

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1016874	(X3) Date Survey Completed 05/19/2023
Name of Provider or Supplier Chris Burling Md, Pa	Street Address, City, State 618 N Jefferson Suite 1, Mount Pleasant, TX	
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
D0000	An onsite survey conducted 05/19/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to document corrective action for 21 of 126 days where the storage temperature was outside of range specifications for the Boule Hematology controls reviewed from October 2022 to March 2023. The findings included: 1. In a tour of the laboratory on 5/19/2023 at 10:10 hours, the surveyor noted Boule Con-Diff hematology controls used in quality control testing in hematology, in the refrigerator. 2. Review of the laboratory policy titled "Medonic M-Seried Hematology Analyzer" section "Controls and Calibrators" had the following statement: "CDS Boul Con-Diff Controls, tri-level - Store at 2 - 10 degrees Celsius (C)" 3. Review of the laboratory temperature logs from October 2022 to March 2023 had the following days where the refrigerator temperature was out of range with no documented corrective action: October 2022: 2 days 10/17 - 33 degrees F / 0.5 degrees C 10/31 - 33 degrees F / 0.5 degrees C November 2022: 3 days 11/16 - 34</p>

degrees F / 1.66 degrees C 11/17 - 34 degrees F / 1.66 degrees C 11/18 - 34 degrees F / 1.66 degrees C December 2022: 4 days 12/1 - 34 degrees F / 1.66 degrees C 12/19 - 32 degrees F / 0 degrees C 12/21 - 34 degrees F / 1.66 degrees C 12/21 - 34 degrees F / 1.66 degrees C January 2023: 11 days 1/9 - 32 degrees F / 0 degrees C 1/12 - 33 degrees F / 0.5 degrees C 1/13 - 34 degrees F / 1.66 degrees C 1/16 - 33 degrees F / 0.5 degrees C 1/17 - 32 degrees F / 0 degrees C 1/18 - 32 degrees F / 0 degrees C 1/19 - 33 degrees F / 0.5 degrees C 1/24 - 32 degrees F / 0 degrees C 1/25 - 33 degrees F / 0.5 degrees C 1/26 - 32 degrees F / 0 degrees C 1/30 - 32 degrees F / 0 degrees C February 2023: 1 day 2/16/2023 - 33 degrees F / 0.5 degrees C 4. In an interview on 5 /19/2023 at 11:50 hours, in the breakroom, testing person (TP) 1 confirmed that corrective action had not been documented for the refrigerator temperature when it was outside of the acceptable storage range.