

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2263993	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Gezunt Diagnostics Lab Llc	Street Address, City, State 50 Chestnut Ridge Road, Montvale, NJ	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Test Requisitions (TR), Final reports (FR) and interview with the General Supervisor (GS), the laboratory failed to follow the PM for "Turnaround Time" from July 2022 to the date of the survey. The findings include: 1. The PM stated step nine "Specimens can be stored at 2-8C for up to 72 hours" 2. Three out of ten FR revealed two samples where tested ten days after collection and one sample six days after collection.. 3. The GS confirmed on 4/26/23 at 1:30 pm that the laboratory did not follow the PM.</p>