

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D1092163	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Waterville Women's Care	Street Address, City, State 35 Medical Center Parkway, Suite 202, Augusta, ME	
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	<p>An announced CLIA Recertification Survey was completed on December 15, 2021 at WATERVILLE WOMEN'S CARE by the Maine Department of Health and Human Services, Division of Licensing and Certification. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY finding:</p>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER 96D report, lack of Proficiency Testing (PT) records and documentation, and staff interviews, the laboratory failed to enroll in an approved PT program or test their system twice annually in the subspecialty of bacteriology. Testing personnel #1 (TP1) confirmed the laboratory performed Gonorrhea and Chlamydia testing and did not enroll in an approved proficiency testing program or test their system twice a year with previously analyzed or internal blind samples. Findings include: 1. Record review on 12/15/2021 of the CASPER 96D report revealed, no scores for Gonorrhea and Chlamydia testing. 2. Record review on 12/15/2021 of the CMS form 116 revealed the laboratory performs Gonorrhea and Chlamydia testing on the Cepheid GeneXpert. 3. During interview with (TP1) on 12/15/2021 at 9:15 AM, TP1 stated: a. "The laboratory does not have PT records</p>

	<p>available." b. "The technical consultant (TC) left the laboratory in 2018 and he used to take care of PT." c. "The laboratory has not participated in PT since the TC left in 2018." 4. The laboratory performs approximately 2,000 Gonorrhea and Chlamydia tests on the Cepheid GeneXpert per year.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor observation, lack of documentation record review and staff interviews, the laboratory failed to ensure the laboratory performed quality control for Gonorrhea and Chlamydia testing run on the Cepheid GeneXpert as required by the manufacturer (refer to D5453); failed to perform maintenance on the Cepheid GeneXpert as required by the manufacturer (refer to D5429); failed to perform calibration on the Cepheid GeneXpert as required by the manufacturer (refer to D5437); and failed to have a procedure manual available to testing personnel (refer to D5401). The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the specialty of Microbiology.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview with testing personnel #1 (TP1), the laboratory failed to have a written procedure manual in the laboratory. Findings include: 1. Record review of the CMS form 116 on 12/15/2021 revealed the laboratory performs Gonorrhea and Chlamydia testing on the Cepheid GeneXpert. 2. Staff interview with TP1 on 12/15/2021 at 9:15 AM revealed the laboratory did not have a procedure manual available in the laboratory. TP1 stated he/she did not know where the procedure manual was located. 3. The laboratory performs approximately 2,000 Gonorrhea and Chlamydia tests on the Cepheid GeneXpert per year.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with testing personnel #1 (TP1), the laboratory failed to document routine maintenance and function checks on the Cepheid GeneXpert. Findings include: 1. Record review of the CMS form 116 on 12/15/2021 at 9:00 AM revealed the laboratory performs Gonorrhea and Chlamydia testing on the Cepheid GeneXpert. 2. During interview with (TP1) on 12/15/2021 at 9:15 AM, TP1 stated: a. "The laboratory does not have maintenance records for the Cepheid GeneXpert." b. "The technical consultant (TC) left the laboratory in 2018 and he used to take care of maintenance." c. "The laboratory has not documented routine maintenance on the Cepheid GeneXpert since the TC left in 2018."

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 lack of documentation, record review and interview with testing personnel #1 (TP1), the laboratory failed to perform calibration verification for Gonorrhea and Chlamydia testing performed on the Cepheid GeneXpert in the subspecialty of bacteriology. Findings include: 1. Record review on 12/15/2021 of the Cepheid GeneXpert manufacturer's maintenance manual, Preventative Maintenance: tasks /frequency section revealed, "Yearly maintenance or after 2000 tests/module, calibrate all modules once a year or every 2000 tests/module whichever comes first." 2. During interview with (TP1) on 12/15/2021 at 9:15 AM, TP1 stated: a. "The laboratory does not have maintenance records for the Cepheid GeneXpert." b. "The technical consultant (TC) left the laboratory in 2018 and he used to take care of maintenance." c. "The laboratory has not documented maintenance on the Cepheid GeneXpert since the TC left in 2018." 3. The laboratory performs approximately 2,000 Gonorrhea and Chlamydia tests on the Cepheid GeneXpert per year.

D5453

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iv)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of documentation, record review and interview with testing personnel #1 (TP1) the laboratory failed to perform external quality control (QC) to detect errors in the extraction phase when performing the CT/NG assay on the Cepheid GeneXpert. Findings include: 1. Record review on 12/15/2021 of the package insert for the Cepheid GeneXpert CT/NG assay revealed: "QC Section: External controls (one positive and one negative) may be used in accordance with local, state and/or federal accrediting organizations as applicable." 2. During interview with (TP1) on 12/15/2021 at 9:15 AM, TP1 stated: a. "The laboratory does not have external QC records for the CT/NG assay on the Cepheid GeneXpert." b. "The technical consultant (TC) left the laboratory in 2018 and he used to take care of all of that." c. "The laboratory has not documented external QC on the Cepheid GeneXpert since the TC left in 2018." 3. The laboratory performs approximately 2,000 Gonorrhea and Chlamydia tests on the Cepheid GeneXpert per year.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with testing personnel #1 (TP1) the technical consultant (TC) failed to document annual competency of testing personnel to assess the knowledge and skills necessary to perform moderate complexity laboratory testing. Findings include: 1. Record review on 12/15/2021 of the CMS form 209 revealed 2 of 2 TP perform moderate complexity testing. 2. During interview with (TP1) on 12/15/2021 at 9:15 AM, TP1 stated: a. "The laboratory does not have competency records for 2 of 2 moderate complexity testing personnel." b. "The technical consultant (TC) left the laboratory in 2018 and he used to take care of all of that." c. "The laboratory has not documented competency of testing personnel since the TC left in 2018." 3. The laboratory performs approximately 2,000 Gonorrhea and Chlamydia tests on the Cepheid GeneXpert per year.