

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1021808	(X3) Date Survey Completed 03/01/2023
Name of Provider or Supplier Mchc Harlan Medical Clinic	Street Address, City, State 132 Village Center, Harlan, 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 03/01/2023 and the laboratory was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with a deficiency cited.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation and interview, it was determined the facility failed to document the Wright-Giemsa Stain quality of blood smears (manual differentials) performed in 2021, 2022, and 2023. The findings include: A review of the facility's procedure manual revealed there was no documentation of stain quality control. A review of the "Sigma-Aldrich Wright-Giemsa Stain, Modified" package insert, revised 11/2016, revealed "Wright- Giemsa solution is intended for use in staining blood films or bone marrow films". The package insert further revealed "Nuclei will be varying shades of purple. Cytoplasmic staining will be varying shades of blue to light pink. Fine reddish to lilac granules may be present in cytoplasm of some cell types. Basophils will demonstrate dark blue black granules in the cytoplasm. Eosinophils will demonstrate orange granules in the cytoplasm. Red blood cells should be pink to orange". Observation during the laboratory tour, on 03/01/2023 at 10:15 AM, revealed staff used Sigma-Aldrich Wright-Giemsa Stain, Modified, for staining blood smears. During an interview with Testing Personnel (TP) #1, on 03/01/2023 at 12:20 PM, she stated a stain quality control was not performed or documented on blood smears performed in the laboratory for 2021, 2022, and 2023.</p>