

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0707957	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier St Helena Parish Hospital	Street Address, City, State 16874 Highway 43 North, Greensburg, LA	
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 Certification Survey was conducted on June 18, 2018 through June 21, 2018 at St Helena Parish Hospital - CLIA ID # 19D0707957. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues for Blood Bank refrigerator temperature checks. Findings: 1. Review of the laboratory's Quality Assurance Protocol policy revealed under "Refrigerator/Temperature Checks" that "Refrigerator/Temperature checks are to be performed daily in the laboratory. This is to ensure proper storage and performance of reagents, controls, instrumentation, supplies, etc." 2. Further review of the laboratory's Quality Assurance Protocol policy revealed under "Thresholds for Evaluation" that "If the Daily Refrigerator /Temperature checks are not met, the workload, organization of workload, and techniques employed by the General Supervisor and/or other personnel responsible for processing and testing as well as the competency of lab staff/tech performing testing will be reviewed to identify problems that contribute to their inability to meet established criteria." 3. Review of the Quality and Appropriateness Review for Laboratory Blood Bank Temp Charts form revealed the following criteria: a. Are blood bank/temp charts changed every 7 days weekly? b. Are laboratory personnel documenting date/time and initials when putting charts on and off? c. Are laboratory</p>

personnel documenting directly on Revco/blood bank temp charts and discrepancies /fluctuations in temperature? 4. Review of the Blood Bank refrigerator circular charts revealed the following fluctuations in temperature with no documentation: a. Week of January 23, 2017 through January 30, 2017 showed a spike in temperature on Wednesday, January 25, 2017 b. Week of April 30, 2018 through May 7, 2018 showed a spike in temperature on Sunday, May 6, 2018 5. Review of the Quality and Appropriateness Review for Laboratory Blood Bank Temp Charts form for January 2017 and May 2018 revealed that Quality Assurance (QA) was checked for those months with no issues documented. 6. In interview on June 20, 2018 at 1:06 pm, Personnel 2 stated that Personnel 4 changes the circular charts and inspects them. Personnel 2 stated she had no explanation for the changes in temperature. Personnel 2 confirmed that the QA monitors established by the laboratory did not identify the above issues. II. Based on record review and interview with personnel, the laboratory's Quality Assurance (QA) monitors failed to identify and correct quality issues for the Blood Bank Temperature/Humidity checks. Findings: 1. Review of the laboratory's Quality Assurance Protocol policy revealed under "Refrigerator /Temperature Checks" that "Refrigerator/Temperature checks are to be performed daily in the laboratory. This is to ensure proper storage and performance of reagents, controls, instrumentation, supplies, etc." 2. Review of the laboratory's Blood Bank Temperature/Humidity Log Sheet revealed the following three (3) days in February 2017 with unacceptable temperatures recorded: a. On February 24, 2017 - temperature recorded as -70.0 degrees b. On February 25, 2017 - temperature recorded as -69.9 degrees c. On February 26, 2017 - temperature recorded as -67.9 degrees 3. Review of the laboratory's Quality and Appropriateness Review form for February 2017 revealed the QA monitor for Temp/Humidity in lab was checked with no issues documented. 4. In interview on June 21, 2018, Personnel 2 confirmed the QA monitors established did not identify the above issues.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.