

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0451291	<b>(X3) Date Survey Completed</b>  04/12/2019
<b>Name of Provider or Supplier</b>  William Newton Hospital	<b>Street Address, City, State</b>  1300 E 5th Ave, Winfield, KS	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and interview with the technical supervisor on April 12, 2019 at 1:30 PM confirmed the laboratory failed to twice annually verify the accuracy of DAT testing in 2018.</p>
<b>D5403</b>	<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.</p>

(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of blood gas quality control (QC), blood gas procedure and interview with blood gas testing personnel #2, the laboratory failed to follow "Arterial blood gas /COOX Quality Assurance Plan". Findings: 1. Review of "Arterial blood gas/COOX Quality Assurance Plan" states "external controls performed monthly by alternating staff members". 2. Review of blood gas QC showed no documentation for QC for December 2018, January 2019, February 2019 and March 2019. 3. Interview with blood gas testing personnel #2 on April 12, 2019 at 1:30 PM confirmed the laboratory failed to follow QC blood gas procedure.

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of ROM Plus kit quality control (QC) and interview with technical supervisor #2 the laboratory failed to perform a negative and positive QC each day of patient testing in March 2019. Findings: 1. Review of ROM Plus Kit QC and patient log showed patient's results were documented on March 6, 2019, March 7, 2019, March 8, 2019, March 10, 2019 and no QC was documented. 2. Interview with technical supervisor #2 at 1:30 PM confirmed the laboratory failed to perform a negative and positive ROM Plus QC each day of patient testing in March 2019.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of 2017, 2018, 2019 proficiency testing (PT) and interview with technical consultant #2 the laboratory director failed to ensure all PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of ROM Plus competencies and interview with technical supervisor #2, the technical supervisor failed to identify training needs and ensure initial training was completed on two of seven new testing personnel. Findings: 1. Review of ROM Plus initial training competencies showed no documentation of initial competency for testing personnel #4 and #6. 2. Interview with technical supervisor #2 on April 12, 2019 at 1:30 PM confirmed the technical supervisor failed to identify training needs for testing personnel #4 and #6.

**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 review of competencies and interview with technical supervisor #2, the technical supervisor failed to evaluate and document competency semiannually for nine of nine testing personnel for ROM Plus testing and one of thirteen testing personnel for hematology and chemistry. Findings: 1. Review of semiannual competencies for ROM Plus testing showed no documentation of semiannual competency for testing personnel #1, #2, #3, #4, #5, #6, #7, #8 and #9. 2. Review of semiannual competencies for hematology and chemistry showed no documentation of semiannual competency for testing personnel #9. 3. Interview with technical supervisor #2 on April 12, 2019 at 1:30 PM confirmed the technical supervisor failed to evaluate and document competency semiannually for ROM Plus testing personnel and one semiannual competency for hematology and chemistry testing person.

**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 annual competencies and interview with the technical supervisor #2 the technical supervisor failed to evaluate and document competency annually for nine of nine testing personnel for ROM testing, for nine of thirteen testing personnel for chemistry and hematology, for two of thirteen competencies for blood bank and one of thirteen competencies had no documentation. Findings: 1. Review of annual competencies for ROM Plus testing showed no documentation of annual competency for testing personnel #1, #2, #3, #4, #5, #6, #7, #8 and #9. 2. Review of annual competencies for hematology and chemistry showed no documentation of annual

competency for testing personnel #2, #3, #5, #6, #7, #8, #10, #11 and #13. 3. Review of annual competency for blood bank showed no documentation of annual competency for testing personnel #7 and #8. 4. Review of annual competencies showed testing personnel #9 had no documentation of annual competency. 5. Interview with technical supervisor #2 on April 12, 2019 at 1:30 PM confirmed the technical supervisor failed to ensure annual competency was complete on all testing personnel.