

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472771	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Harper County Community Hospital	Street Address, City, State 1003 Hwy 64 North, Buffalo, 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 recertification survey was performed on 01/29/19 through 02/01/19. The findings were reviewed with the laboratory manager at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform a technical consultant and general supervisor competency based on the position responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence competencies had been performed for the technical consultant and general supervisor, based on their job responsibilities; (2) The surveyor asked the laboratory manager if competencies had been performed for the technical consultant and general supervisor, based on job responsibilities. The laboratory manager stated the competencies had not been performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

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 follow a written procedure for verifying donor units of packed red blood cells. Findings include: (1) On the third day of the survey, the laboratory manager stated to the surveyor that verifying ABO/Rh donor packed RBC's (red blood cells) was performed using the tube method; (2) The surveyor reviewed the Quick Retyping On Oklahoma Blood Institute Units policy which stated, "A. Follow the ABO/Rh Blood Typing -Tube Procedure (forward type only). B. Read and record all reactions in the Blood Bank Record Book."; (3) The surveyor reviewed 21 donor unit retyping records for testing performed from 08/15/18 through 12/18/18. For 6 of the 21 donor unit records there was no indication the laboratory staff followed their written procedure for retyping donor units: (a) Unit# W09101829922 - There was no documentation of results for the forward type (Anti A cells, Anti B cells, and Anti A,B cells); (b) Unit# W091018289925 - There was no documentation of results for the forward type (Anti A cells, Anti B cells, and Anti A, B cells); (c) Unit# W091018345109 - There was no documentation of results for the forward type (Anti A cells, Anti B cells, and Anti A,B cells); (d) Unit# W091018362942 - There was no documentation of results for the forward type (Anti A cells, Anti B cells, and Anti A,B cells); (e) Unit# W091018329435 - There was no documentation of result for the forward type (Anti A,B cells); (f) Unit# W091018329433 - There was no documentation of result for the forward type (Anti A, B cells). (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated the laboratory failed to follow their procedure for retyping donor units.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) On the second day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory performed D-Dimer testing using the Biosite Triage Meter Plus analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective 05/01/16). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable test results; (3) The surveyor reviewed the records with the laboratory manager and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 03/17/17. The laboratory manager stated a policy had not been written and a QA review had not been performed as indicated above.