Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1060709	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Digestive Medicine Pc	50 Route 111, Suite 302, Smithtown, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of Standard Operating Procedures (SOPs), as well as interview with the Laboratory Director (LD), the laboratory failed to retain waived test manufacturer's instructions. FINDINGS: 1. There was no documentation of Henry Schein Urine Pregnancy and Contour Glucose Meter waived test manufacturer's instructions. 2. The current, approved SOPs did not include instructions for performing Schein Urine Pregnancy and Contour Glucose Meter waived testing. 3. The LD confirmed the findings on December 11, 2024, at approximately 11:00 A.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review SOPs, Contour Glucose Strip and Henry Schein

	Urine Pregnancy product label storage instructions, as well as interview with the LD, the laboratory failed to comply with manufacturer's storage requirements. FINDINGS: 1. The Contour Glucose Strip product label indicated storage temperature range of 40 F - 86 F. 2. The Henry Schein Urine Pregnancy product label indicated storage temperature range of 36 F - 86 F. 3. There was no documentation of storage temperature in the area where Contour Glucose Strip and Henry Schein Urine Pregnancy were stored from 2022 through survey date. 4. The current, approved SOPs did not include instructions for performing such activity. 5. The LD confirmed the findings on December 11, 2024, at approximately 11:30 A.M.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of SOPs, as well as interview with the LD, the laboratory failed to remove from inventory expired patient specimen testing materials. FINDINGS: 1. One vial of Contour Glucose Strips lot: DW2HJ3B03A expiration: August 31, 2024, was stored in the patient testing area. 2. The current, approved SOPs did not include instructions for removal of expired patient specimen testing materials from inventory. 3. LD informed the surveyor that the respective expired Contour Glucose Strip lot was not utilized for patient specimen testing. 4. The LD confirmed the findings on December 11, 2024, at approximately 11:00 A.M.