

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0931105	(X3) Date Survey Completed 02/26/2018
Name of Provider or Supplier Oklahoma Blood Institute	Street Address, City, State 4601 E 81st Street, Tulsa, 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 00051555). The laboratory was found out of compliance with the following CLIA regulations: 493.805: D2000: CONDITION: Enrollment and Testing of Samples 493.1441: D6076: CONDITION: High Complexity Laboratory Director
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, laboratory policies, and interview with the regulatory submission manager and the Tulsa reference lab and transfusion services manager, the laboratory 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 inter-laboratory communication and collaboration in the performance of proficiency testing during 2015 and 2016. Refer to D2011.</p>
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p>

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:

Based on a review of records, laboratory policies, and interview with the regulatory submission manager and the Tulsa reference lab and transfusion services manager, the laboratory failed to enroll in a proficiency testing program for the services it provides, test proficiency 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 and 2016.

Findings include: (1) At the beginning of the complaint survey (03/26/18 09:55AM), the surveyor interviewed the regulatory submission manager and the Tulsa reference laboratory and transfusion services manager. The surveyor then requested the laboratory's proficiency testing policies for 2015 through 2018. The policy (DOC: OBI-QM- SOP-612) had been revised 5 times since 2015. The following was identified: (a) Revision 10: Effective 06/01/15 (b) Revision 11: Effective 04/11/16 (c) Revision 12: Effective 12/12/16 - This revision stated that each CLIA number must enroll separately in proficiency testing (d) Revision 13: Effective 10/02/17 (e) Revision 14: Effective 01/15/18 through the date of the survey (2) The surveyor asked the regulatory submission manager and the Tulsa reference laboratory and transfusion services manager to explain the OBI-Tulsa sub-center's procedure for testing blood bank proficiency testing samples in 2015, 2016, 2017, and 2018. The regulatory submission manager and the Tulsa reference laboratory and transfusion services 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-C 2015): (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 its CLIA number (37D470358): (i) Kit #1: Remained at the OBI-OKC laboratory (ii) Kit #2: Delivered by OBI courier to the OBI-Tulsa sub-center (37D0931105) (iii) Kit #3: Delivered by OBI courier to the OBI-Fort Smith sub-center (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 sub-center (iii) Kit #3: Delivered by OBI courier to the OBI-Fort Smith sub-center (iv) Kit #4: Delivered by OBI courier to the OBI-Little Rock sub-center (04D2096885) (b) Proficiency sample testing performance at the OBI-Tulsa sub-center: (i) The regulatory submission manager and the Tulsa reference laboratory and transfusion services manager explained Transfusion Medicine (Comprehensive) proficiency testing (e.g. ABO Group typing, Rh typing, Antibody Detection, Antibody Identification, and Crossmatch Serology) was performed at the sub-center; (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 placed in a Red Folder with the raw data, the

attestation statement, and worksheets and then taken by OBI courier back to the OBI-OKC headquarters; (bb) At the OBI-OKC headquarters, the results underwent a "medical review" and were then submitted to the proficiency testing program by personnel 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 12/11/16): (aa) The Tulsa reference laboratory and transfusion services manager obtained computer access to the proficiency testing program's website in 2016, although the exact date could not be recalled by the Tulsa reference laboratory and transfusion services manager (03/26/18 10:45AM). The Tulsa reference laboratory and transfusion services manager began entering the OBI-Tulsa sub-center's proficiency testing results into the proficiency testing program website, but did not submit the results; (bb) The Tulsa reference laboratory and transfusion services manager printed the proficiency testing results, placed them with the result forms, raw data, the attestation statement, and worksheets in a Red Folder, which was then taken by OBI courier to the OBI-OKC headquarters; (cc) At the OBI-OKC headquarters, the results underwent a medical review and were then submitted to the proficiency testing program by personnel at the OBI-OKC headquarters under the OBI-OKC headquarter's CLIA number. (iv) In 2017, through the day of the survey in 2018: (aa) Beginning with the First proficiency event of 2017 (CAP J-A 2017), the OBI-Tulsa sub-center began ordering its own proficiency testing samples under its CLIA certificate number, performed the testing, printed and reviewed the results, and submitted the results at the OBI-Tulsa sub-center under its 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-Tulsa sub-center. (3) From the review of proficiency testing policies, and from the interviews with the regulatory submission manager and the Tulsa reference laboratory and transfusion services manager, the surveyor identified the following: (a) During 2015 and 2016, the OBI-Tulsa sub-center: (i) Failed to enroll in a proficiency testing program, order proficiency testing, and failed to report the results under its own CLIA certificate number (37D0931105); (ii) Engaged in inter-laboratory communication and collaboration in the performance of proficiency testing, with the OBI-OKC headquarters (37D0470358).

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 review of records, laboratory polices, proficiency testing records, and interview with the regulatory submission manager and Tulsa reference lab and transfusion services manager, the labortory failed to neroll in a proficiency testing program for tests performed in house under their own CLIA number. 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 (OBI) , Tulsa (CLIA number 37D0931105) for the years of 2015 or 2016. B. Review of proficiency testing documentation for 2015 and 2016, events CAP J-A, CAP J-B, CAP J-C showed the proficiency testing specimens were ordered, distributed to the Tulsa location from the Oklahoma City OBI. The Tulsa location tested the samples; and then forwarded the results to the Oklahoma City OBI location ; who in turn reported the test results to CAP under the Oklahoma City OBI CLIA number. C. The Tulsa location failed to notify the Center for Medicare and Medicaid Services (CMS) of the proficiency testing inter-laboratory communication between the Tulsa and the Oklahoma City OBI location. Cross refer 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:
 Based on a review of records, laboratory policies, and interview with the regulatory submission manager, and the Tulsa reference lab and transfusion services manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure the laboratory enrolled in an approved proficiency testing program for the testing it performed during 2015 and 2016. Refer to D6088; (2) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart 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 on a review of records, laboratory policies, and interview with the regulatory submission manager and the Tulsa reference lab and transfusion services manager, 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-Tulsa sub-center laboratory enrolled in a proficiency testing program for the services it provides, tested proficiency 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:

Based on a review of records, laboratory policies, and interview with the regulatory submission manager and the Tulsa reference lab and transfusion services manager, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H of this part. Findings include: (1) The laboratory director failed to ensure the OBI-Tulsa sub-center laboratory did not engage in inter-laboratory communication and collaboration in the performance of proficiency testing during 2015 and 2016. Refer to D2011.