

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095725	(X3) Date Survey Completed 03/14/2018
Name of Provider or Supplier William W Backus Hospital Lab	Street Address, City, State 326 Washington St, Norwich, CT	
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
D2061	<p>VIROLOGY CFR(s): 493.831(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence of appropriate investigation and corrective action when proficiency testing results are not submitted within the acceptable time frame. Findings include: 1. Record review of the Centers for Medicare Medicaid Services CASPER 0155D report on 3/14/18 revealed the 2016 Event 3 Virology had an unsatisfactory score of 0. 2. Record review of the College of American Pathologist 2016 VR4-C survey results on 3/14/18 revealed an unsatisfactory score of 0. 3. Record review of the laboratory Proficiency Result Review and Action Record on 3/14/18 revealed the following: a. Deviant Results: Exception code 41-Results were submitted past the due date b. Conclusion and Action Taken: Responses matched the intended responses; results were not submitted on time due to staffing shortages. c. Mechanism to monitor to prevent reoccurrence was not available. 4. Staff interview with the laboratory manager on 3/14/18 at 9:50 AM confirmed the above findings. The LM stated due to staffing shortages managerial work was not done in a timely manner. In addition, the LM stated training new staff and the hiring of a microbiology supervisor resolved the problem.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231</p>

through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. Findings include: 1. Record review on 3/14/18 of the American Proficiency Institute (API) proficiency testing (PT) Result and Action Record summary pages revealed: a) Immunology Event 1 2016 - samples were switched for C-Reactive Protein (CRP) tested on the Cobas Instrument. b) Chemistry Event 3 2016- samples were switched for Urine Total Protein (UTP) tested on the Cobas Instrument. c) Chemistry Event 2 2017- samples were switched for Alpha-fetoprotein (AFP) tested on the Cobas Instrument. d) Immunology Event 3 2017 - samples were switched for High sensitive (HsCRP) tested on the Cobas Instrument. 2. Record review on 3/14/18 of the laboratory's performance review and corrective action for the above events revealed the laboratory failed to develop written policies to prevent recurrence. 3. Staff interview with the section chemistry supervisor on 3/14/18 at 1:30 PM confirmed the above findings. 4. The laboratory performs 2,574 CRP, 3,244 UTP, 500 AFP and 3,244 HsCRP tests annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to ensure policies and procedures are followed by testing personnel (TP) in the specialty of immunohematology. Findings include: 1. Record review of the laboratory's "Notification of prior transfusion recipient of receipt of blood possibly infectious for HIV-1/HIV-2 or HCV" documents on 3/14/18 revealed there were three market withdrawals/transfusion recipients that matches the above category in 2016 and 2017. 2. Record review of laboratory's "Lookback-HCV/HIV and market withdrawal" procedure (Doc# BB-10052) on 3/14/18 revealed TP were not following the procedures below. a. "When the HCV/HIV notification form has been signed by the physician and returned to the Blood Bank, it will be sent to Medical Records to be scanned into the EMR." b. "The lookback/notification process should be completed within 12 weeks from the time of notification by the supplier." c. "If notification takes longer than 12 weeks, there must be documentation that there have been extenuating circumstances beyond the hospital's control. Documentation should include the reasons and details for the delay." 3. Staff interview with hematology section technical supervisor on 3/14/18 at 3:30 PM confirmed the following: a. HCV/HIV notification form signed by the physician and returned to the blood bank were not available. b. Evidence of documentation not available for such notification entered into patient's EMR. c. Evidence of documentation not available to ensure the process was completed in 12 weeks or reasons for any delay from the time of notification.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to assess day-to-day reproducibility for procalcitonin prior to reporting patient test results. Findings include: 1. Record review of the Siemens Cobas validation report on 3/14/18 revealed the following: a. Page 2 of the Validation Protocol states "Assessment of both within run and between run precision at least two points". b. Validation raw data failed to provide evidence that precision studies were conducted. c. The report was signed by the laboratory director on 5/5/17. 2. Staff interview with section chemistry supervisor on 3/14/18 at 11:00 AM confirmed the laboratory failed to conduct precision studies. 3. The laboratory performs 45 Procalcitonin tests annually in the specialty of chemistry.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to document routine maintenance for laboratory equipment as required by the manufacturer. Findings include: 1. Record review on 3/14/18 of the Leica BOND-MAX cleaning and maintenance logs revealed the following: a) The 6 tasks required for monthly maintenance were not documented from February 2016 through February 2018. b) Documentation of the 10 required weekly maintenance tasks were partially documented from February 2016 through February 2018. 2. Record review on 3/14/18 of the Leica BOND-MAX user manual section 12.1, 'Cleaning and Maintenance Schedule', revealed: a) "Carry out cleaning and maintenance tasks according to the schedule below." b) There are 6 task listed under monthly. c) There are 10 tasks listed under weekly. 3. Staff interview with the histology supervisor on 3/14/18 at 1:00 PM confirmed the above findings.

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 record review and staff interview, the laboratory failed to provide evidence of daily external positive and negative controls for qualitative testing in the specialty of microbiology. Findings include: 1. Record review of microbiology quality control (QC) records on 3/14/18 revealed daily positive and negative external controls results were not available each day of patient testing for the following assays: a. Binax Legionella Urinary Antigen b. Binax Streptococcus pneumoniae Urinary Antigen c. Meridian Shiga Toxin 2. Staff interview with microbiology section supervisor (MSS) on 3/14/18 at 1:30 PM confirmed the above. MSS was unaware that external QC was required each day of use. 3. The laboratory performs 328 Legionella urinary antigen, 344 Streptococcus pneumoniae urinary antigen and 1,339 Shiga toxin tests annually in microbiology.

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 record review and staff interview, the laboratory technical supervisor failed to ensure testing personnel (TP) were evaluated and competent to perform test procedures in the specialties of microbiology and hematology. Findings include: 1. Record review of the microbiology test menu on 3/14/18 revealed microbiology performs patient test procedures for Pinworm Preparation in parasitology and India Ink stain in mycology. 2. Record review of the microbiology competency assessment forms on 3/14/18 revealed the test systems listed did not include Pinworm Preparation or India Ink. 3. Staff interview with the microbiology section supervisor (MSS) on 3/14/18 at 1:45 PM confirmed the above findings. MSS stated 5 microbiology testing personnel perform Pinworm Preparations or India Ink tests. 4. The laboratory performs 10 India Ink stains and 7 Pinworm Preparations annually. 5. Record review of TP training records on 3/14/18 revealed 1 new TP hired on 11/14/16 did not have training records in the specialty of hematology. 6. Staff interview with hematology section technical supervisor on 3/14/18 at 10:30 AM confirmed the above finding.

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 record review and staff interview, the technical supervisor failed to ensure testing personnel (TP) were assessed semiannually during the first year of testing

patient samples. Findings include: 1. Review of 2016 and 2017 competency assessment records on 3/14/18 revealed the following: a. 3 new microbiology testing personnel (MTP) began patient testing. b. 3 of 3 new MTP semiannual competency assessments were not available. 2. Staff interview with microbiology section supervisor (MSS) on 3/14/18 at 10:00 AM confirmed the above findings. MSS stated 2 of the 3 new MTP semiannual assessment was not done because they had been employed elsewhere in the laboratory prior to being trained in microbiology. In addition, the MSS stated the other new MTP were not assessed twice in their first year of patient testing. 3. Record review of TP competency evaluation records on 3/14/18 revealed 1 new TP hired on 11/14/16 did not have a semiannual competency evaluation during the first year of testing patient samples in the specialty of hematology. 4. Staff interview with hematology section supervisor on 3/14/18 at 10:30 AM confirmed the above finding.