

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0963697	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Sovah Pediatrics	Street Address, City, State 201 South Main Street Suite 2100, Danville, VA	
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	An announced CLIA Recertification on-site survey was conducted at SOVAH Pediatrics on December 15, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on November 16, 2020 with off-site record review of documentation on December 11, 2020. Specific deficiencies cited are as follows:
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and primary testing personnel (TP) interview, the laboratory failed to retain the "Coulter AcT Diff Control Plus" manufacturer's package inserts (PI) documenting Complete Blood Cell (CBC) count QC acceptable ranges for four (4) of 5 lot numbers utilized from January 1, 2020 up to December 15, 2020. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from January 1, 2020 through December 15, 2020 revealed the laboratory received and utilized 5 lot numbers of the "Coulter AcT Diff Control Plus". The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's PI: 360120 (370120, 380120), 360320 (370320, 380320), 360520 (370520, 380520) and 360720 (370720, 380720). 2. An interview with the primary TP at approximately 10:30 AM on December 15, 2020 confirmed the findings.</p>