

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2166539	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Sasha Salloum Md Inc, A Professional Medical Corp	Street Address, City, State 1045 E Pennsylvania Ave, Escondido, CA	
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's validation records, and EP Evaluator for "Two Instrument Comparison Summary" records, and interview with the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures to monitor, assess, and verify the accuracy of the validation documents. The findings included. a. The laboratory used i-Stat to perform Chem 8 cartridges which includes BUN, iCa (ionized CA), Chloride, Creatinine, Glucose, Hematocrit, Potassium, Sodium, Total CO2. b. Review of the "Experiment Description" in "Two Instrument Comparison", the "Expt Date" under X method and Y method were both dated "30 Oct 2020" to do "experiment". c. The laboratory director had reviewed and "accepted" with signature on 10/1/2020. d. The laboratory director had reviewed, accepted, signed, and dated the EP Evaluator studies before the "Two Instrument Comparison" studies were completed.</p>