Official Accreditation Report

West Virginia University Hospitals, Inc.
1 Medical Center Drive
Morgantown, WV 26506

Organization Identification Number: 6444

Executive Summary

Requirements for Improvement

Observations noted within the Requirements for Improvement (RFI) section require follow up through the Evidence of Standards Compliance (ESC) process. The timeframe assigned for completion is due in either 45 or 60 days, depending upon whether the observation was noted within a direct or indirect impact standard. The identified timeframes of submission for each observation are found within the Requirements for Improvement Summary portion of the final onsite survey report. If a follow-up survey is required, the unannounced visit will focus on the requirements for improvement although other areas, if observed, could still become findings. The time frame for performing the unannounced follow-up visit is dependent on the scope and severity of the issues identified within the Requirements for Improvement.

Opportunities for Improvement

Observations noted within the Opportunities for Improvement (OFI) section of the report represent single instances of non-compliance noted under a C category Element of Performance. Although these observations do not require official follow up through the Evidence of Standards Compliance (ESC) process, they are included to provide your organization with a robust analysis of all instances of non-compliance noted during survey.
Executive Summary

Program(s) | Survey Date(s)
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Laboratory Accreditation | 11/03/2015-11/05/2015

Laboratory Accreditation: As a result of the accreditation activity conducted on the above date(s), Requirements for Improvement have been identified in your report. You will have follow-up in the area(s) indicated below:

- Evidence of Standards Compliance (ESC)

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.
Requirements for Improvement – Summary

Observations noted within the Requirements for Improvement (RFI) section require follow up through the Evidence of Standards Compliance (ESC) process. The timeframe assigned for completion is due in either 45 or 60 days, depending upon whether the observation was noted within a direct or indirect impact standard. The identified timeframes of submission for each observation are found within the Requirements for Improvement Summary portion of the final onsite survey report. If a follow-up survey is required, the unannounced visit will focus on the requirements for improvement although other areas, if observed, could still become findings. The time frame for performing the unannounced follow-up visit is dependent on the scope and severity of the issues identified within the Requirements for Improvement.

Evidence of INDIRECT Impact Standards Compliance is due within 60 days from the day the survey report was originally posted to your organization’s extranet site:

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<thead>
<tr>
<th>Program:</th>
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<td>Standards:</td>
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Requirements for Improvement – Detail

Chapter: Document and Process Control
Program: Laboratory Accreditation
Standard: DC.02.03.01

Standard Text: The laboratory report is complete and is in the patient's clinical record.

Element(s) of Performance:

1. The laboratory report is maintained in the patient’s clinical record.

   Scoring Category : A
   Score : Insufficient Compliance

2. The laboratory report includes the following information: The name and address of the laboratory performing the test.

   Scoring Category : A
   Score : Insufficient Compliance

Observation(s):

EP 1
Observed in Individual Tracer at WVU Cheat Lake Physicians operated by WVU Hospitals, Inc. (608 Cheat Road, Morgantown, WV) site for CLIA #(s) 51D0985637.
The laboratory legal copy of the test report for the PPMP-fern test was not maintained in the patient’s clinical record. The laboratory results were documented in the clinical notes by the provider. The laboratory did not have a process in place to issue a legal laboratory report.

Observed in Individual Tracer at University Town Centre Clinic operated by WVU Hospitals, Inc (6040 University Town Centre Drive, Morgantown, WV) site for CLIA #(s) 51D2092989.
The laboratory legal copy of the test report for the PPMP-wet mount/ KOH preparation was not maintained in the patient’s clinical record. The laboratory results were documented in the clinical notes by the provider. The laboratory did not have a process in place to issue a legal laboratory report.

EP 2
Observed in Tracer Activities at WVU Heart Institute operated by WVU Hospitals, Inc. (600 Suncrest Towne Centre, Morgantown, WV) site for CLIA #(s) 51D2031072.
The laboratory report in the clinical did not include the name and address of the laboratory performing the test. When the hospital information system had updates, the name and address of the laboratory performing the tests reverts back to the main site. This was a finding on the previous survey.
Program: Laboratory Accreditation
Standard: EC.02.04.01
Standard Text: The laboratory manages laboratory equipment risks.

Element(s) of Performance:

2. The laboratory maintains a written inventory of laboratory equipment and equipment incident history. The laboratory evaluates new types of equipment before initial use to determine whether they should be included in the inventory.

Scoring Category: A
Score: Insufficient Compliance

Observation(s):

EP 2
Observed in Building Tour at University Town Centre Clinic operated by WVU Hospitals, Inc (6040 University Town Centre Drive, Morgantown, WV) site for CLIA #(s) 51D2092989.
Microscopes were located in the Pediatrics Clinic, the Dermatology Clinic, and the Family Medicine Clinic. The microscopes were not made part of the inventory of laboratory equipment.

Chapter: Quality System Assessment for Nonwaived Testing
Program: Laboratory Accreditation
Standard: QSA.01.01.01
Standard Text: The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes. Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).
Element(s) of Performance:

5. For each specialty, subspecialty, analyte, or test, the laboratory’s proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.

Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88), Subpart H, include the following:
- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho (D) typing and compatibility testing
- Attaining a score of 100% for ABO group and Rho (D) typing or compatibility testing
- Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.
- Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.

Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer. (For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

Scoring Category: C
Score: Insufficient Compliance

Observation(s):
EP 5
Observed in Proficiency Testing at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #s 51D0876698. For the i-Stat pCO2 in cardiology, the laboratory’s proficiency testing results did not meet satisfactory performance criteria in accordance with law and regulation. Event 2-2014 scored a 60% due to a clerical error.

Observed in Proficiency Testing at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #s 51D0876698. For i-Stat activated clotting times performed in the operating room, the laboratory’s proficiency testing results did not meet satisfactory performance criteria in accordance with law and regulation. Event 3-2014 scored a 50%.

Observed in Proficiency Testing at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #s 51D0876698. For PPMP-fern testing, the laboratory’s proficiency testing results did not meet satisfactory performance criteria in accordance with law and regulation. Event 3-2014 scored a 0% failure to participate. The laboratory did not submit the proficiency testing results back to the proficiency testing vendor prior to the due date.

Chapter: Quality System Assessment for Nonwaived Testing
Program: Laboratory Accreditation
Standard: QSA.01.03.01
Standard Text: The laboratory has a process for handling and testing proficiency testing samples.

Element(s) of Performance:

7. The laboratory staff who performed the proficiency testing along with the laboratory director sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens.
Note: The laboratory director may delegate this responsibility in writing to a technical consultant meeting the qualifications of 42 CFR 493.1409 (for moderate-complexity testing) or a technical supervisor meeting the qualifications of 42 CFR 493.1447 (for high-complexity testing).

Scoring Category: A
Score: Insufficient Compliance

Observation(s):
Observed in Proficiency Testing at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #(s) 51D1038342.

For i-Stat creatinine, the laboratory director on the CLIA certificate (PET/CT) did not sign the attestation statement documenting that proficiency testing samples were tested in the same manner as patient specimens for Event 3-2014.

Element(s) of Performance:

6. The laboratory performs external quality controls at the following frequencies:
   - As defined by the evaluation (either weekly or monthly)
   - According to the manufacturer’s recommendations
   - With each new lot number, shipment, or package of reagents

The external quality control results are documented.

Scoring Category: A
Score: Insufficient Compliance

Observation(s):
EP 6

Observed in Building Tour at WVU Heart Institute operated by WVU Hospitals, Inc. (600 Suncrest Towne Centre, Morgantown, WV) site for CLIA #(s) 51D2031072.

For i-Stat G-3+ cartridges Lot #N15105, the three levels of external quality control were not performed by the WVU Heart Institute CLIA# 51D2031072. The three levels of external quality control were performed by the cardiology department at the main hospital CLIA #51D0876698.

Observed in Individual Tracer at WVU Heart Institute operated by WVU Hospitals, Inc. (600 Suncrest Towne Centre, Morgantown, WV) site for CLIA #(s) 51D2031072.

The December 2014 external quality control for i-Stat G-3+ cartridges was not performed on the same lot number of cartridges. Level 1 was performed on Lot #N14170. Level 2 was performed on Lot #N141170. Level 3 was performed on Lot # N101170. The monthly external quality control was performed on two different lot number, not the same lot number.

Observed in Individual Tracer at WVU Heart Institute operated by WVU Hospitals, Inc. (600 Suncrest Towne Centre, Morgantown, WV) site for CLIA #(s) 51D2031072.

For i-Stat G-3+ cartridges Lot # L14327, the three levels of external quality control were not performed by the WVU Heart Institute CLIA# 51D2031072. The three levels of external quality control were performed by the cardiology department at the main hospital CLIA #51D0876698.

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Chapter: Quality System Assessment for Nonwaived Testing
Program: Laboratory Accreditation
Standard: QSA.02.14.01
Standard Text: The laboratory labels reagents and solutions completely and accurately.

Element(s) of Performance:

5. The laboratory does not use expired reagents or solutions. (See also QSA.02.13.01, EP 8)

Scoring Category : A
Score : Insufficient Compliance

Observation(s):

EP 5

Observed in Building Tour at WVU Heart Institute operated by WVU Hospitals, Inc. (600 Suncrest Towne Centre, Morgantown, WV) site for CLIA #(s) 51D2031072.

There were six i-Stat G-3+ cartridges Lot # L15052 in the refrigerator that were expired as of October 18, 2015. The expired cartridges were disposed of at the time of survey.
Element(s) of Performance:

3. Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (See also DC.02.03.01, EP 14)

Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance.

Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the patient's permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the patient's clinical record.

Scoring Category: A
Score: Insufficient Compliance

Observation(s):

EP 3

Observed in Tracer Activities at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #51D0236626.

The MRI patients had a calculated GFR test result in the patient's clinical record. The GFR test results were not accompanied by reference intervals (normal values) specific to the test method used and the population served. The creatinine values from the I-Stat (waived method) was used in the GFR calculation.
Opportunities for Improvement – Summary

Observations noted within the Opportunities for Improvement (OFI) section of the report represent single instances of non-compliance noted under a C category Element of Performance. Although these observations do not require official follow up through the Evidence of Standards Compliance (ESC) process, they are included to provide your organization with a robust analysis of all instances of non-compliance noted during survey.

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Opportunities for Improvement – Detail

Chapter: Document and Process Control
Program: Laboratory Accreditation
Standard: DC.01.02.01
Standard Text: The laboratory performs testing based on written laboratory test orders.

Element(s) of Performance:
11. Clinical standing orders, order sets, and protocols are dated, timed, authenticated, and included in the patient’s clinical record.

Scoring Category: C
Score: Satisfactory Compliance

Observation(s):

EP11
Observed in Individual Tracer at West Virginia University Hospitals, Inc. (One Medical Center Drive, Morgantown, WV) site for CLIA #s 51D0236626
The perfusion staff stated that activated clotting times were performed according to a protocol. The protocol was not included made part of the patient’s clinical record. At the time of survey, the baseline activated clotting time, the hemoglobin by Hemocue, and the glucose meter testing was authenticated by a provider. There were other activated clotting times performed and reported based on a protocol.