Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2150941	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wake Diagnostics Inc	5129 Nc Highway 55, Suites 103-104, Durham, NC	

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: Based on review of verification of performance records, review of laboratory procedure manual, review of manufacturer's instructions, review of 2022 and 2023 calibration records and interview with technical supervisor (TS) 3/14/24, the laboratory procedure for urine drug screens was incomplete and/or inaccurate. The laboratory performs urine drug screens for the following analytes on the CLC 1600 Chemistry analyzer; Amphetamines (AMPH), Benzodiazepine (BENZ), Buprenorphine (BUP), Cannabinoid (THC), Cocaine (COC), Opiate (OPIT) and Oxycodone (OXYC). 1. The laboratory procedure for urine drug screens, "Drug

	screening by Chemistry Analyzer", was inaccurate and failed to include the correct cutoff values for BUP and OXYC. Findings: Review of verification of performance records revealed BUP had a cut-off value of 5 nanograms per Milliliter (ng/mL) and OXYC had a cut-off value of 300 ng/mL. Review of procedure "Drug screening by Chemistry Analyzer" revealed a BUP cutoff of 20 ng/mL and a OXYC cutoff of 100 ng/mL. Interview with TS at approximately 12:15 p.m. confirmed the correct cutoff values for BUP is 5 ng/mL and OXYC is 300 ng/mL. 2. The laboratory procedure for urine drug screens, "Drug screening by Chemistry Analyzer", was incomplete and failed to include the type and levels of quality control (QC) reagent used for each analyte. Findings: Review of procedure "Drug screening by Chemistry Analyzer" revealed "...7.2 Quality Controls (QC)...Two levels of QC are run with each assay...a) Check the lot number and expiry date of calibrators before use. b) Run the QC before testing the patient sample for screening....". Interview with TS at approximately 12:15 p.m. confirmed the procedure failed to include the type and levels of QC reagent used for each analyte. 3. The laboratory procedure for urine drug screens, "Drug screening by Chemistry Analyzer", was incomplete and failed to include the type and levels of calibration reagent used for each analyte and fails to correctly state the frequency of calibration utilized by the laboratory. Findings: Review of procedure "Drug screening by Chemistry Analyzer" revealed "...7.1 Calibrator...Calibration is performed according to manufacturer's instructions...b) Calibration of reagent required before after adding new lot of reagents and or once a week to calibrate on board reagents....d) Run calibration test at two levels for all calibrators...". Review of manufacture's instructions for each urine drug screen analyte tested on the CLC 1600 Chemistry analyzer revealed "Quality Control and Calibration...Each laboratory should establish its own calibration and control frequency.". Review of 2022 and 2023 calibration records for the CLC 1600 Chemistry analyzer revealed calibrations were not performed on a weekly basis. Interview with TS at approximately 12:15 p.m. confirmed the procedure failed to include the type and levels of calibration reagent used for each analyte. They also confirmed the procedure failed to correctly state the frequency of calibrations utilized by the laboratory. They stated they perform calibrations when they feel it is necessary and they were focused on quality control.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of QuantStudio 5 Real-Time PCR Instrument calibration records, observation, review of SARS/COVID quality control records, and interview with the technical supervisor (TS) 3/14/24, the laboratory failed to perform RNase P verification at the frequency specified by the manufacturer. Patients were tested approximately 113 days from 9/10/23 - 3/14/24 without a valid RNase P verification. Findings: The QuantStudio 5 Real-Time PCR Instrument User Guide (for Human Identification) states in Chapter 5 "... Perform instrument verification using RNase P plates During instrument installation, your HID Support Representative will perform instrument verification. However, perform instrument verification: After performing instrument calibrations. As needed to confirm instrument performance. ..." The manufacturer's instructions specify

	instrument calibrations be performed every two years. Review of QuantStudio 5 Real-Time PCR Instrument calibration records revealed the instrument calibrations were performed at installation 9/9/21 and again 2/15/23. Review of the 2/15/23 calibration report revealed "INVALID" for RNase P. Observation of instrument settings on the QuantStudio 5 Real-Time PCR Instrument at approximately 2:25 p.m. revealed RNase P was last performed 9/9/21 and expired 9/9/23. Review of quality control records for SARS/COVID Assay performed on the QuantStudio 5 Real-Time PCR Instrument revealed the laboratory performed patient testing approximately 113 days from 9/10 /23 - 3/14/24 without a valid RNase P verification. During interview at approximately 1:45 p.m., the TS stated the RNAse P was invalid on the 2/15/23 calibration report because the RNAse P verification was not performed. He stated they they didn't think it was required. He confirmed patient testing was conducted without a valid RNase P verification.