Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2085362	08/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lab Diagnostics, Llc	1515 Nw 167th St Ste 410, Miami Gardens, FL	

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 complaint survey, #2020013663, conducted on 08/25/20 to 08/26/20 at Niznik Lab Corp found that the laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The following conditions were cited: -D3000 - D6076
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). This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow Florida Department of Health (FDOH) guidelines for reportable diseases. Findings include: - Refer to D3009 During an interview on 08/26/2020 at 4:30 PM, the Chief Executive Officer confirmed that the laboratory failed to follow FDOH guidelines for reportable diseases.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to report to the Florida Department of Health (FDOH) positive results for reportable disease since 5

	/2019 to 8/26/2020 for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis(CT). For Coronavirus 2019 (COVID-19), the laboratory failed to report to FDOH following COVID-19 special reporting requirements from June 5, 2020 to August 5, 2020. Findings include: -Review of FDOH reportable disease guidelines revealed timeframes and reportable diseases requirements for NG/CT, which are that the laboratory must report to the FDOH by next business day for positive results. -Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F.A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). -Review of test menu revealed the laboratory is testing reportable diseases for: a) NG and CT since May 2019. - During year 2019: the laboratory had 14 positive cases: 3 NG (63637, 63982 and 64068) and 10 CT (63567, 63888, 63674, 63732, 63739, 63772, 63838, 63910, 64033, 64049) and 1 case with NG and CT (64118). -During year 2020: up until 8/27, they had 15 positive cases: 1 NG (64471), 12 CT (64202, 64150, 64188, 64322, 64388, 64550, 64551, 64624, 64731, 64700, 64703, 64739) and 2 NG and CT (64496 and 64655). The laboratory had no documentation that they reported these cases listed above to the FDOH. b) COVID-19. From 6/5/2020 to 8/5/2020 the laboratory tested 16600 cases. The case list is available on surveyor notes. -The laboratory reported 1 positive case (10070) to the Collier County by fax on 6/19/2020, they should have reported this case to Lee County which is the actual residency of the positive case, as per summary provided by the Chief executive Officer (CEO), and available on surveyor notes. -The laboratory contacted the FDOH by e-mail on June 23rd to request the setup of the Electronic Laboratory Reporting System (ELR). They received instruction to contact the FDOH ELR liaison to set up the system. In the e-mail, it was noted that "FDOH is requesting ALL COVID-19 (positive, negative, and inconclusive) laboratory results be submitted electronically. Once an electronic feed has been established and in production for COVID-19 testing, it is no longer necessary to report COVID-19 results via other means." -Review of their data submission showed one (1) unsuccessful attempt on 7/27/2020, the first data submission was done on 8/5/2020. -The laboratory could not provide documentation of submitted results by other means to FDOH before the ELR successful data transmission. During an interview on 08/2/2020 at 4:30 PM, the laboratory Chief Executive Office (CEO) provided a summary of the events that they faced during the process of set up of the ELR. He confirmed that the laboratory faxed one (1) case to Collier County, but he could not provide documentation that the laboratory sent reports for the remaining tests performed via other means until the laboratory had their ELR set up with the FDOH.
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 record review and staff interview, the laboratory procedure manual failed to include a policy for reportable diseases. Findings include: Based on review of the test menu, it was revealed that the laboratory started testing for the following reportable diseases: Neisseria gonorrhoeae (NG) and Chlamydia tracomatis (CT) since May 2019 and for Coronavirus (COVID-19) since 6/5/2020. Review of the laboratory's procedure manual revealed that there was no policy to describe how to report to the Florida Department of Health (FDOH) these reportable diseases. During an interview on 8/26/20 at 11:00 AM, the General Supervisor (GS) acknowledged that the procedure manual failed to include a policy for reportable diseases.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to have oversight of laboratory operations regarding Florida Department of Health (FDOH) guidelines for reportable diseases since 5/2019 until 8/26/2020. Findings include: - Refer to D6079 During an interview on 08/26/2020 at 4:30 PM, the Chief Executive Officer confirmed that the laboratory director failed to provide oversight to the laboratory for FDOH guidelines for reportable diseases.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory director (LD) failed to provide oversight of the laboratory from May 2019 until 8/26/2020 to comply with reportable disease requirements. Findings include: -See 3009 -See 5403 During an interview on 08/26/2020 at 4:30 pm with the Chief Executive Officer, he confirmed that the LD failed to have oversight of the laboratory for the period of time listed above regarding the guidelines from Florida Department of Health for reportable diseases.