

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0705936	(X3) Date Survey Completed 08/21/2023
Name of Provider or Supplier Sahetya Medical Group	Street Address, City, State 1573 Ky Hwy 259 N, Brownsville, 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 initiated and concluded on 08/21/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review and interview, the laboratory failed to ensure quality control materials for the hematology analyzer were labeled with an open vial stability expiration date. The Findings include: During an observation, on 08/21/2023 at 11:00 AM, the Cell-Dyn quality controls currently in use for the hematology analyzer, were not labeled with an open vial stability expiration date. Review of the undated package insert labeled, "Cell-Dyn 18 Plus Control," revealed "Once opened, containers can be used only for the number of days stated on the assay sheet." Review of the undated "Cell-Dyn 18 Plus Control Assay Sheet", stated "8 Consecutive-Day Open-Tube Stability." In an interview on 08/21/2023 at 11:15 AM, Testing Personnel #1 confirmed she did not label the quality control vials with the opened vial stability expiration date.</p>