

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1013018	(X3) Date Survey Completed 03/08/2022
Name of Provider or Supplier Windham & Rentrop Urology Pllc DbA Starkville Urol	Street Address, City, State 1207 Hwy 182 W, Ste B, Starkville, MS	
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	<p>PROCEDURE MANUAL 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 the laboratory's procedure manual, the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using Real-Time Reverse Transcriptase Qualitative Polymerase Chain Reaction (RT-QPCR), and patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22, the laboratory's procedure manual did not include a procedure for specimen collection, storage, preservation, processing, criteria for specimen acceptability and rejection, and step-by step performance of RT-QPCR testing on rectal swab specimens. Findings include:</p>

Review of the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using RT-QPCR revealed the Specimen Collection section stated a clean-catch urine specimen is used for testing. Review of the Test Procedure for Preparation of UTI Samples Using Promega ReliaPrep Viral TNA Miniprep revealed the test procedure only included the procedure for preparation of urine specimens. There were no procedures available on the day of the survey, 3/8/22, for specimen collection, storage, preservation, processing, criteria for specimen acceptability and rejection, or step-by step performance of RT-QPCR testing of rectal swab specimens. Review of patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22 revealed 54 specimens tested during this time frame were rectal swab specimens.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using Real-Time Reverse Transcriptase Qualitative Polymerase Chain Reaction (RT-QPCR), the laboratory's Individual Quality Control Plan (IQCP), and patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22, the laboratory failed to establish performance specifications for rectal swab specimens and for clean-catch urine specimens tested up to five days after collection. Findings include: 1. Review of the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using RT-QPCR revealed the Specimen Collection section stated a clean-catch urine specimen is used for testing. Review of the laboratory's IQCP for RT-QPCR revealed the Risk Assessment stated under the Specimen section that the specimen type is Andwin Scientific Sterile Urine Cup and stated under Possible Sources of Error, "Incorrect collection of specimen." The Risk Assessment stated under How to Reduce Error, "Train collectors on proper urine collection." Review of patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22 revealed 54 specimens tested during this time frame were rectal swab specimens. There was no documentation available on the day of the survey, 3/8/22, of establishment of performance specifications for RT-QPCR testing of rectal swab specimens, with the Promega ReliaPrep Viral TNA Miniprep extraction process and the Bio-Rad CFX Opus Real-Time PCR System. 2. Review of the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using RT-QPCR revealed the Storage Conditions section stated, "If the specimen will be processed (nuclear extraction) for analysis within 5 days after collection, keep it at room temperature (20 - 25 degrees Celsius) or refrigerate at 4 - 8 degrees Celsius. Samples must be tested within 5 days after collection." There was no documentation of establishment of performance specifications for urine specimens stored up to 5 days after collection available on the day of the survey, 3/8/22.

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 calibration verification records for the TOSOH AIA-900 Immunoassay System since the last survey on 1/14/20 and confirmation by the testing personnel listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to perform calibration verification for prostate specific antigen (PSA) testing, which only uses two calibrators, at least every six months. Findings include: Review of calibration verification records for the TOSOH AIA-900 Immunoassay System since 1/14/20 revealed no documentation of performance of calibration verification for PSA testing since 8/6/20. The individual listed as testing personnel on the CMS 209 personnel form confirmed calibration verification for PSA testing has not been performed since 8/6/20.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individual Quality Control Plan (IQCP) and patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22, the laboratory failed to identify potential failures and errors in the RT-QPCR testing process in

conducting the risk assessment and to evaluate the impact of those failures and sources of error on test quality for rectal swab specimens. Rectal swab specimens were used for RT-QPCR testing on 54 patients during this time frame. Findings include: Review of the laboratory's IQCP for RT-QPCR testing with the Bio-Rad CFX Opus 96 Real-Time PCR System revealed the Risk Assessment stated in the Specimen section that the specimen type is Andwin Scientific Sterile Urine Cup and stated under Possible Sources of Error, "Incorrect collection of specimen." The Risk Assessment stated under How to Reduce Error, "Train collectors on proper urine collection." There was no documentation available on the day of the survey, 3/8/22, of a risk assessment conducted for rectal swab specimens to identify possible sources of error and evaluate the impact of those sources of error on test quality. Review of patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22 revealed 54 specimens tested during this time frame were rectal swab specimens.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual, the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using Real-Time Reverse Transcriptase Qualitative Polymerase Chain Reaction (RT-QPCR), and patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22, the laboratory director failed to ensure an approved procedure manual was available to testing personnel for performing RT-QPCR testing on rectal swab specimens, to include a procedure for specimen collection, storage, preservation, processing, criteria for specimen acceptability and rejection, and step-by step performance of RT-QPCR testing on rectal swab specimens. Refer to D5403 (Failure to include procedures for performance of RT-QPCR testing on rectal swab specimens in procedure manual).

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Protocol for Determination of Urinary Tract Infection Pathogens Using Real-Time Reverse Transcriptase Qualitative Polymerase Chain Reaction (RT-QPCR), the laboratory's Individualized Quality Control Plan, and patient plate maps for RT-QPCR testing from 4/13/21 through 2/25/22, the technical supervisor failed to ensure performance specifications were established for RT-QPCR testing on rectal swab specimens and on clean-catch urine specimens tested up to five days after collection. Refer to D5423 (Failure to establish performance specifications for rectal swab specimens and for clean-catch urine specimens tested up to five days after collection).

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individual Quality Control Plan (IQCP) and patient plate maps for Real-Time Reverse Transcriptase Qualitative Polymerase Chain Reaction (RT-QPCR) testing from 4/13/21 through 2/25/22, the technical supervisor failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance for RT-QPCR testing on rectal swab specimens, when rectal swab specimens were used for RT-QPCR testing on 54 patients during this time frame. Refer to D5445 (Failure to conduct risk assessment of rectal swab specimens for IQCP).