Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2275008	02/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Citizensdx Texas Llc	309 Water Street Suite 112, Boerne, TX	

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 onsite initial certification survey conducted February 13, 2024, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, surveyor observations, and staff interview, the laboratory failed to have a mechanism in place to ensure samples were maintained at the required temperature during transport for three of three months between November 2023 and January 2024. The findings included: 1. A review of the laboratory's policy titled "Laboratory Operations Manual for DNA/RNA Based Pathogen Testing" (approved by the laboratory director on 09/01/2023) under the section titled Pre-analytical Error Root Causes (page 4), stated: "The pre-analytical system shall take care of the following aspects, as each can have a major effect on the accuracy of the result: Patient preparation Request Forms Specimen Collection, containers, labeling, and phlebotomy equipment and procedure - Specimen transport Specimen preparation Specimen storage" Under "Stability of Samples and Storage" (page 5), the policy stated: "Samples are collected by swab and placed in Copen eSwab Media or collected as a cutting and placed in Copen eSwab Media for storage or shipping. The eSwabs are stored in their original container at 5-25C until used. Specimens are to be held at room temperature at 20-25C and processed within 3 days." Under Shipping Specimens (page 6), the policy stated: "Specimen should be

	shipped overnight to ensure temperatures do not reach above 25C. While bacteria and fungi often grown well in warmer environments, it is important to maintain sample integrity. Specimens transported to the lab on the same day should be kept in the refrigerator until transported and transported in a cooler with ice packs to prevent overheating." 2. A review of the laboratory's policy titled "Client Manual - Pre-analytical" (approved by the laboratory director on 09/01/2023) determined: "Specimens should be refrigerated at 4-8C or stored at room temperature at 20-25C and processed within 72 hours. Specimens can be stored frozen (below 2C) for 30 days, or in the fridge (4-8C) for 72 hours. (Room temperature specimens should not be tested after 72 hours)." 3. During a tour of the laboratory on 2/13/2024 at 10:00 a. m., Testing Person 2 (as listed on the CMS 209 Laboratory Personnel report) demonstrated that specimens were sent overnight in Lab Paks, a leak-resistant packs designed with tough material, a tight seal and an absorbent pad. 4. In an interview conducted 2/13/2024 at 10:57 a.m. in the conference room, Testing Person number 2 confirmed the laboratory did not have a process in place to ensure that specimens shipped at room temperature did not exceed extremes in temperature when shipped.
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 policies, and staff interview, the laboratory failed to have documentation of performing monthly wipe tests for two of two months. The findings include: 1. The laboratory's policy titled "Laboratory Operations Manual for DNA/RNA Based Pathology Testing" (approved by the laboratory director on 09/01 /2023) under the section titled "Wipe Test" (page 10) stated: "Once every month, take a patient sample swab and swab the area where sample preparation is performed. Run this sample as if it were a patient sample on ALL panels. Name the sample "YEARMONTHDAY Panel Name Wipe Test." Results should be negative for all targets. If they are not, perform complete decontamination by soaking the area in a 1: 10 bleach solution for five minutes, followed by a water wipe down. Repeat the test to confirm decontamination is completed. Record the test and any corrective actions on the Maintenance Log and keep the raw data for two years." 2. Testing Person 2 (as listed on the CMS-209 laboratory personnel report)and the Compliance Director were asked to provide documentation of the wipe test being performed in December 2023 and January 2024. No documentation was provided. 3. In an interview at 14:26 hours on 02/13/2024 in the conference room, both Testing Person 2 and the Compliance Director confirmed the laboratory had not performed wipe tests since testing began in November 2023.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies, review of patient test records from December 2023 to February 2024, and staff interview, the laboratory's post-analytic quality assessment procedures failed to identify and correct that nine of nine patient reports did not contain results for analytes that failed the laboratory's establishment studies. The findings included: 1. Based on review of the establishment studies performed 6/6/23 through 6/9/23 titled "Summary Report for Wound Microbiota and Antibiotic Resistance Marker Assays on the Applied Biosystems QuantStudio 12K Flex TaqMan Array Card (TAC) Platform", under 1.6 - Conclusions, the study stated, "Due to higher than acceptable variation, ACC, MRSA Specific Clindamycin, TEM, and Enterobacter Species failed validation." 2. Based on a review of patient records, the following patient reports contained analytes/targets that failed the establishment study protocols: CDX0061714 - report date 12/20/2023 CDX0060534 - report date 12/27/2023 CDX0045928 - report date 1/18/2024 CDX0060533 - report date 1/18/2024 CDX0061251 - report date 1/29/2024 CDX0061255 - report date 1/29/2024 CDX0061435 - report date 2/5/2024 CDX0045916 - report date 2/12/24 CDX0061434 - report date 2/13/2024 3. In an interview on 2/13/2024 at 12:47 hours in the conference room, Testing Person 2 and the Compliance Director confirmed the laboratory had reported patient results for analytes that did not meet the laboratory's acceptability criteria in the establishment studies.