

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>04D0469076 | <b>(X3) Date Survey Completed</b><br><br>02/07/2019 |
| <b>Name of Provider or Supplier</b><br><br>Mercy Hospital Paris  | <b>Street Address, City, State</b><br><br>500 East Academy, Paris, 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>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Through observation, review of manufacturer package insert, laboratory temperature records, and interview with laboratory staff it was determined that the laboratory failed to properly define storage requirements for chemistry quality control material and maintain an acceptable storage temperature on 13 of 365 days in 2018. Findings follow: A. During a tour of the laboratory on 2/7/19 at approximately 09:30 AM, six boxes of Multiquel Level 1 quality control material lot # 45791, expiration date 2020-03-31 and six boxes of Multiquel Level 3 quality control material lot # 45793 expiration date 2020-03-31 were observed in the reagent freezer in the blood bank area. B. Review of the manufacturer's package insert for the Multiquel quality control material revealed a storage temperature requirement of -20 degrees C. to -70 degrees C. C. Review of daily temperature records for the reagent freezer in the blood bank area revealed that the acceptable temperature range is defined as -10 degrees C. to -20 degrees C. and the temperature was recorded as: * -14 on 1/20/18, * -18 on 1/19/18, * -18 on 9/20/18, * -18 on 9/24/18, * -18 on 9/25/18, * - 18 on 9/26/18, * -18 on 9/27/18 * - 18 on 9/28/18, * - 16 on 9/29/18, * -18 on 9/30/18 * -18 on 10/1/18, * - 18 on 10/2/18, and * -18 on 10/3/18. All of the temperatures documented above are warmer than the manufacturer defined requirements for Multiquel quality control material. D. In an interview on 2/7/19 at approximately 11:00 AM the general supervisor identified</p> |

as number 3 on the CMS 209 form confirmed that the reagent freezer does not maintain an appropriate temperature range for the storage of Multiqual quality control material.

**D5555**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Through review of the blood bank refrigerator temperature recording charts, lack of documentation and interview with staff it was determined that the temperature of the blood bank refrigerator was not recorded in one of twenty weeks examined when blood products were stored in the refrigerator. Findings follow: A. During the review of the blood bank refrigerator chart from July 2018 through January 2019 it was revealed that a chart for the week of January 1, 2019 through January 7, 2019 was not included. B. Upon request, the laboratory was unable to produce a recording chart for the time period identified above. C. In an interview on 2/7/19 at approximately 11:00 AM, the General Supervisor, identified as number three on the CMS 209 form, confirmed that the Blood Bank refrigerator recording chart for January 1, 2019 through January 7, 2019 was not available.