

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0322792	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier White House Clinic - Mckee	Street Address, City, State 1010 Main St Us Hwy 421, Mc Kee, KY	
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	A recertification survey was conducted on 01/24/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
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 record review and interview, it was determined personnel who routinely performed testing in the laboratory failed to test proficiency samples as per the laboratory's policy. This was noted for six out of six proficiency testing events reviewed for 2021-2022. The findings include: Review of the facility protocol titled, "Proficiency Testing", effective 05/2018 and signed by the Laboratory Director (LD) on 11/30/2022, revealed, "Each MBO (Medical Back-Office, or Testing Personnel (TP)) team member will perform testing at different intervals throughout the year". Review of the proficiency testing (PT) records revealed the laboratory participated in the American Academy of Family Physicians (AAFP) PT Module 629, Auto Diff 9 (Beckman Coulter DXH500 Series) for 2021 and 2022, for complete blood count (CBC) testing. Review of the PT attestation forms, which were signed by the LD, revealed the following TP attested in performing PT for those events, which included Module 629, Auto Diff 9 (Beckman Coulter DXH500 Series): -AAFP-PT 2021-A was signed 03/22/2021 by TP #1 and TP #6 -AAFP-PT 2021-B was signed 06/29/2021 by TP #1 - AAFP-PT 2021-C was signed 10/27/2021 by TP #1 and TP #6 - AAFP-PT 2022-A was signed 03/29/2022 by TP #1 - AAFP-PT 2022-B was signed 06/20/2022 by TP #1 - AAFP-PT 2022-C was signed 10/26/2022 by TP #1 Review of the Centers</p>

for Medicare and Medicaid Services (CMS)-209 form, dated and signed by the LD on 01/20/2023, listed eleven (11) individuals who performed testing, which included the LD and TP #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10. Interview with TP #1, on 01/24/2023 at 10:40 AM, who functions as the Team Lead, revealed that in addition to herself, MBO team members TP #2, TP #3, TP #4, TP #5, and TP #6 routinely performed CBC testing on patients during the time when these PT events were conducted. Further interview on 1/24/2023 at 10:55 AM revealed that except for two (2) events in 2021 when TP #6 participated, other TPs were not performing PT at different intervals throughout the year, but she did all the PT herself.