Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0046878	06/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ashley Clinic	505 South Plummer Avenue, Chanute, KS	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the available documentation and confirmed during interview with the Chief Finance Officer (CFO), the laboratory failed to have the current Individualized Quality Control Plans (IQCP)s approved, signed, and dated by the current laboratory director (LD) before use. Findings: 1. Upon review of the laboratory IQCP procedures, the current laboratory director did not approve, sign, and date the laboratory IQCPs for: 9 of 9 IQCP procedures in the laboratory at time of survey. 2. The following are IQCPs were identified without the current LD approval signature and date: a. Biofire Respiratory Panel 2.1 b. Hgb A1C, Afinion, Abbott c. Mycoplasma, Immuncocard, Meridian Bioscience d. Prothrombin Time (PT), Hemochron, IL e. Serum HCG, Consult, McKesson f. Helicobacter pylori (H. pylori), Consult, McKesson g. Microalbumin, Clinitek Status, Siemens h. Erythrocyte Sedimentation Rate (ESR), Excyte mini, ELITechGroup i. Vaginal Panel (Candida species, Gardnerella vaginalis, Trichomonas vaginalis), Affirm, BD 2. Interview with the CFO on June 28, 2021 at 10:30 a.m. confirmed, the laboratory failed to have 9 of 9 IQCP procedures approved, signed, and dated by the current laboratory director before use.