Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2060159	02/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Logistic And Distribution Lld, Dba	4060 Innslake Drive, Glen Allen, VA	

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 announced CLIA Validation survey was conducted at the RCA Laboratory Services, LLC dba Genetworx on 02/9/22-2/10/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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 the review of a patient final report, quality control (QC) records, policy and

	procedures (P&P), lack of documentation, and interviews, the established P&P for the gastrointestinal pathogen panel (GPP) failed to include corrective action protocol for QC results that did not meet the acceptable range for one of one patient reviewed. Findings include: 1. Review of one randomly selected patient final report revealed Patient A (2030603258) resulted as negative for the Norovirus GI/GII on the Luminex xTAG GPP assay on 11/02/20. 2. Review of batch/plate QC records for the aforementioned date and patient revealed the positive Norovirus QC failed to meet acceptable range (reported as negative for that batch/plate). 3. In an interview with the quality assurance manager on 02/10/22 at approximately 11:20 AM, they stated, "testing personnel should have rejected the results and submitted the samples for retesting." 4. Review of the P&P "SOP 603.006.4 Luminex xTag GPP Assay" revealed lack of documentation of an established corrective action protocol for QC results that fail to meet the acceptable range. 5. An exit interview with the compliance team, quality assurance managers and technical supervisor on 02/10/22 at approximately 3:00 PM confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of the lab test menu, manufacturer's intended use, patient final reports, lack of documentation, and interviews, the laboratory failed to include the intended use statement regarding presumptive positive results of the gastrointestinal pathogen panel (GPP) on four of four patient reports reviewed. Findings include: 1. Review of the lab test menu revealed the site performs the Luminex xTAG GPP assay. 2. Review of the manufacturer's intended use directions revealed the following statement, "xTag GPP positive results are presumptive and must be confirmed by FDA-cleared tests or other acceptable reference methods." 3. A phone conference with a Luminex Technical Specialists on 02/09/22 at approximately 5:37 PM confirmed the aforementioned intended use statement regarding positive results from the assay. 4. Review of four patient reports (random selection) for the Luminex xTAG GPP assay revealed that the laboratory reported the following: Patient A (2030603314) - C. difficile toxin- "A (Positive)", Patient B (200870778)-Campylobacter- "A (Positive)" and C. difficile toxin "A (Positive)", Patient C (2115400188)-Giardia- "A (Positive)", Patient D (2120901865-Salmonella "A (Positive)". The above-mentioned patient final reports' interpretation of results lacked documentation of the intended use statement "xTag GPP positive results are presumptive and must be confirmed by FDA-cleared tests or other acceptable reference methods." The technical supervisor, lab manager, quality assurance team, and lab director confirmed in an interview on 02/09/22 at 4:30 PM that the above-mentioned patients reported as positive and additional confirmatory testing was not

	conducted. 5. An exit interview with the technical supervisor, compliance team, quality assurance managers on 02/10/22 at approximately 3:00 PM confirmed the findings.