

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0706467	(X3) Date Survey Completed 01/31/2023
Name of Provider or Supplier Sovah Family Medicine Gretna	Street Address, City, State 305 N Main St, Gretna, 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 survey was conducted at Sovah Family Medicine Gretna on January 31, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
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 a tour, review of procedures, manufacturer's package insert, and interviews, the laboratory failed to label three of three hematology quality control (QC) vials with appropriate expiration date, observed in use to monitor patient Complete Blood Count (CBC) performance, on the date of the survey January 31, 2023. Findings include: 1. A laboratory tour on 1/31/23 at approximately 10:00 AM revealed three vials of CDS Boule Con-Diff Quality Control(Low-Lot Number # 22209-31, Normal- Lot # 22209-32, High- Lot # 22209-33) stored in a reagent refrigerator outside of the manufacturer's package (placed within a specimen cup). The inspector noted the three QC vials did not have an open date with revised expiration date. 2. The inspector inquired regarding the laboratory's protocol for monitoring hematology QC open stability. The lead testing personnel stated at approximately 10:30 AM, "The CBC controls are good for 14 days after opening and our procedure is to write the date on each along with the expiration date." 3. Review of the Boule Con-Diff Tri-Level QC</p>

package insert revealed a manufacturers defined open vial stability of fourteen (14) days. 4. The inspector inquired if the identified/observed control materials, outlined above, were currently in use for the monitoring the laboratory's Medonic hematology analyzer. The facility's lead testing personnel stated on 1/31/23 at approximately 11:00 AM, "Yes, the CBC machine's QC tubes that you checked are the opened ones in use. The QC should have been labeled with the date they were opened and expiration date." 5. An exit interview with the practice manager and lead testing personnel on 01/31/23 at approximately 11:30 AM confirmed the above findings.