

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468990	(X3) Date Survey Completed 08/16/2019
Name of Provider or Supplier Millard Henry Clinic	Street Address, City, State 101 Skyline Dr, Russellville, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: Through review of manufacturer's package inserts, review of the laboratory's temperature and humidity records, observation and interview it was determined that the laboratory did not provide proper storage conditions for three of three boxes of Biorad Multiquel quality control material and did not maintain laboratory humidity level required for the operation of the Advia Centaur XP immunology analyzer on ninteteen of twenty-six days of operation in January 2019. Findings follow: 1. The laboratory failed to provide proper storage conditions for Biorad Multiquel quality control material. A) Review of the manufacturer's package insert for Biorad Multiquel quality control material revealed the statement "for optimum performance, avoid storing this product in a frost-free freezer". B) During a tour of the laboratory on 8/16 /19 at approximately 10:45 AM, three boxes of Biorad Multiquel quality control material lot # 45790, expiration date 2020-03-31 were observed stored in a frost-free freezer. C) In an interview on 8/16/19 at approximately 10:45 AM, the laboratory staff member identified as number two on the CMS 209 form, confirmed that the Multiquel quality control material was stored in a frost-free freezer. 2. The laboratory failed to maintain the required operating humidity level for the Advia Centaur XP immunology instrument. A) Review of the manufacturer's manual for the Advia Centaur XP immunology analyzer revealed an operating humidity requirement of 20% to 80%. B)</p>

Review of the laboratory's room humidity records for January 2019 revealed an acceptable range of 10% to 85% and a recorded room humidity of 19% on 1/2/19, 1/5/19, 1/9/19/ 1/10/19, 1/11/19, 1/12/19, 1/14/19, 1/15/19, 1/16/19, 1/21/19, 1/22/19, 1/23/19, 1/24/19, 1/25/19, 1/26/19, 1/29/19, 1/30/19 and 1/31/19. C) In an interview on 8/16/19 at approximately 10:45 AM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the proper acceptable humidity range should be 20% to 80% and the humidity level was below the required level on the days identified above.

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Through review of the manufacturer's manual for the Atellica CH Analyzer, patient THC result logs for 2019, and interview with laboratory staff it was determined that the laboratory did not refer eighty-seven of eighty-seven positive THC results for confirmatory procedures as directed by the manufacturer. Findings follow: A) Review of the manufacturer's manual for the THC assay performed on the Atellica CH analyzer revealed, "The THC assay provides only a preliminary analytical test result. A more specific chemical method must be used to obtain a confirmed analytical result". B) Review of the THC patient result logs revealed that eighty-seven positive THC results were reported from 1/1/19 through 7/31/19 on patients identified as numbers one through eighty-seven on the patient result log. C) In an interview on 8/15/19 at approximately 01:45 PM, the laboratory staff member, identified as number two on the CMS 209 form, stated that positive THC tests are not referred unless the ordering physician requests confirmation and the positive results on the patient identified above had not been referred for confirmation.

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, the laboratory's January 2019 and May 2019 quality control records for CCP IgAb testing, patient result reports, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful quality control on two of two occasions affecting three patients when quality control failed to meet the laboratory's acceptable criteria. Findings follow: A) Review of the laboratory's

policy and procedure for quality control reveals that "patient results obtained immediately prior to the failed control run must be verified if the cause of the problem was such that it existed at the time of the previous tests." B) Review of quality control records for CCP IgAb testing for January 2019 revealed that QC1 with an acceptable range of 0.15 to 4.91 had reported results greater than 5.0 on six successive attempts between 08:14 AM and 03:38 PM on 1/30/19 with comments describing corrective action which include, "new reagent" and "calibrating this reagent". A comment written on 1/31/19 states "I discovered a WASH 1 reservoir leak and slowed it significantly until can order a new O-ring". The comments indicate a cause that might have existed at the time of previous tests. C) Review of quality control records for CCP IgAb testing for January 2019 revealed that QC2 with an acceptable range of 42.89 to 54.59 had reported results greater than 56.0 on six successive attempts between 08:14 AM and 03:38 PM on 1/30/19 with comments describing corrective action which include "Called service and recalibrating", which indicates a cause that might have existed at the time of previous tests. D) Review of quality control records for CCP IgAb testing for January 2019 revealed that the successful results for QC1 and QC2 immediately prior to 1/30/19 was performed at 10:14 AM on 1/28/19. E) Review of the laboratory's log of CCP IgAb testing for January 2019 revealed that testing was performed on 1/28/19 and one patient, identified as number one on a separate patient identification list, was reported on 1/28/19 at 03:18 PM. F) Upon request, the laboratory was unable to provide documentation that the CCP IgAb results on the patient identified as number one on the separate patient identification list had been verified. G) Review of quality control records for CCP IgAb testing for May 2019 revealed that QC2 with an acceptable range of 42.89 to 54.59 had reported results greater than 56.0 on two successive attempts between 01:45 PM and 03:28 PM on 5/17/19 with comments describing corrective action which include "mixing reagent will rerun, and will start with new reagent on Monday, which indicates a cause that might have existed at the time of previous tests. H) Review of quality control records for CCP IgAb testing for May 2019 revealed that the successful results for QC1 and QC2 immediately prior to 5/17/19 was performed at 09:33 AM on 5/16/19. I) Review of the laboratory's log of CCP IgAb testing for May 2019 revealed that testing was performed on 5/16/19 and two patients, identified as numbers two and three on a separate patient identification list, were reported on 5/16/19 at 12:21 PM and 03:06 PM. J) Upon request, the laboratory was unable to provide documentation that the CCP IgAb results on the patient identified as numbers two and three on the separate patient identification list had been verified. K) In an interview on 8/15/19 at approximately 01:45 PM, the laboratory staff member identified as number three on the CMS 209 form confirmed that quality control failures on 1/30/19 and 5/17/19 indicated a system failure and the results on the patients obtained immediately prior to the failed control run were not verified.