

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2025496	<b>(X3) Date Survey Completed</b> 09/09/2020
<b>Name of Provider or Supplier</b> Jefferson Regional Cancer Center	<b>Street Address, City, State</b> 4310 South Mulberry St, Pine Bluff, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:                      . Through a review of the manufacturer instructions for Coulter 4C-ES Cell Controls, Coulter 4C-ES table of expected results, observations made during a tour of laboratory, laboratory patient logs, as well as interview with staff, it was determined the laboratory performed patient testing for Complete Blood Counts (CBC) when the Hematology quality controls had exceeded their open vial expiration date. Survey findings follow: A. A review of manufacturer instructions for Coulter 4C-ES Control storage and stability requirements revealed "when stored at 2-8 degrees Celsius, sealed /unopened tubes are stable until the expiration date show on the vials. For opened vial stability, refer to the Table of Expected results." B. A review of the Table of Expected results for Coulter 4C-ES Controls revealed "open vials of Coulter 4C-ES Controls are stable for thirty-five days. C. During a tour of the laboratory on 9/9/20 at 1342, the surveyor observed three vials of Coulter 4C-ES quality control in the laboratory refrigerator. Low Control lot #068000, Normal control lot #078000, and High Control lot #88000 with an open date of 07/30/2020. The open vial expiration date for Low, Normal, and High Controls was 9/03/2020. D. A review of laboratory patient logs from 9/3/2020 to 9/9/2020 revealed fifteen patients had Complete Blood Counts (CBC) analyzed when the quality controls had expired. E. In an interview on 9/9/2020 at 14:00 technical consultant confirmed the quality controls had exceeded their expiration date and patients were tested for Complete Blood Counts.</p>
<b>D5785</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

. Through a review of the temperature records for 2019 and 2020, lack of documentation, and interviews with staff, it was determined the laboratory failed to document corrective actions taken when refrigerator temperatures were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of temperature logs for 2019 and 2020 revealed the laboratory refrigerator temperature acceptable range was listed as 35 to 46 degrees Fahrenheit. B. A review of the temperature logs for two of twelve months in 2019 revealed the refrigerator temperature was documented outside the acceptable criteria and no corrective actions were performed on three of fifteen days in November 2019, and eleven of fifteen days in December 2019. C. A review of the temperature logs for three of nine months in 2020 revealed the refrigerator temperature was documented outside the acceptable criteria and no corrective actions were performed on one of twenty-two days in March 2020, three of seventeen days in August 2020, and two of five days in September 2020. D. In an interview at 10:30 on 09/09/2020, the technical consultant confirmed the lack of documented corrective actions for refrigerator temperatures outside acceptable criteria.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Through review of the CMS form 209, personnel records, lack of documentation, and interview it was determined that the laboratory failed to document personnel competency on an annual basis for two of five personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records revealed no competency evaluations for 2018 and 2019 were performed for moderate complexity testing personnel identified as number 3 and number 5 on the CMS form 209. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 09/09/2020 at 10:00 a.m., the technical consultant confirmed that competency evaluations had not been performed on the personnel identified above.