

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0324451	<b>(X3) Date Survey Completed</b>  12/08/2022
<b>Name of Provider or Supplier</b>  Primary Plus - Denham Medical Clinic	<b>Street Address, City, State</b>  525 Tucker Drive, Maysville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on 12/08/2022 and the facility was found not to be in substantial compliance with the laboratory requirements of 42 CFR Part 493, with a deficiency cited.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure quality control (QC) material for hematology testing was not used past the open vial stability date for three (3) of three (3) vials of QC material reviewed. The findings include: Observation on 12/08/2022 at 11:20 AM revealed laboratory personnel performed complete blood count (CBC) testing on the Sysmex KX-21N hematology analyzer. Review of the "Sysmex KX-21N Operator's Manual", revised 11/2009, revealed "Quality Control checks are performed to monitor an instrument's performance over time. Eightcheck-3WP X-tra is the quality control material recommended by Sysmex to monitor the performance of the KX-21N analyzer." Review of the package insert for the "Eightcheck-3WP X-tra" controls revealed, "Opened and recapped vials and vials whose caps have been pierced will retain stability for fourteen (14) days if stored at 2-8 (degrees Celsius) after being re-capped". During the laboratory tour, on 12/08/2022 at 11:20 AM, Testing Personnel (TP) #1 was asked to see the current vials of controls. TP #1 presented three (3) vials labeled "11/2" (Lot numbers 22770710(L), 22770711(N), and 22770712(H)). Based on the manufacturer's specified stability timeframe, the vials would have been acceptable for use through 11/16/2022. A review of QC records revealed QC was performed through 11/29/2022. Interview with TP #1, on 12/08/2022 at 12:40 PM,</p>

confirmed the QC vials dated 11/02/2022 were used through 11/29/2022. Further review of QC records revealed patient testing was performed on the following days after the QC material had exceeded the open vial stability date of 11/16/2022: - 11/22/2022 (six (6) days past open vial stability) - three (3) patients tested. - 11/23/2022 (seven (7) days past open vial stability) - two (2) patients tested. - 11/28/2022 (twelve (12) days past open vial stability) - two (2) patients tested. - 11/29/2022 (thirteen (13) days past open vial stability) - one (1) patient tested.