

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657854	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Public Health Lab City Of Philadelphia	Street Address, City, State 1930 South Broad Street, Philadelphia, PA	
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
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 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of Proficiency Testing (PT) records, Laboratory PT exception investigation forms, and interview with the Administrative Scientist and Biosafety Outreach Quality Officer at the time of survey, the laboratory failed to monitor and assess the American Proficiency Institute (API) 2017 (2nd event) and 2018 (1st event) Chemistry PT unsuccessful performances and correct the problems. Findings include: 1. The American Proficiency Institute (API) PT 2017 2nd event and 2018 1st event revealed the following unsuccessful performances: - 2017 Chemistry - Miscellaneous - 2nd event -- Luteinizing Hormone (LH)- 33% -- Testosterone - 0% - 2018 Chemistry - Miscellaneous - 1st event -- Luteinizing Hormone - 67% -- Testosterone - 67% 2. A review of the laboratory PT exception investigation forms revealed the following: - 2017 Chemistry 2nd event PT results with a LH unsatisfactory score of 33% and Testosterone 0% were received 12/17/17. The PT performance was not reviewed to correct the problem until 9/24/18, two days before the recertification inspection. The PT exception investigation forms reviewed at the time of survey did not indicate the action taken to correct this unsatisfactory PT performance. - 2018 chemistry 1st event PT results recorded another unsatisfactory performance for the same analytes, with a LH unsatisfactory score of 67% and Testosterone 67%. These results were received 5/31/18. The PT performance was not reviewed until 9/25/18, a day before the recertification survey. The PT exception investigation forms reviewed at the time of survey did not indicate the action taken to correct this unsatisfactory PT performance. 3. The forms were signed by the Quality</p>

Assurance Officer, Operations Director on 9/25/18 and Laboratory Director (Medical Director) on 9/26/18. 4. 400 patient specimens were tested for LH (2017 - 2018) 5. 200 patient specimens were tested for Testosterone (2017 - 2018) 6. The Administrative Scientist, Biosafety Outreach Quality Officer, Operations Director and laboratory Director confirmed the findings at the exit interview on 9/26/18 around 2: 20 pm.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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. (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 surveyor observation of the GTA lead solution, and interview with the Chemistry Supervisor and Administrative Scientist at the time of survey, the laboratory failed to have a procedure manual that includes the preparation of the GTA solution used for blood lead testing from 3/13/18 through the date of survey. Findings include: 1. The laboratory performs blood lead testing on the Perkin Elmer AS 800 analyzer. 2. A bottle labeled GTA lead solution prepared in house (9/12/18 and expiration date 3/12/19) was observed on the table at the time of survey. 3. The laboratory could not provide a procedure manual for the preparation of the GTA solution. 4. 1000 patient specimens were tested for blood Lead 2017 - 2018. 5. The Administrative Scientist, Biosafety Outreach Quality Officer, Operations Director and laboratory Director confirmed the findings about at the exit interview on 9/26/18 around 2:20 pm. Note: GTA - Graphic Tube Atomizer.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on Surveyor review of Bio-Rad Geenius HIV Supplemental Assay manufacturer's instructions for use, and interview with the Administrative Scientist and Laboratory Director at the time of inspection, the laboratory failed to define the criteria, monitor and document the temperature for the storage area of the Geenius HIV Supplemental Assay kit components or the testing area from 3/13/18 through the day of inspection. Findings includes: 1. The laboratory performs HIV confirmation testing using the Bio - Rad Geenius HIV . 2. The manufacturer's instructions reviewed at the time of inspection states: Test the Geenius HIV 1/2 Controls under the following circumstances: When opening a new test kit lot. Whenever a new shipment of test kits is received. If the temperature of the test storage area falls outside of 2 to 30C (36 to 86F) (Note that if this occurs, the Geenius HIV 1/2 Controls should be included in every test run that is performed using test kit lots that have been stored in that area). If the temperature of the testing area falls outside of 18 to 30C (64 to 86F). At periodic intervals as indicated by the user facility. All components of the Geenius HIV 1/2 Supplemental Assay are ready to use as supplied. The Geenius HIV 1/2 Supplemental Assay cassettes and Buffer should be stored at 2 to 30C. If the samples and / or kit components have been refrigerated, bring to room temperature (18 to 30 C) prior to testing. 3. The laboratory's IQCP (Individualized Quality Control Plan) developed for the Geenius HIV Supplemental assay was obtained from the laboratory director around 1:30 pm. A review of the Risk Assessment section revealed, #4 'How can we reduce the identified sources of error? Store at correct temperature; monitor temperature. Room temperature storage of reagent kits allows for a wide range of temperatures.' 4. The laboratory could not provide documentation of the temperature for the storage of the Bio - Rad Geenius HIV Supplemental Assay's Kit component and that of the testing area. 5. 200 patient specimens were tested on the Geenius HIV 1/2 Supplemental Assay in 2017 - 2018. 6. The Administrative Scientist, Laboratory Operations Director, Biosafety Outreach Quality Officer and Laboratory Director interviewed around 2 pm on 9/26/18 confirmed that the testing was performed at room temperature, but the temperature of the testing area was not monitored and documented. Note : HIV - Human Immunodeficiency Virus (HIV)

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
 Based on observation of the Hematology and Urinalysis laboratory, review of reagents in the laboratories and interview with the Technical Supervisor (TS) #1 the laboratory failed to set expiration dates on 4 of 4 bottles of mineral oil and 1 of 1 bottle of immersion from 2017 to the date of survey. Findings Include: 1. The Administrative Policy and Procedure Manual. Reagents and Solutions Labeling Policy States: II. Procedures - A. All containers must be dated and inventoried upon arrive and dated again when first opened. - C. Expiration guidelines. -- 4. If no expiration date is indicated by the manufacturer a reagent or solution, the section supervisor should

evaluate and set an expiration date. One year is usually recommended for reagents that are relatively stable, such as water, saline, etc. 2. On the day of survey, 09/26/2018, while on tour of the Hematology and Urinalysis laboratory, it was observed that the reagents listed below were not labeled with expiration dates: - 1 of 1 bottle of Cargille Non-dry Immersion Oil. Lot #092892, Received: 08/17/2017. - 4 of 4, 4 Liter bottles of Fisher Chemical Mineral Oil, Lot #161545. 3. TS #1 confirmed the findings above on 09/26/2018 around 11:30 am.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Surveyor review of Proficiency Testing (PT) records, Laboratory PT exception investigation forms, and interview with the Administrative Scientist, Biosafety Outreach Quality Officer at the time of survey, the laboratory director failed to ensure that an approved corrective action was followed for the unsuccessful American Proficiency Testing (API) Chemistry 2017 (2nd event) and 2018 1st event PT performances. Findings: 1. The American Proficiency Institute (API) PT 2017 2nd event and 2018 1st event revealed the following unsuccessful performances: - 2017 Chemistry - Miscellaneous - 2nd event -- Luteinizing Hormone (LH)- 33% -- Testosterone - 0% - 2018 Chemistry - Miscellaneous - 1st event -- Luteinizing Hormone - 67% -- Testosterone - 67% 2. A review of the laboratory PT exception investigation forms revealed the following: - 2017 Chemistry 2nd event PT results with a LH unsatisfactory score of 33% and Testosterone 0% were received 12/17/17. The PT performance was not reviewed to correct the problem until 9/24/18, two days before the recertification inspection. The PT exception investigation forms signed by the laboratory director 9/26/18, reviewed at the time of survey did not indicate the action taken to correct this unsatisfactory PT performance. - 2018 chemistry 1st event PT results recorded another unsatisfactory performance for the same analytes, with a LH unsatisfactory score of 67% and Testosterone 67%. These results were received 5/31/18. The PT performance was not reviewed till 9/25/18, a day before the recertification survey. The PT exception investigation forms signed by the laboratory director 9/26/18, reviewed at the time of survey did not indicate the action taken to correct this unsatisfactory PT performance. 3. The forms were signed by the Quality Assurance Officer, Operations Director on 9/25/18. 4. 400 patient specimens were tested for LH (2017 - 2018) 5. 200 patient specimens were tested for Testosterone (2017 - 2018) 6. The Administrative Scientist, Biosafety Outreach Quality Officer, Operations Director and laboratory Director confirmed the findings about at the exit interview on 9/26/18 around 2:20 pm.

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 Testing Personnel (TP) competency assessment records and interview with the Biosafety Outreach Quality Officer, the Technical Supervisor failed to evaluate and document the performance of 2 of 13 TP at least semi-annually during the first year. Findings include: 1. At the time of survey, 09/26/2018, the laboratory was unable to produce competency assessment records for TP #8 and #11. 2. TP #08 joined the practice 02/07/2018 but no 6 month competency assessment was performed by 08/07/2018. 3. TP #11 joined the practice 03/12/2018 but no 6 month competency assessment was performed by 09/12/2018. 4. The Biosafety Outreach Quality Officer confirmed the finding above on 09/26/2018 around 01:00 pm.