

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0867947	<b>(X3) Date Survey Completed</b>  06/12/2019
<b>Name of Provider or Supplier</b>  Uw Health Central Laboratory	<b>Street Address, City, State</b>  20 S Park St Suite 465, Madison, WI	
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>D5401</b>	<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 surveyor review of laboratory procedures and interview with the technical consultant of coagulation testing, the laboratory did not have a procedure available for the new Instrumentation Laboratory ACL TOP 300 CTS coagulation analyzer. Findings include: 1. The laboratory replaced the Sysmex CA 1500 coagulation analyzer with the Instrumentation Laboratory ACL TOP 300 CTS coagulation analyzer effective March 26, 2018. Protime, activated partial thromboplastin time (aPTT), and D-Dimer testing is performed on the new coagulation analyzer. 2. Review of the laboratory procedures show no evidence of an approved procedure available for staff for the new coagulation analyzer. 3. Interview with the technical consultant on June 12, 2019 confirmed that a procedure has not been completed and approved by the laboratory director for coagulation testing performed on the new coagulation analyzer.</p>
<b>D5409</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of procedures and interview with the technical supervisor, the laboratory has not documented the date of discontinuance for the Cobas Chlamydia Trachomatis (CT)/Neisseria Gonorrhoea (GC), Anti nDNA, and the Sysmex CA 1500 Coagulation procedures. Findings include: 1. Review of the Cobas CT/GC, Anti nDNA, and Sysmex CA 1500 Coagulation procedures show that a discontinuance date has not been documented on the procedures. 2. Interview with the technical supervisor on June 12, 2019 at 12:45 PM confirmed that testing on the new coagulation analyzer was effective March 26, 2018 but the procedure for the previous coagulation analyzer (Sysmex CA 1500) was the current procedure available for staff use and the date of discontinuance was not documented on the procedure. 4. Further interview with the technical supervisor at 1:30 PM confirmed that Cobas CT/GC testing was possibly discontinued June 22, 2018 but the date of discontinuance was not documented on the procedure. The technical supervisor also confirmed that the Anti nDNA procedure was discontinued in "early 2018" but the date of discontinuance was not documented on the procedure. This is a repeat deficiency previously cited on July 14, 2015.

**D6055**

**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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of training and competency evaluation records and interview with the technical consultant, the technical consultant did not evaluate competency after the implementation of the new coagulation analyzer. Findings include: 1. The laboratory replaced the Sysmex CA 1500 coagulation analyzer with the Instrumentation Laboratory ACL TOP 300 CTS coagulation analyzer effective March 26, 2018. Staff training to operate the new coagulation analyzer was completed in March 2018 prior to the go-live of the new analyzer but staff competency evaluation was not reevaluated for the use of the new instrumentation. 2. Interview with the technical consultant on June 12, 2019 at 12:45 PM confirmed that staff competency evaluation was not assessed with the new coagulation analyzer.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 the verification studies performed for the new Antinuclear Antibody (ANA) test and interview with the technical supervisor, the laboratory director did not ensure the verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics for the ANA test prior to performing patient testing. Findings include: 1. Review of the verification

studies performed for the Nova Lite HEp-2 ANA assay showed that this assay testing started July 16, 2018. Verification studies to determine the accuracy, precision, and other pertinent performance characteristics were not reviewed and approved by the laboratory director prior to performing patient testing. 2. Interview with the technical supervisor on June 12, 2019 at 3:00 PM confirmed that the new ANA assay verification studies to ensure acceptable test performance had not been reviewed or approved by the laboratory director prior to patient testing.