Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2142995	12/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Port Health Services	2602 Courtier Drive, Greenville, 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 laboratory procedure manual, review of manufacturer's package inserts and interview with general supervisor (GS) 12/17/19, the laboratory's procedure manual was not complete and current for the testing performed. Findings: The laboratory performs urine toxicology qualitative analysis on the Diatron Pictus 700 analyzer using Thermo Scientific DRI reagents. 1. Review of laboratory procedure manual and manufacturer's package inserts revealed the laboratory procedures failed to include the level of calibrator used for each analyte tested on the Diatron Pictus 700 analyzer. Review of laboratory procedure "Quality Control Drug

	Testing" revealed "Calibration requirements: - at least once per week. Urine Drug testing (Refer to manufacturer's requirements for each analyte.)". Review of Thermo Scientific DRI package inserts for manufacture's requirements revealed the inserts did not specify what level of calibrator is used by the laboratory for the calibration of each analyte. For example: a. Package insert for "DRI Cannabinoid Assay" revealed "Qualitative analysis...For qualitative analysis of samples, use the 20 nanograms per milliliter (ng/mL), or 50 ng/mL, or 100 ng/mL...calibrators as a cutoff level. The... calibrators are used as cutoff references for distinguishing "positive" from "negative" samples. The package insert does not specify what level of calibrator is used by the laboratory. b. Package insert for "DRI Cocaine Metabolite Assay" revealed "Qualitative analysis...For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1, which contains 150 ng/mL benzoylecgonine, or DRI Multi-Drug Calibrator 2, which contains 300 ng/mL benzoylecgonine as a cut-off level. 2. Review of laboratory procedure manual and manufacture's package inserts revealed calibration procedures failed to include the laboratory's criteria for calibration acceptability. 3. Review of laboratory procedure manual and manufacture's package inserts revealed calibration procedures failed to include the corrective action to take if calibration fails to meet the laboratory's criteria for acceptability. Interview with GS at approximately 11:30 a.m. confirmed the laboratory calibration procedures failed to specify the level of calibrator to be used, failed to define the laboratory's criteria for calibration acceptability and failed to specify corrective actions if calibration fails to meet the laboratory's criteria for acceptability.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the TS (technical supervisor) 12/17/19, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: During a tour of the laboratory at approximately 1:30 p.m., the surveyor observed the following expired supplies in refrigerator #2, available for use: 1. DRI THC 50 ng/ml Urine Calibrator (Lot #73207055), expiration date 8/31/2019; 2. DRI Multi-Drug Urine Calibrator 4 (Lot #72994545), expiration date 9/30/2019. During interview at approximately 1:45 p.m., the TS stated she thought the laboratory had checked all supplies to ensure they were not expired.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of calibration verification records 12/17/19, the laboratory failed to perform calibration verification at least once every six months as required. Findings: The laboratory's "Calibration Verification" policy states "Perform every 6 months per regulatory requirements for all analytes that have less than 3 point calibration". Review of calibration verification records revealed: 1. Calibration verification for pH was performed 8/20/18 and was not performed again until 7/1/19, approximately 10 and a half months later. 2. Calibration verification for ETOH (ethyl alcohol) was performed 10/24/18 and was not performed again until 7/1/19, approximately 8 months later.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2018 and 2019 quality assessment records, review of email, and interview with reference laboratory representative 12/17/19, the laboratory failed to ensure providers were notified when errors were identified in patient ETOH (ethyl alcohol) test results and failed to maintain duplicates of the original and corrected reports. Findings: 1. The laboratory's "CORRECTED REPORT POLICY" states "A. Corrected In-House Reports: If a mistake or error has been made, a corrected report must be generated and sent to appropriate individuals. ... The physician or his nurse must be notified either in person or by phone. ... B. Reports received from Reference Labs: ... a call to the physician or his nurse should be documented in the QA Problem Log as to the person called, time called, and correct result and your initials. The physician should be told at that point that a correct report will follow." Review of quality assessment record dated 10/16/18 noted an unexpected high number of positives for ETOH that the laboratory determined to be false positives. The record noted that ETOH was recalibrated and the 11 patient samples were retested 10/22/18. Review of an email from a reference laboratory representative to "Supervisors" dated 10/25/18 revealed "Please note that the false positive ETOH screens have been and corrected. ... If there are any (reference laboratory) reports that need to be corrected that haven't been already

	please let me know." There was no documentation available to indicate that providers were notified of the problem and the corrected results. 2. Review of laboratory records revealed no documentation of the original patient test reports. Interview with reference laboratory representative at approximately 2:15 p.m. confirmed the laboratory failed to retain the original patient test reports. He stated the original test results were corrected in the computer system but when making the correction the original result was deleted from the report. He also stated the corrected reports do not indicate that results were corrected.