

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0936089	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Cullman Internal Medicine	Street Address, City, State 1890 Alabama Hwy 157 Suite 300, Cullman, AL	
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: Based on a review of the temperature records, a review of the BioRad Liquid Assayed MultiQual Quality Control (QC) package insert, and an interview with Testing Personnel #1, the surveyor determined the laboratory's criteria for Freezer temperatures failed to be consistent with the manufacturer's storage requirements. The laboratory further failed to ensure QC was stored as per manufacturer's requirements for seven out of seven months from January 2022 to July 2022 reviewed by the surveyor. The findings include: 1. A review of temperature records revealed the acceptable range for the Freezer was -17 to -23 degrees Celsius. The temperature records also revealed the following: a) January 2022 - 21 out of 21 days were warmer than -20 degrees Celsius. b) February 2022 - 17 out of 20 days were warmer than -20 degrees Celsius. c) March 2022 - 16 out of 23 days were warmer than -20 degrees Celsius. d) April 2022 - 19 out of 21 days were warmer than -20 degrees Celsius. e) May 2022 - 18 out of 21 days were warmer than -20 degrees Celsius. f) June 2022 - 19 out of 21 days were warmer than -20 degrees Celsius. g) July 2022 - 14 out of 19 days were warmer than -20 degrees Celsius. 2. A review of the BioRad Liquid Assayed MultiQual QC package insert revealed storage requirements of -20 to -70 degrees Celsius. 3. During an interview on 08/02/2022 at 3:30 PM, Testing Personnel #1 confirmed the above findings.</p>

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the QIAstat-Dx Respiratory Panel Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to run controls at least once each day of patient testing or implement an Individualized Quality Control Plan (IQCP) for the QIAstat-Dx Analyzer. From December 2020 through June 2022, the surveyor noted 231 days of patient testing, and only 42 days when QC was performed. The findings include: 1. A review of the QIAstat-Dx Respiratory Panel QC records revealed Pos A, Pos B-1, and Negative QC was performed with each new kit lot number from 12/29/2020 to 06/28/2022. 2. During an interview on 08/02/2022 at 11:45 AM, Testing Personnel #1 confirmed QC was only run with each new lot number, and the laboratory had not implemented an IQCP to allow decreased frequency of QC performance.