Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1038950	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Health Gauge Laboratory	2407 Sw 9th Street, Des Moines, IA	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the chemistry procedures, Ortho-Clinical Diagnostics Vitros instructions for use, Vitros maintenance logs and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report); the laboratory failed to follow manufacturer's instructions for specimen stability as specified in D5411 and perform and document Vitros weekly maintenance as specified in D 5429.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of chemistry procedures, Ortho-Clinical Diagnostics Vitros information for use, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 1/12/2023, the laboratory failed to follow the manufacturer's instructions for specimen stability for four analytes performed on 9/27/2022 for 38 out of 38 patients. The findings include: 1. The chemistry procedures and Ortho-Clinical Diagnostics Vitros information for use stated

	for the analytes: cholesterol, high density lipoprotein, total protein and high sensitivity C-reactive protein, testing must be performed within 3 days of specimen collection. 2. On 9/23/2022, the laboratory collected cholesterol, high density lipoprotein, total protein and high sensitivity C-reactive protein specimens on 38 patients. 3. Test reports documented the laboratory performed cholesterol, high density lipoprotein, total protein and high sensitivity C-reactive protein testing on 9/27/2022. 4. Laboratory personnel identifier #1 confirmed that the laboratory performed testing within 4 days and did not meet the manufacturer's specimen stability requirements for cholesterol, high density lipoprotein, total protein and high sensitivity C-reactive protein testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Vitros chemistry analyzer maintenance records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 10:00 am on 01/12/2023, the laboratory failed to perform and document weekly maintenance on the Vitros chemistry analyzer for two out of four weeks in September 2022. The findings include: 1. The Vitros maintenance log stated the laboratory must weekly perform the following: *W1 - clean microwell incubatory, *W4 - clean sample supply, *W5 - clean tip locator, *W6 - clean dispense blade & sensors, *W7 - clean leak pads, *W8 - clean touchscreen monitor and keyboard, *W9 - perform subsystem cleaning, and *W10 - process Vitros microscensor check fluids I & II. 2. The week of 9/19/2022 the laboratory did not perform W1, W5, W6 or W7. 3. The week on 9/26/2022 the laboratory did not perform W1, W4, W5, W6, W7, W8, W9 or W10.