

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469039	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier Johnson Regional Medical Center	Street Address, City, State 1100 East Poplar, Clarksville, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Through review of the CMS 209 form, personnel records and confirmed by interview it was determined that the competency of one of ten testing personnel reviewed was not performed at least on an annual basis and competency evaluations did not contain documentation that competency evaluations were performed utilizing the six required elements of competency evaluations , i.e. through direct observation of test performance, reveiw of test results, review of maintenance and quality control files, direct observation of maintenance procedures, review of intermediate test results and assessment of test performance through proficiency testing or blind samples. Findings follow: 1. Competency evaluations were not performed on an annual basis. A) Review of personnel files for the testing personnel, identified as number sixteen on the CMS 116 form, revealed that the employees date of hire was 12/18/18.. B) Review of personnel files revealed documentation of annual evaluation of the competency of the testing personnel, identified as number sixteen on the CMS 209 form, were dated 12 /23/18 and the last competency evaluation was dated 7/19/19 and no other competency evaluations were present . C) Upon request, the laboratory was unable to provide an additional competency evaluation of the testing personnel, identified as number sixteen on the CMS 209 form, since 7/19/19 . D) In an interview on 5/4/21 at 01:45 PM, the laboratory staff member, identified as number six on the CMS 209 form. stated the the date of hire of the testing personnel, identified as number two on the CMS 209 form, was in December of 2018 and competency evaluation had not been performed for the testing personnel since 7/19/19. 2. Competency evaluations were not performed utilizing the required elements of assessing testing personnel</p>

competency. A) Review of the competency evaluation of the testing personnel, identified as number sixteen on the CMS 209 form, revealed that competency was assessed as " 1- below standard, 2- meets standard. 3-above standard" but does not confirm the methods used in determining the assessment. B) In an interview on 5/4/21 at 01:45 PM, the laboratory staff member, identified as number six on the CMS 209 form, confirmed that documentation does not specify the required elements of competency evaluation.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Through interview and lack of documentation and review of specimen logs it was determined that the laboratory did not provide clients with written instructions for specimen submission, handling, and referral as specified in CFR 493.1242 paragraphs (a)(1) through (a)(7). A. In an interview on 5/4/21 at 11:03, AM the laboratory staff member, identified as number six on the CMS 209 form, said that the laboratory received and tested specimens referred from "two or three" outside home health agencies. B. Upon request, the laboratory could not provide a copy of a client services manual or evidence of instructions for specimen collection and handling that is provided to clients . C. In an interview on 5/4/21 at 11:03 the laboratory staff member identified as number six on the CMS 209 form confirmed that the laboratory did not provide instruction manuals for specimen submission, handling and referral to outside clients . D) Review of the laboratory's "Sign-In Log For Specimens Brought" revealed that sixteen specimens were received from three outside agencies for testing between the dates of 4/26/21 to 5/5/21.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:
Through observation, review of the manufacturer's instrument user's manual and package inserts, the laboratory's plan of correction for the CLIA survey performed on 9/28/18, review of the laboratory's humidity records and interview it was determined that the laboratory failed to assure that humidity levels were maintained within instrument manufacturer's requirements and that amended expiration date or the date opened was not present on three of three vials of hematology control material. Findings follow: 1. Operating humidity levels did not meet the manufacturer's requirement. A) During a tour of the laboratory on 5/4/21 at 10:45 AM, two Beckman

AU 480 chemistry analyzers were observed in the laboratory. B) In an interview on 5/4/21 at 10:45 AM, the laboratory staff member, identified as number six on the CMS 209 form, stated that the two Beckman AU 480 analyzers were the main chemistry instruments and specified the laboratory testing performed on each instrument. C) Review of the manufacturer's user's manual for the Beckman AU 480 analyzers revealed an operating humidity level of 40% to 80% non-condensing. D) Review of the plan of correction for the CLIA survey performed on 9/28/18 revealed that the laboratory was cited for not monitoring required humidity in the laboratory and a sample humidity log was submitted listing a humidity requirement of 40% to 80%. E) Review of the laboratory's humidity records for 2020 revealed that the acceptable humidity levels were listed as 20% to 80% and the humidity level was recorded as below 40% on 25 of thirty-one days in January 2020, 21 of 29 days in February 2020, 17 of 30 days in April 2020, 17 of 31 days in November 2020 and 25 of 31 days in December 2020. F) In an interview on 5/5/21 at 01:30 PM, the laboratory staff member, identified as number six on the CMS 209 form, confirmed that the required operating humidity level for the Beckman AU 480 chemistry analyzers was 40% to 80% and that the laboratory failed to maintain the required levels in the instances identified above and the manufacturer had not provided documentation that relaxed the humidity requirement for the Beckman AU 480 analyzers.

2. Amended expiration date or the date opened was not present for hematology control material. A) Review of the package insert for Coulter 4C hematology controls revealed that expiration date should be changed to ten days after the control material vials were opened and placed into use. B) During a tour of the laboratory on 5/5/21 at 02:30 PM three vials of Coulter 4C hematology controls lot numbers 069700, 079700, and 089700 were observed in the laboratory refrigerator without a date opened or amended expiration date. C) In an interview on 5/5/21 at 04:09, the laboratory staff member, identified as number six on the CMS 209 form, confirmed that the hematology control material, identified above, were currently in use and the date of opening or amended expiration date were not present on the control vials.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the laboratory's Quality Control Summary report for June of 2020, lack of documentation, review of patient results and interview with laboratory staff it was determined that the laboratory performed and reported seven Troponin results on one of thirty days reviewed without QC being performed. Finding follow: A) Review of the laboratory's Quality Control Summary report revealed that no quality control results for Troponin were listed for 6/19/20. B) Upon request, the laboratory was unable to provide quality control results for Troponin performed on 6/19/20. C) Review of patient results revealed that Troponin tests were performed and reported on seven patients, identified as numbers thirty-three through thirty-nine on 6/19/20. D) In

an interview of 5/12/21 at 03:35 PM the laboratory staff member, identified as number six on the CMS 209 form confirmed that Troponin tests were performed and reported on the patients identified above without quality control being performed on the day the tests were performed.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

1) Through a review of the laboratory's "Quality Control Protocol", review of Complete Metabolic Profile (CMP) quality control summary for January 2021, review of patient result reports and interview with laboratory staff, it was determined that eighteen CMP patient results were reported when results of control material failed to meet the criteria for acceptability in one of thirty-one days reviewed. Survey findings follow: A. Review of the laboratory's quality control protocol revealed that "two levels of three levels of QC must be within 2 SD for each test run". B. Review of the laboratory's quality control summary for Biorad Mutliqual QC material lot #'s 45811, 45812, 45813 revealed that on 1/5/21 on instrument 8021809 that QC results were unacceptable on 1/5/21 at 02:53 PM and 1/5/21 at 04:07 PM with no other QC results being performed on 1/5/21. The previous successful QC for instrument 8021809 was performed on 1/4/21 at 01:56 PM. C. Upon request, the laboratory could not show that quality control results had been within acceptable range on the day identified above for instrument 8021809. D. Review of patient reports revealed that CMP results had been reported on eighteen patients, identified as numbers one through eighteen on the separate patient identification list, on instrument 8021809 on 1/5/21 from 01:56 PM until 1/6/21 at 03:54 PM, the date and time for the next successful QC performed on instrument 8021809. E. In an interview on 5/12/21 at 3:35 PM, the laboratory staff member identified as number six on the CMS 209 form confirmed that patient CMP results had been performed on instrument 8021809 and reported when CMP quality control had not been within acceptable limits on the date identified above. 2) Through a review of the laboratory's "Quality Control Protocol", review of Albumin (Alb) quality control summary for June 2020, review of patient result reports and interview with laboratory staff, it was determined that fourteen Alb patient results were reported when results of control material failed to meet the criteria for acceptability in one of thirty days reviewed. Survey findings follow: A. Review of the laboratory's quality control protocol revealed that "two levels of three levels of QC must be within 2 SD for each test run". B. Review of the laboratory's quality control summary for Biorad Mutliqual QC material lot #'s 45811, 45812, 45813 revealed that on 6/26/20 on instrument 8021807 that Alb QC results were unacceptable on at 08:56 AM with no other QC results being performed on 6/26/20. The previous successful QC for instrument 8021807 was performed on 6/25/20 at 09:00 AM. C. Upon request, the laboratory could not show that quality control Alb results had been within acceptable range on the day identified above for instrument 8021807. D. Review of patient reports revealed that Alb results had been reported on fourteen patients, identified as numbers nineteen through thirty-two on the separate patient identification list, on instrument 8021807 on 6/26/20 from 01:56 PM until 6/27/20 at 09:17 AM, the date and time for the next successful QC performed on instrument 8021807. E. In an interview on 5/12/21 at 3:35 PM, the laboratory staff member identified as number six

on the CMS 209 form confirmed that patient Alb results had been performed on instrument 8021807 and reported when Alb quality control had not been within acceptable limits on the dates identified above.

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 quality control (QC) records for white blood cell counts (WBC) for July 2020, review of the laboratory policy/procedure for "Quality Control Shifts and Trends", lack of documentation and interview it was determined that the laboratory failed to document corrective action on one of three months reviewed when WBC QC demonstrated a negative trend. Findings follow: A) Review of the laboratory policy for "Quality Control Shifts and Trends" revealed that a trend is defined when "10 consecutive runs greater than one S.D. on one side of the mean" B) Review of WBC QC records for July 2020 revealed that QC results were one S.D. or greater below the mean on 16 consecutive days between 7/16/21 to 7/31/21 for low hematology control lot # 067600, QC results were one S.D. or greater below the mean on 24 consecutive days between 7/2/21 to 7/25/21 for normal hematology control lot # 077600 and QC results were one S.D. or greater below the mean on 28 consecutive days between 7/1/21 and 7/28/21 for high hematology control lot # 087600. C) Upon request, the laboratory was unable to provide documentation of corrective action for WBC testing for July 2020. D) In an interview on 5/6/21 at 11:00 AM, the laboratory staff member, identified as number 6 on the CMS 109 form, confirmed that the WBC QC for July 2020 was defined as a trend and that there was no corrective action taken.

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 a review of the laboratory's "Quality Control Protocol", review of Complete Metabolic Profile (CMP) quality control summary for January 2021, review of patient result reports, lack of documentation and interview with laboratory staff, it was

determined that sixteen CMP patient results performed since the last successful QC were not evaluated when results of control material failed to meet the criteria for acceptability in one of thirty-one days reviewed. Survey findings follow: A. Review of the laboratory's quality control protocol revealed that "two levels of three levels of QC must be within 2 SD for each test run". B. Review of the laboratory's quality control summary for Biorad Mutliqual QC material lot #'s 45811, 45812, 45813 revealed that on 1/5/21 on instrument 8021809 that QC results were unacceptable on 1/5/21 at 02:53 PM and 1/5/21 at 04:07 PM with no other QC results being performed on 1/5/21. The previous successful QC for instrument 8021809 was performed on 1/4/21 at 01:56 PM. C. Upon request, the laboratory could not show that quality control results had been within acceptable range on the day identified above for instrument 8021809. D. Review of patient reports revealed that CMP results had been reported on sixteen patients, identified as numbers forty through fifty-five on the separate patient identification list, on instrument 8021809 from 1/4/21 at 01:56 PM, the date and time for the last successful QC performed on instrument 8021809, to 1/5/21 at 02:53 PM. E. Upon request, the laboratory was unable to provide documentation that the results, identified above, had been evaluated. F. In an interview on 5/12/21 at 3:35 PM, the laboratory staff member identified as number six on the CMS 209 form confirmed that patient CMP results performed on instrument 8021809 had not been evaluated back to the last successful QC when CMP quality control had not been within acceptable limits on 1/5/21 .