Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D2183799	10/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Midlands Family Urgent Care	17650 Wright Street Ste 5, Omaha, NE	

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 unannounced CLIA complaint survey was conducted at GS Labs LLC on 9/22 /2021 and 10/1/2021 by the Nebraska Department of Health and Human Services. Immediate Jeopardy was identified related to the following conditions: D3000 - Facility administration D5400 - Analytic systems D6000 - Laboratories performing moderate complexity testing; laboratory director
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: The laboratory failed to retain analytic systems records (Refer to D3031).
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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.

	This STANDARD is not met as evidenced by: The laboratory was unable to provide records for 3/1/2021 - 5/18/2021 and 9/3/2021 - 9/6/2021 during time of survey. Findings are: 1. The laboratory was unable to provide quality control records, instrument print outs, and patient reports from 3/1/2021 - 5/18 /2021 and 9/3/2021 - 9/6/2021. 2. Confirmed via interview with the laboratory director and technical consultant on 10/1/2021 at 9:50 AM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to follow controls procedure and have a complete procedure (Refer to D5401 and D5403); failed to monitor temperatures (Refer to D5413); failed to perform the verification of performance specifications on 20 of 20 DiaSorin analyzers prior to performing patient testing (Refer to D5421); failed to document corrective action (Refer to D5781); and failed to document corrective actions for failed quality control (Refer to D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's "ZeptoMetrix NATrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls" procedure, not available to testing personnel, that was emailed to the surveyor by the technical consultant, review of quality control documentation, and interview, the laboratory failed to follow its procedure for quality control. Findings: 1. Review of the laboratory's "ZeptoMetrix NATrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls" procedure revealed the laboratory is required to run "NATSARS(COV2)-NEG" as their negative control, with every patient testing run. 2. Review of quality control documentation for 9/21/2021 revealed the laboratory failed to run "NATSARS(COV2) -NEG" as their negative control on 12 out of 25 Luminex analyzers. The laboratory ran unspiked VTM as the negative control on the following Luminex analyzers. a. Luminex 25 b. Luminex 24 c. Luminex 23 d. Luminex 22 e. Luminex 8 f. Luminex 7 g. Luminex 6 h. Luminex 5 i. Luminex 4 j. Luminex 3 k. Luminex 2 l. Luminex 1 3. Review of the quality control documentation for 9/22/2021 revealed the laboratory failed to run "NATSARS(COV2)-NEG" as their negative control on five out of 25 Luminex analyzers. The laboratory ran unspiked VTM as the negative control on the following instruments. a. Luminex 16 b. Luminex 14 c. Luminex 13 d. Luminex 12 e.

	Luminex 10 4. Interview with the laboratory director and technical consultant on 10/1 /2021 at 9:40 AM confirmed the laboratory failed to follow the "ZeptoMetrix NATrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls" procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Luminex COVID-19 testing procedure and confirmed during interview, the laboratory failed to include all required elements in the procedure. Findings: 1. The laboratory's testing personnel were unable to provide a copy of the Luminex COVID-19 testing procedure to the surveyor. 2. The laboratory's technical consultant emailed the surveyor the laboratory's Luminex COVID-19 testing procedure. 3. Review of the emailed Luminex COVID-19 testing procedure revealed that the test procedure failed to include: a. Requirements for patient preparation; b. Requirements for specimen collection, labeling, storage, preservation, transportation, processing, and referral; c. Criteria for specimen acceptability and rejection as described in 493.1242; d. Reference intervals (normal values); e. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; and f. Description of the course of action to take if a test system becomes inoperable. 4. Confirmed during interview with laboratory director and technical consultant on 10/1/2021 at 9:20 AM.
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 observation, lack of documentation and interviews with laboratory staff, the laboratory failed to monitor temperatures of four of four laboratory freezers located in the laboratory. Findings: 1. Observation of the laboratory's testing area revealed three freezers located in the laboratory testing area. 2. Interview with the laboratory supervisor, on 9/22/2021 at 12:30 PM confirmed the three freezers were used for patient sample storage. The laboratory failed to monitor the freezer temperatures. 3. Observation of the laboratory's specimen receiving area revealed one large freezer storing testing reagents and controls. 4. Interview with the laboratory's informatics data miner, testing personnel #48, on 9/22/2021 at 2:50 PM confirmed the laboratory failed to monitor freezer temperatures.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on interview with the laboratory supervisor, lack of verification of performance specifications on 20 of 20 DiaSorin analyzers, and review of four random testing dates revealed the laboratory performed COVID-19 patient testing prior to verifying performance specifications of COVID-19 testing performed on the DiaSorin analyzers. Findings: 1. Observation of 20 of 20 DiaSorin analyzers at 10:34 AM revealed signs on 20 of 20 DiaSorin analyzers stating "Not for patient testing", that were posted on the instruments on 9/22/2021. 2. Review of four random testing dates revealed 32 patients were tested for COVID-19 on the DiaSorin instruments that had not been verified for performance specifications: a. 8/23/2021 revealed eight patients were tested. b. 9/15/2021 reveled nine patients were tested. c. 9/16/2021 revealed six patients were tested. d. 9/21/2021 revealed nine patients were tested. 3. Interview with the laboratory supervisor on 9/22/2021 at 10:34 AM confirmed the laboratory had not performed verification of performance specifications on 20 of 20 DiaSorin analyzers used for COVID-19 patient testing, and that the signs were placed on the analyzers after the unannounced on-site arrival of the surveyor.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of laboratory's procedure and temperature logs, the laboratory failed to perform corrective action when temperatures fell outside of the acceptable range. Findings: 1. The laboratory's procedure "General Maintenance" states the following: "Record temperatures daily. If the temperature is outside of the acceptable range, note on the daily temperature log. Complete the following corrective actions: a. Check for the source of the problem door left open or ajar power turned off or unplugged electrical power failure. b. Adjust thermostat if necessary c. check temperature later during the same day. If temperature has returned to acceptable range, record adjusted temperature on the daily temperature log. If temperature remains outside of the acceptable range, notify the supervisor. Call service, if necessary, and remove any temperature sensitive items, e.g. reagents and control, that may have been affected by the temperature fluctuation. Store temperature sensitive items in an alternate refrigerator/freezer or coolers with thermometers, as necessary, until the proper temperature has been restored." 2. Review of the temperature log provided for the freezer located in the laboratory's specimen receiving, AFS49ML-21010017, indicates a range of less than or equal to -15 to less than or equal to -70 Celsius. 3. Review of one of six days for freezer AFS49ML-21010017 revealed a temperature was recorded as out of range. No corrective action was documented. 4. Review of temperature logs provided for freezer located in the laboratory's testing area, ABS-20128989-2101, indicates a range of less than or equal to -15 to less than or equal to -70 Celsius. 5. Review of 37 of 111 days for freezer ABS-20128989-2101 revealed temperatures were recorded as out of range. No corrective action was documented. 6. Review of temperature logs provided for freezer located in the laboratory's testing area, ABS-20129006-2101, indicates a range of less than or equal to -15 to less than or equal to -70 Celsius. 7. Review of 41 of 110 days for freezer ABS-20129006-2101 revealed temperatures were recorded as out of range. No corrective action was documented. 8. Review of temperature logs provided for freezer located in the laboratory's testing area, 6541-1714-2009-0313, indicates a range of less than or equal to -15 to less than or equal to -70 Celsius. 9. Review of 26 of 110 days for freezer 6541-1714-2009-0313 revealed temperatures were recorded as out of range. No corrective action was documented. 10. Confirmed during interview with laboratory director and technical consultant on 10/1/2021 at 9:11 AM, the laboratory failed to perform corrective action when temperatures fell outside of the acceptable range.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality control results and confirmed during interview, the laboratory failed to document corrective actions for failed quality control. Findings: 1. Review of seven of seven quality control records revealed quality control failures on 6

	/9/2021 (Luminex 7), 6/15/2021 (Luminex 7), 8/2/2021 (Luminex 9), 8/7/2021 (Luminex 5), 8/24/2021 (Luminex 13), 8/30/2021 (Luminex 6), 8/16/2021 (Luminex 1). 2. Review of quality control documentation for 9/21/2021 revealed six of 12 patient test runs had quality control failures on the following Luminex instruments. a. Luminex 23 b. Luminex 22 d. Luminex 8 e. Luminex 7 f. Luminex 6 g. Luminex 4 3. Review of quality control documentation for 9/22/2021 revealed three of five patient test runs had quality control failures on the following Luminex instruments. a. Luminex 16 b. Luminex 14 c. Luminex 10 4. The laboratory's daily quality control log revealed "NOTE: All QC failures require documentation of corrective actions" 5. The laboratory was unable to provide documentation of corrective actions. 6. Confirmed during interview with laboratory director and technical consultant, on 10/1/2021 at 9: 40 AM, patients were tested on dates with quality control failures.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to ensure overall operation and administration of the laboratory (Refer to D6007) and failed to have a written procedure for COVID-19 testing available to laboratory personnel (Refer to D6031).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of documentation, lack of documentation, and interview with the laboratory supervisor, the laboratory director failed to ensure facility administration (Refer to D3000) and monitor and evaluate the overall quality of the analytic systems of the laboratory (Refer to 5400).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory supervisor and the laboratory's owner, the laboratory director failed to have a written procedure for Luminex COVID-19 testing available to laboratory personnel. Findings: 1. The laboratory failed to have a written procedure for Luminex COVID-19 testing available to laboratory testing personnel. 2. Interview with the laboratory supervisor and laboratory owner on 9/22/2021 at 3:20 PM confirmed the laboratory failed to have a written procedure for Luminex COVID-19 testing available to laboratory testing personnel.