

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2207424	(X3) Date Survey Completed 03/02/2022
Name of Provider or Supplier DbA - Brookside Rehabilitation & Wellness	Street Address, City, State 1055 S Perry St, Castle Rock, CO	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's written policies and interview with the facility executive director, the laboratory failed to have a written hematology policy manual available to laboratory personnel. Findings include: 1. Review of hematology documentation revealed there was no procedure for Complete Blood Counts (CBC) performed on the Medonic M Series CBC analyzer. 2. In an interview conducted on 03-02-2022 at approximately 1:00 PM, the facility executive director confirmed there was not a policy for CBCs performed on the Medonic M Series CBC analyzer. 3. In an interview conducted on 03-02-2022 at approximately 1:00 PM, the facility executive director confirmed that there here have been no patient test results released as of this date.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's written policies, procedure manuals, and staff interview, the laboratory failed to have the laboratory director sign and approve any of</p>

their test procedures since assuming the directorship in April 2021. Findings include: 1. Review of the written test procedures revealed the laboratory director had not signed the following procedures to show their review and approval of complete blood count (CBC) testing using the Medonic M-Series hematology analyzer. 2. Staff confirmed the laboratory director had not signed the written test procedure for complete blood count (CBC) testing using the Medonic M-Series hematology analyzer since assuming directorship in April 2021. 3. In an interview conducted on 03-02-2022 at approximately 1:00 PM, the facility executive director confirmed that there here have been no patient test results released as of this date.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on the direct observation of supplies stored in the laboratory refrigerator, freezer and on open shelves, and interview with the facility executive director, the laboratory failed to replace laboratory supplies when they had exceeded their expiration date. Findings include: 1. Direct observation of the laboratory refrigerator on 03-02-2022, at approximately 11:30 AM, revealed: One box of FrenD Vitamin D assay cartridges with lot number 500010 and expiration date 2021-03-30 One box of Natrol Strep A verification panel with lot number 323278 and expiration date 2021-02-21 One box of Natrol Strep A negative control with lot number 324738 and expiration date 2021-09-18 One box of Natrol Strep A positive control with lot number 324737 and expiration date 2021-09-17 One box of Boule Con-Diff Tri-level controls with lot number 22106-3K and expiration date 2021-11-10 One box of Boule Calibrator with lot number 22101-24 and expiration date 2021-04-27 One box of Gene Xpert Flubundle Mini controls with lot number 322328 and expiration date 2020-11-28 One box of Gene Xpert Xpress Strep A bundle containing 3 vials of strep A positive control with lot number 324737 and expiration date 2021-09-17; 2 vials of strep A negative control with lot number 324738 and expiration date 2021-09-18; 1 vial of strep A negative control with lot number 325187 and expiration date 2021-10-30 One box of Piccolo lipid panel cartridges with lot number 1074AB2 and expiration date 2022-02-11 One box of CDS CBC Reportable Range Verification kit with lot number 2012-101 and expiration date 2021-05-06 2. Direct observation of the laboratory freezer on 03-02-2022, at approximately 12:20 PM, revealed: One box of BRT-BioResource Technology Inc liquid assayed chemistry and lipid controls with lot number 2004021 and expiration date 2021-09-30 and lot number 2007036 and expiration date 2022-01-31 . 3. Direct observation of the laboratory shelves on 03-02-2022, at approximately 12:30 PM, revealed: 15 BD Vacutainer Lithium Heparin tubes with lot number 9315400 and expiration date 2021-03-31 13 Abbott Afinion Hemoglobin A1c test cartridges with lot number 10208217 and expiration date 09-27-2021 3 unopened bags containing Aerobic/anaerobic e-swabs Amies media with lot number 201530400 and expiration date 2021-09-30 One case of BD Bactec standard /10 aerobic/F blood culture vials with lot number 0057880 and expiration date 2021-03-31 One box of Cepheid Xpert Xpress Strep A cartridges with lot number 1000240925 and expiration date 2022-01-16 4. Interview with the facility executive

director, at approximately 1:00 PM, confirmed that the laboratory failed to discard the expired materials before their expiration dates, but that no patient testing has been performed with any of the expired laboratory supplies.