoma Blood Institute, Arkansas laboratory (CLIA number 04D0469265) for the years of 2015 and 2016. (b) Review of proficiency testing documentation for 2015 and 2016, for the proficiency testing series of CAP ABT-A, CAP ABT-B, CAP DAT-A, CAP DAT-B, CAP ELU-A, CAP ELU-B, CAP J-A, CAP J-B, CAP J-C, CAP SCS-A, CAP SCS-B, revealed that twenty-two of twenty-two CAP proficiancy testing events reviewed were identified as proficiency testing events for a laboratory with the CLIA certification number of 37D0470358. (c) In an interview on 2/15/18 at approximately 1100, the reference laboratory personnel identified as number 3 on the Entrance and/or Exit Conference Attendance Record stated that in 2015 and 2016 all proficiency testing was ordered by and reported under the CLIA certification number of the main Oklahoma Blood Institute Laboratory in Oklahoma City (CLIA 37D0470358). 2. The laboratory engaged in inter-laboratory communication and collaboration in the performance of proficiency testing during 2015, 2016. (a). The surveyor in an interview on February 23, 2018 at approximately 0900 asked the testing personnel identified as number 7 on the CMS 209 form and the Compliance Officer (via telephone) identified as number 1 on the February 15, 2018 Entrance and /or Exit Conference Attendance Record, to explain the OBI- Arkansas laboratory's process for testing immunohematology proficiency testing samples in 2015, 2016, 2017, and 2018. The testing personnel and the Compliance Officer, identified above, explained the following: (a) Proficiency testing sample kits: (i) During 2015-Proficiency testing events (CAP) (College of American Pathologists) J-A 2015, CAP J-B 2015, and CAP J-C2015): (aa) As per the proficiency testing policy (revision 10), three proficiency testing sample kits for blood bank services were ordered by and received at the OBI-OKC headquarters located in Oklahoma City, under CLIA number (37D470358): (i) Kit # 1: Remained at the OBI-OKC laboratory (ii) Kit # 2: Delivered by OBI courier to the OBI-Tulsa laboratory (37D0931105) (iii) Kit # 3: Delivered by OBI courier to the OBI-Fort Smith, Arkansas laboratory (04D0469265) (ii) During 2016-Proficiency testing events CAP J-A 2016, CAP J-B 2016, and CAP J-C 2016: (aa) As per the proficiency testing policy (Revision 11) four proficiency testing sample kits were ordered by and received at the OBI-OKC headquarters, under its CLIA number: (i) Kit # 1: Remained at the OBI-OKC headquarters (ii) Kit # 2: Delivered by OBI courier to the OBI-Tulsa laboratory (iii) Kit # 3: Delivered to the OBI-Fort Smith Arkansas Laboratory (iv) Kit # 4: Delivered by OBI courier to the

	OBI-Little Rock laboratory (04D2096885) (b) Proficiency sample testing performance at the OBI-Fort Smith laboratory: (i) The testing personnel and Compliance Officer, identified above, stated that the Transfusion Medicine (Comprehensive) proficiency testing (i.e. ABO Group typing, Rh typing, Antibody detection, Antibody identification, and Crossmatch) was performed at the OBI- Fort Smith Arkansas laboratory: (ii) During 2015- As per the proficiency testing policy (Revision 10 and Revision 11) (aa) The proficiency testing results were documented on the proficiency testing program's :Comprehensive Transfusion Medicine Survey Result Forms" and sent to the OBI-OKC headquarters by courier along with the raw data, the attestation statement, and worksheets: (bb) At the OBI-OKC headquarters, the results underwent a medical review" and were then submitted to the proficiency testing program at the OBI-OKC headquarters under the OBI-OKC headquarter's CLIA number. (iii) During 2016- As per proficiency testing policy (Revision 11, effective through 1211/16): (aa) The OBI-Fort Smith Arkansas manager obtained computer access to the proficiency testing program's website in 2016. The OBI-Fort Smith Arkansas manager began entering the OBI-Fort Smith Arkansas laboratory's proficiency testing results into the proficiency testing program website, but did not submit the results: (bb) Personnel at OBI-Fort Smith Arkansas then printed the proficiency testing results, and sent them along with result forms, the attestation statement, and worksheets which was taken to the OBI-OKC headquarters by courier. (cc) At the OBI-OKC headquarters, the results underwent a "medical review" and were then submitted by personnel at the OBI-OKC headquarters under the OBI-OKC headquarters CLIA number. (iv) In 2017, through the days of the survey in 2018: (aa) Beginning with the first proficiency event of 2017, the OBI-Fort Smith Arkansas laboratory began odering its own proficiency testing samples under its own CLIA certificate number, performed the testing, printed and reviewed the results, and submitted the results at the OBI-Fort Smith Arkansas laboratory under its own CLIA certificate number (As per proficiency testing policy Revision 12, effective 12/12/16): (bb) After the scores were received for the events, the proficiency testing documents, raw data, attestation statement. and worksheets were stored at the OBI-Fort Smith Arkansas laboratory. (3) From the review of the CASPER 155 report, review of proficiency testing documentation, review of proficiency testing policy and procedure, and interviews with personnel at the the OBI-Fort Smith Arkansas laboratory and the OBI Compliance Officer, the surveyor identified the following: (a) During 2015 and 2016, the OBI-Fort Smith Arkansas: (i) Failed to enroll in a proficiency testing program, order proficiency testing, and failed to report the results under its own CLIA certificate number (04D 0469265) (ii) Engaged in inter-laboratory communication and collaboration in the performance of proficiency testing, with the OBI-OKC headquarters (37D0931105)
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: Through review of the Casper 155 report, policy and procedure for "Proficiency Testing Program", proficiency testing documentation and interview it was determined that the laboratory failed to notify CMS of receipt of samples identified with the CLIA certification number for another laboratory. Findings follow: A. Review of the Casper 155 report revealed that no proficiency testing scores were posted for Oklahoma Blood Institute, Arkansas Blood Institute laboratory (CLIA number 04D0469265) for the years of 2015 or 2016. B. Review of proficiency testing documentation for 2015 and 2016, events CAP ABT-A, CAP ABT-B, CAP DAT-A, CAP DAT-B, CAP ELU-A, CAP ELU-B, CAP J-A, CAP J-B, CAP J-C, CAP SCS-A, CAP SCS-B revealed that twentry-two of twenty-Two CAP proficiency testing events received were identified as proficiency testing events for a laboratory with the CLIA certification number of 37D0470358. C. Review of proficiency testing documentation for 2015 and 2016 revealed that all proficiency testing events were performed by personnel listed on the CMS 209 form for Oklahoma Blood Institute, Arkansas Blood Institute Laboratory CLIA number 04D0469265. D. Review of the policy and procedure for "Proficiency Testing Program" revealed that there is a discrepancy between laboratory policy and procedure and regulatory requirements. Review of the laboratory's policy and procedure revealed that all revisions of the policy and procedure with the effective dates of 22 Dec 2014, 1 Jun 2015, 11 Apr 2016, 12 Dec 2016, 2 Oct 2017 and 15 Jan 2018 contained the statement: "If samples are received from another laboratory for testing, notify the PT provider within 72 hours of receipt or identification". CFR 493.801(b) requires the laboratory to notify CMS if the laboratory receives proficiency testing assigned to another laboratory. E. In an interview on February 15, 2018 at approximately 11:00 AM the the reference laboratory personnel identified as number 3 on the Entrance and/or Exit Conference Attendance Record stated that until the year 2017 all proficiency testing was reported under the CLIA number for the Oklahoma City Laboratory (37D0470368). F. The OBI Arkansas location failed to follow their own procedure and did not notify the proficiency testing provider and CMS. F. In an interview on February 23, 2018 at approximately 09:00 AM the testing personnel identified as number 7 on the CMS 209 form and the Compliance Officer (via telephone) identified as number 1 on the February 15, 2018 Entrance and/or Exit Conference Attendance Record, confirmed the information. Cross reference to D2000, D2011.
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: Through review of proficiency testing documentation, laboratory policies and procedures and interview it was determined that the laboratory director failed to fulfill the laboratory director responsibilities. Findings include: (1) The director failed to

	authorize testing personnel to perform testing.Refer to D6107 (2) The director failed to ensure the laboratory enrolled in an approved proficiency testing program for the testing performed during 2015 and 2016. Refer to D6088 (3) The director failed to ensure that proficiency testing samples were tested as required under sub-part H of this part during 2015 and 2016. Refer to D6089.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based upon review of CASPER 155 report, review of proficiency testing records, laboratory policies and procedures, and interviews it was determined that the laboratory director failed to ensure the laboratory enrolled in an approved proficiency testing program for the testing it performed. Findings include: (1) The laboratory director failed to ensure the OBI-Fort Smith Arkansas laboratory enrolled in a proficiency testing program for the services it provides, tested proficiency testing samples, and reported proficiency testing results under its own CLIA certificate number in 2015 and 2016. Refer to D2011.
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: Through review of proficiency testing records, laboratory policy and procedure, and interview it was determined that the laboratory director failed to ensure that proficiency testing samples are tested as required under Subpart H of this part. Findings include: (1) The laboratory director failed to ensure that the OBI-Fort Smith Arkansas Laboratory did not engage in inter-laboratory communication and collaboration in the performance of proficiency testing during 2015 and 2016. Refer to D2011.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of personnel records, lack of documentation, and interview it was

	determined that the laboratory director failed to specify in writing the examinations and procedures that personnel are authorized to perform for four of four testing personnel identified on the CMS 209 form. Findings follow: 1. Upon review, personnel files for testing personnel identified as numbers 6 through 9 inclusive on the CMS 209 form did not contain written authorization by the laboratory director to perform procedures and examinations. 2. Upon request, the laboratory was unable to provide written authorization by the laboratory director to perform procedures and examinations for testing personnel identified as numbers 6 through 9 inclusive on the CMS 209 form. 3. In an interview on February 15, 2018 at approximately 1027, the Compliance Officer identified as number 1 on the Entrance and/or Exit Conference Attendance Record confirmed that no written authorization to perform procedures or examinations was present and indicated a lack of knowledge of the requirement.