Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1047391	10/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Neodiagnostix, Inc	910 Clopper Road, Suite 240 South, Gaithersburg, MD	

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
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: I. Based on review of the daily patient log book, policy and procedure manuals, and interview with the general supervisor, the laboratory's procedure manual did not include an interpretation of the abbreviations used when documenting information on the daily patient log. Findings: 1. The laboratory's daily patient log book included abbreviations such as "R", "(sp)" and "WC." The laboratory staff also recorded an additional "5" behind the patient identification number. Sometimes a single "5" or multiples adding up to 20. 2. Neither the worksheet nor the policy and procedure

	manual identified the meaning of the abbreviations or numbers. 3. During the survey on 10/31/19 at 12:00 PM the general supervisor confirmed that the abbreviations and additional numbers used on the daily patient log book were not identified in the policy and procedure manuals. II. Based on review of the daily patient log book, policy and procedure manuals, and interview with the general supervisor, the laboratory's procedure manual did not include written instructions for documenting when two different batches of the probe are used on the same day for preparation of patient slides. Findings: 1. The laboratory's daily patient log books for 2018 and 2019 were reviewed. Every 7-10 days the records showed the preparation of the probe used for preparing patient slides. 2. The records included the date of the new preparation and the date of the previous preparation. Some records included an asterisk next to the first patient listed on the worksheet with a vertical line down the side of the page to another asterisk next to a patient ID number. 3. According to the general supervisor this documentation differentiated the patients that were prepared with the previous batch of probe and the new batch of probe. 4. During the survey on 10/31/19 at 12:00 PM the general supervisor confirmed that the laboratory's procedure manual did not include written instructions for documenting when two different batches of the probe are used on the same day for preparation of patient slides. III. Based on laboratory procedure manual, record review, and interview with the general supervisor, the laboratory did not ensure that the temperature ranges stated in the procedure manual were consistent the ranges on the temperature log. Findings: 1. The laboratory procedure, "Quality Management Plan," "122.9.4 Equipment & Facility" states that, "Refrigerator temperature shall be between 5 degrees C +/- 3. Laboratory grade freezer temperature shall be -20 degrees C +/- 10." 2. A review of "Daily Temperature" logs showed that the temperature range for "Refrigerator" was stated as "4 degrees C +/- 5 degrees C," and the range for "Freezer" was "-20 degrees C +/- 5 degrees C." 3. During an interview on 10/31/19 at 12:30 PM, the general supervisor stated that the temperature ranges on the "Daily Temperature" log were correct and confirmed that the procedure manual needed to be updated.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the daily patient log book, policy and procedure manuals, and interview with the general supervisor, the laboratory's procedure manual did not include written instructions for documenting corrective actions when errors occurred. Findings: 1. Review of the daily patient log books for 2018 and 2019 showed that patient's identification (ID) numbers were recorded on 12/05/18 and 12/06/18. There was a page in-between the two dates with the same patient ID numbers from 12/06/18 that had been crossed out and re-written. There was no corrective actions documented to explain why the patient ID numbers were crossed out and re-written. 2. Review of the daily patient log books for 2018 and 2019 showed that on 08/30/19 six patients at the end of the run were crossed out. Records showed that the patient slides were read on 10/01/19. There were no corrective actions documented to explain why the six patients were not reviewed with the batch that had been processed on 08/30/19. 3.

	During the survey on 10/31/19 at 12:00 PM the general supervisor confirmed that laboratory's procedure manual did not include written instructions for documenting corrective actions when errors occurred.
D6173	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495 The testing personnel are responsible for specimen processing, test performance and for reporting test results. This STANDARD is not met as evidenced by: Based on laboratory procedure manual, record review, and interview with the general supervisor, the laboratory did not ensure that the testing personnel were preparing the laboratory reagents accurately reflected the current practice in the laboratory. Findings: 1. The laboratory's procedure manual details instructions for "Probe Preparation Using 1:1:1 CytoCell Probe Stock Solutions" for performing Cervical DNA testing. The protocol states to mix "500 ul 3q Orange probe + 500 ul 5p FITC probe + 500 ul CEN 7 Aqua probe = 1500 ul total volume." 2. A review of patient and reagent logs from November, 2018 to January, 2019 showed that 5 of 7 times the "1:1:1 solution" was made in a volume that was less than 1500 ul. 3. During an interview on 10/31/19 at 12:30 PM, the general supervisor stated that testing personnel made different volumes of probe solution dependant on testing volume and confirmed that the procedure manual needed to be updated.