

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0666165	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Wv Office Of Laboratory Services	Street Address, City, State 167 11th Avenue, South Charleston, WV	
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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of refrigerator temperature records, manufacturer's instructions, and interview with TS-1, the laboratory failed to document corrective actions when refrigerator temperatures were outside acceptable limits for the storage of control reagents for 7 of 42 days reviewed between October 2024 and November 2024. Findings Included: 1. During a tour of the laboratory on 11/13/2024 at 10:07am, one refrigerator labeled 'Danby Dual Fridge/Freezer', was observed in the hallway of the laboratory, with the following reagents inside: a. 1 Biorad Antibody to Hepatitis B Surface Antigen reagent box, Lot 16011003, Ref 32591, manufacturer storage temperature requirements 2 to 8 degrees Celsius. b. 1 Biorad Monolista Anti-HBA reagent box, Lot 506607, Ref 25220, manufacturer storage temperature requirements 2 to 8 degrees Celsius. c. 1 Biorad HIV Combo Ag /Ab EIA reagent box, Lot 1000017, Ref 12009912, manufacturer storage temperature requirements 2 to 8 degrees Celsius. d. 1 Biorad Monolisa Anti-HAV IgM EIA, Ref 72495, manufacturer storage temperature requirements 2 to 8 degrees Celsius. e. 1 Biorad Monolisa Anti-HBc EIA, Lot 506536, Ref 26186, manufacturer storage temperature requirements 2 to 8 degrees Celsius. f. 1 Aptima Combo 2 Control Kit, Ref 301110, manufacturer storage temperature requirements 2 to 8 degrees Celsius. g. 1 BD Macro-Vue RPR Card Test, Ref 275005, manufacturer storage temperature requirements 2 to 8 degrees Celsius. h. 1 Biorad HbsAg Confirmatory Assay 3.0 kit, Lot 405VDD, Ref 32594, manufacturer storage temperature requirements 2 to 8 degrees Celsius. 2. A review of the refrigerator temperature log for thermometer 32792 revealed, a refrigerator range of 2 to 8 degrees Celsius, and the following dates</p>

where the refrigerator temperature were out of range, with no corrective action documented: 10/6/24: 1.8 degrees Celsius. 10/12/24: 1.8 degrees Celsius. 10/19/24: 1.1 degrees Celsius. 10/26/24: 1.2 degrees Celsius. 11/2/24: 1.0 degrees Celsius. 11/5/24: 0.3 degrees Celsius. 11/9/24: 1.7 degrees Celsius. 3. During an interview on 11/13/2024 at 10:08 am, the TS-1 corroborated the findings of the refrigerator temperatures out of limits with no corrective actions documents.