

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2146064	(X3) Date Survey Completed 12/22/2021
Name of Provider or Supplier Rainbow City Careplus, Llc	Street Address, City, State 1605 Rainbow Drive, Gadsden, 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 temperature logs, a review of the contents of the laboratory refrigerator, and interviews with Testing Personnel #1 and the Lab Supervisor, the laboratory failed to record the refrigerator temperatures three months in 2021, and failed to ensure the refrigerator maintained temperatures required for the storage of items therein as per manufacturer's specifications for more than two months. The findings include: 1. A review of the refrigerator temperatures revealed the laboratory failed to record the temperatures in April, May and June 2021. The surveyor further noted 2-8 degrees Celsius (C) was documented as the acceptable ranges for the refrigerator, however temperatures were below this range from 10/7 thru 12/21/2021 (two and a half month out of range). 2. On 12/21/2021 at 12/20 PM the surveyor reviewed the contents of the refrigerator with Testing Personnel #1. Contents included the Medonic Hematology quality controls (QC), the DCA Vantage Urine Microalbumin/Creatinine QC, and the Immunocard Mycoplasma kit. A review of the manufacturer's storage requirements for these items revealed a required temperature range of 2-8 degrees C. 3. During the exit summation on 12/21/2021 at 2:30 PM, the above noted findings were reviewed and confirmed with the Lab Supervisor. .</p>
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:

Based on a review of temperature logs, a review of the contents of the laboratory refrigerator, and interviews with Testing Personnel #1 and the Lab Supervisor, the laboratory failed to implement corrective actions when refrigerator temperatures exceeded the manufacturer's requirements for storage of quality controls (QC) and kits therein. This occurred for two and half months in 2021. The findings include: 1. A review of the refrigerator temperatures revealed the laboratory established 2-8 degrees Celsius (C) as the acceptable ranges for the refrigerator, however temperatures were below this range from 10/7 thru 12/21/2021 (two and a half month out of range) with no documentation of corrective action. 2. On 12/21/2021 at 12/20 PM the surveyor reviewed the contents of the refrigerator with Testing Personnel #1. Contents included the Medonic Hematology QC, the DCA Vantage Urine Microalbumin/Creatinine QC, and the Immunocard Mycoplasma kit. A review of the manufacturer's storage requirements for these items revealed a required temperature range of 2-8 degrees C. 3. During the exit summation on 12/21/2021 at 2:30 PM, the above noted findings were reviewed and confirmed with the Lab Supervisor. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of quality assurance documentation, personnel files and temperature records, and an interview with the Lab Supervisor, the surveyor determined the laboratory failed to implement and follow an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the quality of the analytic systems in 2021. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A) Temperature monitoring (Refer to D5413) B) Corrective action documentation (Refer to D5781) C) Testing Personnel training (Refer to D6045) 2. During the exit summation with the Lab Supervisor on 12/21/2021 at 2:30 PM, the surveyor reviewed and confirmed the above noted concerns. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on reviews of personnel files, laboratory records, and an interview with the Lab Supervisor, the Technical Consultant failed to ensure training on the Medonic M Series Hematology analyzer was performed and documented for three of three testing personnel before they began patient CBC (Complete Blood Count) testing. The findings include: 1. A review of personnel files revealed no documentation of training on the Medonic M Series Hematology analyzer (Serial #28615) for three of three testing personnel. A review of laboratory records revealed the Medonic was transferred from another CarePlus facility and installed at this location on 8/20/2020; patient CBC testing began on 4/6/2021. 2. During an interview on 12/14/2021 at 12:30 PM, the Lab Supervisor (not listed on the Form CMS-209 [Laboratory Personnel Report]) explained she had trained the testing personnel on 4/5/2021, including calibrations, Quality Control validation and performance, maintenance and general use of the instrument. The surveyor then asked if she had documented the training; the Lab Supervisor answered, "No". SURVEYOR ID# 32558 Licensure and Certification Surveyor