

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235176	(X3) Date Survey Completed 07/08/2019
Name of Provider or Supplier St Mary's Medical Center Himg Campus	Street Address, City, State 5170 U S Route 60 East, Huntington, WV	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review and interview with Testing Personnel 1 (TP1), the laboratory failed to verify accuracy 2 times a year for tests that are not included in Subpart I. Findings: 1. A review of PT records from 2018 and 2019 established that the laboratory had not performed commercial PT, or utilized other methods, to verify accuracy on the analyte Urine Protein twice a year. 2. An interview with TP1, on 07/08/19 at approximately 2:00 PM, confirmed that no testing of Urine Protein to establish and maintain accuracy had occurred.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) had not signed the attestation statements for numerous PT events. Findings: 1. A review of PT records revealed that the 2019 1st Testing events in Mycology, Hematology, and Chemistry Core had attestation statements signed by the testing personnel, but not signed by the</p>

LD. 2. An interview with TP1, on 7/8/19 at approximately 2:45 PM, confirmed that the attestation statements were not signed by the LD. 3. An interview with TP1, on 7/8/19 at approximately 2:47 PM, confirmed that there was no written delegation of the responsibility for signing the attestation statement from the LD.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on Proficiency Testing (PT) record review and interview with Testing Personnel 1 (TP1), the laboratory failed to verify the accuracy twice a year for tests that are not included in Subpart I. Findings: 1. A review of PT records from 2018 and 2019 established that the laboratory had not performed commercial PT, or utilized other methods, to verify accuracy on the analyte Urine Protein twice a year. 2. An interview with TP1, on 07/08/19 at approximately 2:00 PM, confirmed that no testing of Urine Protein to establish and maintain accuracy had occurred.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based upon a review of the laboratories written policies and procedures, the Quality Control (QC) logs, and an interview with Testing Personnel 1 (TP1), the actual testing procedure for the Quality Control (QC) of the Cepheid has been modified from the written QC procedure. Findings: 1. 1. The Individual Quality Control Plan (IQCP) for the Cepheid GeneXpert states that external controls (both positive and negative) are to be ran "with each new lot or shipment and every 30 days thereafter for the life of the lot/shipment." 2. A review of the Cepheid QC logs identified instances where the documentation of external controls exceeded thirty days for CT/NG, FLU, and MRSA testing. a. For CT/NG testing external controls were ran 2/27/18, 6/26/18, 8/4/18, 10/4/18, 2/21/19, and 4/19/19. All of the intervals between QC testing exceeded 30 days. b. For MRSA testing external controls were ran 2/21/19. c. For FLU testing external controls were ran 3/13/18 and 4/29/18 exceeding 30 days. External QC was not ran again until 1/23/19 greatly exceeding the 30 day interval. 3. An interview with TP1, on 7/8/19 at approximately 1200 noon, confirmed that external QC is "only performed on new lot/new shipment per the Cepheid sales representative." 4. No approval of the QC procedural change by the laboratory director could be located.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based upon review of Quality Control (QC) logs, written laboratory procedures and policies, and an interview with testing personnel the laboratory was not following the QC procedure for the Cepheid GeneXpert testing system. Findings: 1. The Individual Quality Control Plan (IQCP) for the Cepheid GeneXpert states that external controls (both positive and negative) are to be ran "with each new lot or shipment and every 30 days thereafter for the life of the lot/shipment." 2. A review of the Cepheid QC logs identified instances where the documentation of external controls exceeded thirty days for CT/NG, FLU, and MRSA testing. a. For CT/NG testing external controls were ran 2/27/18, 6/26/18, 8/4/18, 10/4/18, 2/21/19, and 4/19/19. All of the intervals between QC testing exceeded 30 days. b. For MRSA testing external controls were ran 2/21/19. c. For FLU testing external controls were ran 3/13/18 and 4/29/18 exceeding 30 days. External QC was not ran again until 1/23/19 greatly exceeding the 30 day interval. 3. An interview with TP1, on 7/8/19 at approximately 1200 noon, confirmed that external QC is "only performed on new lot/new shipment per the Cepheid sales representative."

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based upon a review of the written policies and procedures and an interview with Testing Personnel (TP1), no established system for identifying and maintaining corrected reports could be located. Findings: 1. No written policy or procedure regarding corrected reports could be located. 2. An interview with TP1, on 7/8/19 at approximately 3:30 PM, confirmed that there was no policy in place to identify and maintain corrected laboratory reports.