

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0469076	<b>(X3) Date Survey Completed</b>  09/27/2023
<b>Name of Provider or Supplier</b>  Mercy Hospital Paris	<b>Street Address, City, State</b>  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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Through observation, review of the manufacturer's package insert and interview with laboratory staff members it was determined that the laboratory failed to re-assign an amended expiration date for one of one box of arterial blood gas control material as required by the manufacturer. Findings follow: A) During a tour of the laboratory on 9/27/23 at 2:09 p.m., one of one box of Opti - Check Plus arterial blood gas control with a storage temperature requirement of 2 degrees C. to 8 degrees C. noted on manufacturer's box and with a hand written label of "3-14" was observed in a storage cabinet at room temperature. B) Review of the manufacturer's package insert revealed that the material could be stored "up to 2 months at room temperature" and the expiration date should be amended as appropriate if stored at room temperature. C) In an interview on 9/27/23 at 2:09 p.m, when asked when the material was placed at room temperature the laboratory staff member (# 3 on the CMS 209 form) replied "I don't know". D) In an interview on 9/27/23 at 2:09 p.m., the laboratory staff member (# 3 on the CMS 209 form) stated that the control material identified above should have been labeled with the date it was placed at room temperature and the expiration date amended.</p>
<b>D5783</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Through review of the Troponin (TR) and PRO-B-Type Natriuretic Peptide,(Pro BNP) quality control (QC) summary reports for January and May 2023, the laboratory policy and procedure for quality control of chemistry assays lack of documentation and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in three of three occasions when QC results failed to meet the laboratory's criteria for acceptability and corrective action required making changes in the laboratory's test systems. Findings follow: A) Review of QC results for TR testing for January 2023 revealed that level 1 Biorad Cardiac Control lot # 586866 QC material had consecutive "failed warn" flags on 1/6/23 and note of corrective action stated "recalibrate" which represented a change in the test system. Review of QC results for Pro BNP testing for May 2023 revealed that beginning on 5/3/23 at 7:04 a.m. level 3 of Biorad Cardiac QC material lot # 586867 had flags "failed" on four consecutive attempts before being acceptable at 10:24 a.m. with a final note of corrective action "recalibrate" which represented a change in the testing system. Review of QC results for Pro BNP testing for May 2023 revealed that on 5/16/23 level 1 of Biorad Cardiac QC material lot # 586866 had flags "failed" on two consecutive attempts before being acceptable with a final note of corrective action "recalibrate" which represented a change in the testing system. B) Review of the laboratory policy for quality control of chemistry assays states "previous patient results must be evaluated to determine if the reason for the QC failure may have had an adverse impact on patient results since the last successful QC run". C) Review of patient results for TR revealed that 3 patient (numbers 1 through 3 on a separate patient identification list) TR tests had been performed since 1/5/23 at 7:57 a. m. Review of patient results for Pro BNP tests revealed that 1 patient ( number 4 on the separate patient identification list) had a Pro BNP result reported on 5/15/23 and 1 patient (identified as number 5 on the separate patient identification list) had a Pro BNP result reported on 5/2/23. D) Upon request, the laboratory was unable to provide documentation that the tests results identified above had been evaluated. E) In an interview in 9/27/23 at 11:57 a.m. the laboratory staff member (# 3 on the CMS 209 form) confirmed that the consecutive QC failures identified above did not have previous result evaluation documented and should have had as per laboratory policy.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Through review of personnel competency records for seven testing personnel listed on the CMS 209 form, authorizations to perform tests, and interview, it was determined

that the laboratory did not assess the competency of one of seven testing personnel semi-annually during the first year of employment. Findings follow: A) Review of personnel records of testing personnel ( number 8 on the CMS 209 form) indicated that the employee was hired in November 2021 and authorized by the laboratory director to perform moderately complex testing without direct supervision. B) Upon review of personnel records of testing personnel (number 8 on the CMS 209 form) competency evaluations were dated as performed on May 2021 and March 2023 which do not document competencies performed semi-annually during the first year of employment which was November 3, 2021 to November 3, 2022 for this personnel. C) In an interview on 9/27/23 at 2:45 p.m., the hospital staff member (number 3 on the CMS 209 form) verified that competency evaluations were not performed semi-annually during the first year of employment for the testing personnel (number 8 on the CMS 209 form).