

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0864770	<b>(X3) Date Survey Completed</b>  12/07/2021
<b>Name of Provider or Supplier</b>  Harnett County Health Department	<b>Street Address, City, State</b>  307 W Cornelius Harnett Boulevard, Lillington, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure "GONORRHEA CULTURES Modified Thayer Martin (MTM II)", review of 2019, 2020 and 2021 MTM II media quality control (QC) Logs and interview with TP(testing personnel) #1 (laboratory supervisor) 12/07/21, the procedure for Gonorrhoea cultures (GC) on MTM II media was incomplete and failed to include organisms that would determine selective growth for acceptable QC results. The procedure also failed to state what are acceptable results for QC of the MTM II media. Findings: Review of laboratory procedure "GONORRHEA CULTURES Modified Thayer Martin (MTM II)" revealed "III.</p>

QUALITY CONTROL A. MEDIA...Modified Thayer Martin plates-When received plates from the North Carolina State Lab, place one plate in incubator to check for sterility/no growth, one plate will be sub cultured from the sheep agar plate with pseudo-aeruginosa and one plate will be sub cultured from the sheep agar plate with staph aureus for 48-72hours. Record results on Media Quality Control log. Acceptable results: No growth on sterility check. Positive/Negative result for pseudo-aeruginosa and Positive/Negative result for staph aureus. If results are unacceptable, do not use plates." The organisms used for QC in the procedure fail to include a GC organism to determine selective growth on the MTM II media. And the procedure fails to state what are acceptable results for QC of the MTM II media. Review of media QC logs revealed the laboratory was performing sterility checks on the MTM II media. The laboratory was not performing QC of the MTM II media. See D5477. Interview with TP #1 at approximately 2:00 p.m. confirmed the procedure for GC culture was incomplete and did not include organisms to determine selective growth. She stated the organisms in the procedure are what they use for QC of the oxidase test. She also stated the laboratory was only documenting sterility checks and they did not realize they could not longer accept the QC performed by the manufacturer of the MTM II media.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of 2019, 2020 and 2021 laboratory records, review of manufacturer's letter and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory failed to verify the accuracy, precision and reportable range of the Total Bilirubin (TBIL) testing performed on the Reichert UNISTAT Bilirubinometer before beginning patient testing in April of 2019, approximately 192 patients were tested. Findings: The laboratory began patient testing for TBIL on the Reichert UNISTAT Bilirubinometer in April of 2019. Review of 2019, 2020 and 2021 laboratory records revealed no documentation the laboratory had verified the accuracy, precision and reportable range of the TBIL before performing patient testing, a period of approximately 32 months in which patient testing was performed. Review of manufacturer's letter "Reichert UNISTAT Bilirubinometer, catalog 131030C - Pediatric Application" revealed "Moderately complex test - ...It is advised that practices purchase a Linearity Kit when placing the instrument into service." Interview with TP #1 at approximately 12:00 p.m. confirmed the laboratory failed to verify all performance specifications of TBIL testing performed on the Reichert UNISTAT Bilirubinometer before patient testing began in April of 2019. She stated the sales representative installed it and told them the analyzer was ready for patient testing. She also confirmed the laboratory tested approximately 192 patients since April of 2019.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of 2019, 2020 and 2021 laboratory records and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory failed to follow manufacturer's instructions for the performance of calibration on the Reichert UNISTAT Bilirubinometer since patient testing began in April of 2019. A period of approximately 32 months in which approximately 192 patients were tested and calibration was not performed. Findings: Review of manufacturer's instructions revealed "6.1 Calibration Frequency The REICHERT UNISTAT Bilirubinometer requires calibration upon installation and then at least at six month intervals...6.2 Calibration Material...a stable assayed glass calibration cuvette...which is included with the instrument (Fig. 4)." Fig. 4 shows two calibration cuvettes, a low-level check cuvette and a high-level check cuvette. Review of 2019, 2020 and 2021 laboratory records revealed no documentation the laboratory had performed calibrations of the REICHERT UNISTAT Bilirubinometer every 6 months as required by the manufacturer. Interview with TP #1 at approximately 12:00 p.m. confirmed the laboratory had not performed calibration of the REICHERT UNISTAT Bilirubinometer every 6 months as required by the manufacturer. She also confirmed approximately 192 patients were tested since testing began in April of 2019.

**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 manufacturer's instructions, review of 2019, 2020 and 2021 laboratory records and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory failed to perform a calibration verification every 6 months that included a minimal value, a mid-point value and a maximum value on the Reichert UNISTAT Bilirubinometer since patient testing began in April of 2019. A period of approximately 32 months in which approximately 192 patients were tested and a three point calibration verification was not performed. Findings: Review of manufacturer's instructions revealed "6.1 Calibration Frequency The REICHERT UNISTAT Bilirubinometer requires calibration upon installation and than at least at six month intervals...6.2 Calibration Material...a stable assayed glass calibration cuvette...which is included with the instrument (Fig. 4)." Fig. 4 shows two calibration cuvettes, a low-level check cuvette and a high-level check cuvette. The 6 month calibration required by manufacturer fails to include a minimal value, a mid-point value and a maximum value. Review of 2019, 2020 and 2021 laboratory records revealed no documentation the laboratory had performed calibration verifications that included a minimal value, a mid-point value and a maximum value on the Reichert UNISTAT Bilirubinometer since patient testing began in April of 2019. Interview with TP #1 at approximately 12:00 p.m. confirmed the laboratory had not performed calibration verifications every 6 months that included a minimal value, a mid-point value and a maximum value on the Reichert UNISTAT Bilirubinometer. She stated they were unaware that 3 levels were required. She also confirmed approximately 192 patients were tested since testing began in April of 2019.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of 2021 TBIL QC logs, review of TBIL QC assay sheets and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory failed to use the manufacturer's established QC ranges for TBIL testing performed on the Reichert UNISTAT Bilirubinometer from January thru March of 2021 and September thru November of 2021, a period of approximately 6 months. Findings: 1. The laboratory failed to use the manufacturer's established ranges for TBIL QC, "Bilirubin Control - Pediatric", Level 1 and Level 2 from January thru March 2021. Review of January thru March 2021 TBIL QC logs revealed QC ranges for Level 1, Lot # 33541 and

Level 2, Lot #33542 were written with ranges of 9.4-14.1 and 18.9-28.3, respectively. The QC logs were signed and reviewed by TP #1 and the LD. Review of "Bilirubin Control - Pediatric" QC assay sheets revealed Level 1, Lot #33541 has a range of 8.9-13.4 and Level 2, Lot #33542 has a range of 18.3-27.4. 2. The laboratory failed to use the manufacturer's established ranges for TBIL QC, "Bilirubin Control - Pediatric", Level 1 and Level 2 from September thru November of 2021. Review of September thru November TBIL QC logs revealed QC ranges for Level 1, Lot #33551 and Level 2, Lot #33552 were written with ranges of 9.4-14.1 and 18.9-28.3, respectively. The QC logs were signed and reviewed by TP#1 and the LD. Review of "Bilirubin Control - Pediatric" QC assay sheets revealed Level 1, Lot #33551 has a range of 8.9-13.4 and Level 2, Lot #33552 has a range of 18.3-27.4. Interview with TP#1 at approximately 12:00 p.m. confirmed the "Bilirubin Control - Pediatric" QC ranges were incorrect on the TBIL QC logs. She also confirmed that the TBIL QC logs were reviewed by herself and the LD. She stated she did not realize when reviewing the QC logs that the ranges were incorrect.

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of 2019, 2020 and 2021 MTM II Media QC logs, review of laboratory procedures and policies, review of laboratory records and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory failed to check each batch of MTM II media for its ability to select GC and inhibit other organisms in 2019, 2020 and 2021, a period of approximately three years in which QC was not performed as required and an IQCP plan was not implemented. Findings: Review of 2019, 2020 and 2021 MTM II Media QC logs revealed the laboratory had performed sterility checks for each new lot number or shipment of MTM II media received. There was no documentation the laboratory had performed QC of MTM II media for its ability to select GC and inhibit other organisms. Review of laboratory procedures and policies revealed the laboratory had not implemented an IQCP plan to perform only sterility checks as QC for each batch of MTM II media received. Review of laboratory records revealed the laboratory had maintained the memos from the state laboratory indicating the QC was performed by the state laboratory prior to shipping. The memos indicating QC was performed prior to shipping fails to meet the QC requirements of MTM II media. Interview with TP #1 at approximately 2:00 p.m. confirmed the laboratory was not performing QC of the MTM II plates for each batch received. She stated they only perform sterility checks and they were not aware that they had to perform QC even though they had documentation of QC performed by the state laboratory. She also stated the laboratory had not implemented an IQCP plan to perform sterility checks only for QC.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory procedures and policies, review of verification of performance records, review of 2019, 2020 and 2021 TP and technical consultant (TC) competency assessment records, and review of 2019, 2020 and 2021 laboratory calibration and QC records 12/7/21, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Findings: 1. The LD failed to ensure TP competency assessments were performed by personnel who met the qualifications of a TC and were delegated by the laboratory director to perform TP competency assessments. See D6004. 2. The LD failed to assess the competency of the delegated TC. See D6004. 3. The LD failed to ensure the verification of performance for the Reichert UNISTAT Bilirubinometer was performed before patient testing began. See D6013. 4. The LD failed to ensure calibrations and calibration verifications were performed on the Reichert UNISTAT Bilirubinometer every 6 months as required. See D6013. 5. The LD failed to ensure correct QC ranges were used to determine acceptable QC results on the Reichert UNISTAT Bilirubinometer. See D6020. 6. The LD failed to ensure QC was performed on the MTM II GC culture media. See D6020.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints 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 review of laboratory policies, review of CMS-209, review of TP competency assessments, review of TC job description, review of TC competency assessments and interview with TP #1 (laboratory supervisor) 12/7/21, the laboratory director (LD) failed to ensure 6 of 6 TP competency assessments were performed by personnel who met the qualifications of a TC and were delegated by the LD to perform TP competency assessments. The LD also failed to perform the competency assessments of the duties delegated to the TC (TP #2) in 2020 and 2021. 1. The LD failed to ensure 6 of 6 TP competency assessments were performed by personnel who met the qualifications of a TC and were delegated by the LD to perform TP competency assessments. Findings: Review of laboratory policies revealed "Letter of Delegation...I have delegated (name of TP#2) to oversee the employee competency on all moderate complexity tests performed at the (name of facility). She is assigned as the technical consultant to review the competency on providers performing moderate testing. She is also signing the attestation statements when performing all proficiency

samples.". The delegation is signed by the LD and dated 3/8/19. Review of 2019, 2020 and 2021 TP competency assessments revealed the following: a. The 2020 and 2021 competency of TP #1 was assessed by the director of nursing, who does not perform testing and is not listed as laboratory personnel on the CMS-209 submitted at time of survey. b. The 2019, 2020, and 2021 competency of TP #2 (technical consultant), TP #3, TP #4, TP #5 and TP #6 were assessed by TP #1 who does not meet the qualifications of a TC. Interview with TP #1 at approximately 10:30 a.m. confirmed 6 of 6 TP competency assessments were performed by personnel who were not delegated by the LD and not qualified to perform TP competency assessments. 2. The LD failed to perform the competency assessments of the duties delegated to the technical consultant (TP #2) in 2020 and 2021. Findings: Review of 2020 and 2021 TC competency assessments revealed the delegated duties were evaluated by TP #1, who does not meet the qualifications to perform TC competency assessments. They also revealed the LD had signed his review of the TC competency assessments, when the delegated duties (TP competency assessments) were not performed by the delegated TC (TP#2). Interview with TP #1 at approximately 10:30 a.m. confirmed she performed the TC competency assessments in 2020 and 2021 and the LD had signed off his review of the TC competency assessments.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
 Based on review of 2019, 2020 and 2021 laboratory records, review of manufacturer's letter and instructions, and interview with TP #1 (laboratory supervisor) 12/7/21, the LD failed to ensure the accuracy, precision and reportable range of the Reichert UNISTAT Bilirubinometer was validated before beginning patient testing and failed to ensure calibrations and calibration verifications were performed every 6 months as required on the Reichert UNISTAT Bilirubinometer. 1. The LD failed to ensure the accuracy, precision and reportable range of the Reichert UNISTAT Bilirubinometer was validated before beginning patient testing. Findings: See D5421. 2. The LD failed to ensure calibrations and calibration verifications were performed every 6 months as required on the Reichert UNISTAT Bilirubinometer. Findings: See D5437 and D5439.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of 2021 TBIL QC logs, review of TBIL QC assay sheets, review of 2019, 2020 and 2021 Modified Thayer Martin (MTM II) Media QC logs, review of laboratory records, procedures and policies, and interview with TP #1 (laboratory supervisor) 12/7/21, the LD failed to ensure the laboratory used manufacturer's established QC ranges for TBIL testing performed on the Reichert UNISTAT Bilirubinometer and failed to ensure QC was performed as required for GC cultures on MTM II media. 1. The LD failed to ensure the laboratory used manufacturer's established QC ranges for TBIL testing performed on the Reichert UNISTAT Bilirubinometer. Findings: See D5469. 2. The LD failed to ensure QC was performed as required for GC cultures on MTM II media. Findings: See D5477.