

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469373	(X3) Date Survey Completed 07/23/2021
Name of Provider or Supplier Mercy Waldron	Street Address, City, State 1341 W 6th St, Waldron, AR	
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
D5415	<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 manufacturer's package inserts, and interview with laboratory staff it was determined that the laboratory failed to amend expiration dates of three of three hematology controls, three of three chemistry controls as required by the manufacturer and failed to label one of one bottles of saline solution. Findings follow: 1. Failure to amend expiration dates of control material as required by the manufacturer. A) Review of the manufacturer's package insert for Biorad Multiquel chemistry controls states "when thawed and opened the product is stable for all analytes for 14 days"; review of the manufacturer's package insert for e-check hematology controls states when opened and placed into use the product is stable for 14 days. B) During a tour of the laboratory on 7/23/21 at 09:45a.m., three of three bottles of Biorad Multiquel chemistry controls lot # 56671 levels 1,2 and 3 with an expiration date 2023-06-30 were observed thawed and opened in the laboratory refrigerator and three of three bottles of e-check hematology controls lot# 11520804, 11520805, 11520806 with an expiration date 2021-02-22 were observed opened in the laboratory refrigerator. C) In an interview at 10:00 a.m. the laboratory staff member, identified as number two on the CMS 209 form confirmed that the materials, identified above, were opened and in use and were not labeled with an amended expiration date as required by the manufacturer. 2. Failure to label one of one bottle of saline soution. A) During a tour of the laboratory on 7/23/21 at 09:45 a.m., one of one plastic bottle half filled with a clear liquid was observed on the laboratory counter in</p>

the blood bank area with no label of contents. B) When asked what the bottle, identified above, contained, on 7/23/21 at 09:45 a.m. the laboratory staff member, identified as number two on the CMS 209 form, said the bottle contained "blood bank saline" and confirmed that it was in use and was not labeled.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Through review of of laboratory's policy for Quality Control (#10010), the Quality Control Summary for July 2020, November 2020 and March 2021, lack of documentation and interview with laboratory staff members it was determined that the laboratory failed to document corrective action when results of quality control failed to meet the laboratory's criteria for acceptability in two of the three months reviewed. Findings follow: A) Review of the laboratory policy for "Quality Control Guidelines" revealed that quality control is unacceptable "when one or more controls are out of three SD" (standard deviation index) and "document action taken in action log". B) Review of the Quality Control Summary Report revealed that STA - Coag Control ABN Plus lot# 256275 expiration date 2021-09-30 was reported for prothrombin time (PT) assays as greater than 3SD on five consecutive runs on 11/26/20; STA-Coag Control N Plus lot# 256275 expiration date 2021-09-30 was reported for partial thromboplastin time (PTT) assays as greater than 3 SD on two consecutive runs on 3/14/21 ; and STA - Coag Control ABN Plus lot# 256275 expiration date 2021-09-30 was reported for prothrombin time (PT) assays as greater than 3SD on 3/16/21 and on four consecutive runs on 3/24/21. C) Upon request, the laboratory was unable to provide documentation of the corrective action taken when QC values failed to meet the laboratory's criteria for acceptability on the instances identified above. D) In an interview on 7/21/21 at 3:25 p.m. the laboratory staff member, identified as number two on the CMS 209 form, confirmed that documentation of corrective action was not available for the instances identified above.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(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 laboratory's policy and procedure for quality control, review of the quality control summary reports for July and November 2020, review of patient results, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful quality control run on two of two instances when quality control results for total bilirubin assays failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure for quality control revealed that quality control results are unacceptable when one of two levels of quality controls are greater than two standard deviation index (SDI) from the target value on two consecutive runs. B) Review of the laboratory's policy and procedure for quality control revealed that there was no requirement mentioned in the policy to evaluate patient results back to the last successful quality control run when quality control failed to meet acceptable criteria. C) Review of the quality control summary report revealed that Biorad Multiquel lot 47983 was greater than 2SDI from the target value on four consecutive runs for total bilirubin assay on 7/3/20. The previous successful QC for total bilirubin was recorded at 01:00 a.m. on 7/2/21. D) Review of patient result reports revealed that total bilirubin assays were performed and reported on twenty-two patients, identified as numbers one through twenty-two on a separate patient identification list, on 7/2/21. E) Upon request, the laboratory was unable to provide documentation of the total bilirubin tests performed on the patients identified above, had been evaluated. F) In an interview on 7/22/21 at 10:20 a.m., the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the total bilirubin results identified above had not been evaluated. G) Review of the quality control summary report revealed that Biorad Multiquel lot 47983 was greater than 2SDI from the target value on three consecutive runs for total bilirubin assay on 11/22/20. The previous successful QC for total bilirubin was recorded at 00:15a.m. on 11/21/20. H) Review of patient result reports revealed that total bilirubin assays were performed and reported on eight patients, identified as numbers one through eight on a separate patient identification list, on 11/21/20. I) Upon request, the laboratory was unable to provide documentation of the total bilirubin tests performed on the patients identified above, had been evaluated. J) In an interview on 7/22/21 at 11:10 a.m., the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the total bilirubin results identified above had not been evaluated.