

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0720805	(X3) Date Survey Completed 10/05/2021
Name of Provider or Supplier Prescott Urology	Street Address, City, State 811 Ainsworth Dr, Suite 101, Prescott, AZ	
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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of established performance specification documentation for the Laboratory Developed Test (LDT), Urinary Tract Infections (UTI) by PCR, used to test patient urine specimens and interview with the facility personnel, the laboratory failed to demonstrate the effects of the patients' clinical conditions, disease states, and medications as interfering substances that may effect the analytical specificity of the test system. Findings include. 1. During the survey conducted on October 5, 2021, no documentation was included in the establishment of performance specifications for the UTI PCR test indicating if the patients' clinical conditions, disease states, and any common medications may effect and/or inhibit the analytical specificity of the test system. 2. The facility personnel acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system. 3. The laboratory started patient testing using the LDT, UTI by PCR in January 2020 and has an approximate annual test volume of 45,000.</p>

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of the individual responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began patient testing in January 2020. 2. The facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the testing personnel indicated above.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the facility personnel, the laboratory failed to document the annual competency evaluation of one testing personnel. Findings include: 1. The laboratory began testing patient specimens on January 25, 2020. 2. No annual competency evaluation was presented for review for one out of one testing personnel. The initial training documentation for this testing personnel was completed and dated on 12/15/2019. 3. The facility personnel confirmed the testing personnel indicated above was missing an annual competency evaluation.