

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2138383	(X3) Date Survey Completed 01/31/2020
Name of Provider or Supplier Lab Rx Llc	Street Address, City, State 92 Thomas Johnson Dr, Suite 250, Frederick, MD	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation in the toxicology laboratory and interview with the testing personnel, the laboratory did not have the required eyewash solution in the area where the testing occurred. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The area where the testing personnel prepare solutions and perform toxicology testing was toured during the survey. Observation of the testing area showed that there was an eyewash station secured to the wall but there was no eyewash solution containers in the wall station to aid in flushing out the eyes of the testing personnel if they were to have been splashed with any chemicals used in preparing the stock solution, calibrators and quality control materials. 3. During the survey on 01/15/2020 at 1:30 PM the testing personnel confirmed that the eyewash station did not contain the required eyewash solution in the area where the testing was being performed.</p>
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical supervisor (TS), the laboratory did not retain a copy of the original test report for 2 years. Findings: 1. The TS was asked to retrieve original test reports from after the previous survey conducted on 08/01/2018. 2. According to the TS the new laboratory information system (LIS) was installed in January through February 2019. All the patient test results prior to January 2019 were archived on the old LIS and are not accessible at this time. 3. During the exit survey on 01/31/2020 at 12:30 PM the TS confirmed that laboratory records did not include the documentation of the original test results prior to January 2019.

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:

I. Based on review of the procedure manual and interview with the technical supervisor (TS), the laboratory's standard operating procedure manual (SOPM) did not reflect the activities that the testing personnel were actually performing. Findings: 1. The SOPM states that a 54 well plate is used when pipetting the urine samples to be tested on the toxicology analyzer. According to the technical supervisor the laboratory switched to a 96 well plate on 10/29/2019. 2. During the survey on 01/15/2020 at 1:30 PM the TS confirmed that the policy and procedure manual had not been updated to reflect the current practice. II. Based on review of the procedure manual and interview with the TS, the laboratory's SOPM did not have written instructions for corrective actions to be taken when calibration or control results failed to meet the laboratory's criteria for acceptability for the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The laboratory records show that the LC/MS/MS analyzer was not being used for patient testing on 02/15/2019 through 02/28/2019 and the patients from 02/14/2019 were not reported until 03/01/2019. 2. The laboratory records did not explain why the analyzer was not being used from 02/14/2019 through 02/28/2019, why the patients tested on 02/14/2019 were not reported until 03/01/2019, and why the patients from 02/14/2019 were not repeated

prior to releasing the test results. 3. Review of the SOPM showed that there were no policies and procedures for actions to be taken when the LC/MS/MS analyzer failed to meet the laboratory's criteria for acceptability, what needed to be done to correct the problem, and how to document the corrective actions taken prior to reporting patient test results. 4. During the exit survey on 01/31/2020 at 12:30 PM the current TS confirmed that the laboratory records failed to explain the problems encountered and the delay in reporting patient test results.

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 containers that held the stock solution, calibrators and quality control (QC) materials and interview with the testing personnel, the laboratory did not label the containers with the identity, concentration, preparation and expiration dates for testing on the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The stock solution, calibrators (10 containers), QC materials (4 containers) are stored in an ultra low freezer. The testing person retrieved the solutions from the freezer during the survey for review. 2. The labels only listed the name of the solution, e.g., "Stock Soln", "Calib 1" and "QC 1." The testing personnel confirmed that the stock solution container was labeled with the name and the preparation date. All the other containers were not labeled with the strength or concentration, preparation and expiration dates for testing on the LC/MS/MS analyzer. 3. During the survey on 01/15/2020 at 1:30 PM the testing personnel confirmed that the containers used for performing toxicology testing on the LC/MS/MS analyzer were not labeled as required.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of the laboratory record from 2018 and 2019 and interview with the technical supervisor, the laboratory failed to ensure that chemicals and analytical reference standards purchased for preparing stock solutions, calibrators and quality control (QC) materials used in the laboratory were not used after their expiration date. Findings: 1. Review of the laboratory's records showed that there was no documentation showing the lot numbers and expiration dates of the chemicals and analytical reference standards used in the preparation of the stock solutions, calibrators and QC materials. 2. Review of the laboratory's records system showed that there was no documentation showing when the laboratory validated and switched to a new batch of stock solutions, calibrators and QC materials. 3. The records failed

to show that the stock solutions, calibrators and QC materials were not used past their expiration dates. 4. During the exit survey on 01/31/2020 at 12:30 PM the technical supervisor confirmed that the laboratory records that were available did not show lot numbers and expiration dates and when the laboratory switched to a new batch of stock solutions, calibrators and QC materials.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory director failed to ensure that the verification of the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer included accurate and reliable documentation after the analyzer was not functioning during the month of February 2019 (D6086); failed to ensure that the PT final summary reports were reviewed in a timely manner (D6091); failed to ensure that the quality control (QC) program identified and documented failures in QC results prior to reporting patient test results (D6093); failed to ensure that the laboratory had an approved quality assurance (QA) plan, and failed to ensure that the policies for monitoring the laboratory staff included the TS (D6094); and failed to ensure that the annual maintenance was performed in 2019 (D6095).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on review of the computer verification records and interview with the current technical supervisor (TS), the laboratory director failed to ensure that the verification of the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer included accurate and reliable documentation after the analyzer was not functioning during the month of February 2019. Findings: 1. The laboratory records show that the LC/MS/MS analyzer was not functioning properly from 02/15/2019 through 02/28/2019 and patient test results were not reported. Records do not clearly identify when maintenance was performed but the patients and proficiency testing samples were saved until the analyzer verification procedures were performed on 03/05/2019. 2. The current TS explained that the verification records in the computer showed that the previous TS tested the "Old" and "New" stock solutions along with the calibrators and quality control materials. 3. The computer records did not include documentation of the preparation and expiration dates of the solutions used during the verification of the LC/MS/MS after the maintenance was performed. 4. The current TS could not provide a written policy for the modified verification that had been performed after the maintenance. 5. There were no records in the computer or written documentation stating that the verification had been successfully completed and that the LC/MS/MS was capable of providing accurate and reliable patient test results. 6. During the

survey on 01/15/2020 at 1:30 PM the current TS confirmed that the documentation for the verification did not include preparation and expiration dates of the solutions used during the verification and there was no documentation stating that the LC/MS/MS had successfully been re-verified.

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 the written duties and responsibilities, proficiency testing (PT) records and interview with the current technical supervisor (TS), the laboratory director (LD) failed to ensure that the PT final summary reports were reviewed in a timely manner. Findings: 1. Review of the duties and responsibilities of the laboratory personnel showed that the TS was only responsible for ensuring that all PT specimens were tested as per protocol and results mailed in a timely manner. The duties and responsibilities that were reviewed failed to state who was responsible for evaluating the PT results and taking corrective actions when there were failures. 2. The PT records for 2018 and 2019 were reviewed. The first PT event in 2018- DMPM-A was received 04/13/2018 and reviewed on 07/16/2018 by the LD and the second event in 2018- DMPM-B was received 10/04/2018 and reviewed by the LD on 01/13/2020. The first PT in 2019- DMPM-A was received 02/13/2019 and reviewed by the LD on 01/13/2020 and the second event in 2019- DMPM-B was received 10/06/2019 and reviewed by the LD on 01/13/2020. 3. During the survey on 01/15/2020 at 1:30 PM the current TS confirmed that the PT events were not being reviewed by the LD in a timely manner.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interview with the current technical supervisor (TS), the laboratory director failed to ensure that the quality control (QC) program identified and documented failures in QC results prior to reporting patient test results. Findings: 1. The laboratory records show that the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer tested patient samples on 02/14/2019. Email and laboratory records show that the LC/MS/MS was not being used for patient testing on 02/15/2019 through 02/28/2019 and the patients from 02/14/2019 were not reported until 03/01/2019. 2. The laboratory records did not explain why the analyzer was not being used from 02/14/2019 through 02/28/2019, why the patients tested on 02/14/2019 were not reported until 03/01/2019, and why the patients from 02/14/2019 were not repeated prior to releasing the test results. 3. During the exit survey on 01/31/2020 at 12:30 PM the current TS confirmed that the laboratory records failed to explain the problems encountered and the delay in reporting patient test results.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

I. Based on review of the standard operating procedure manual (SOPM) and interview with the current technical supervisor (TS), the laboratory director (LD) failed to ensure that the laboratory had an approved quality assurance (QA) plan. Findings: 1. The SOPM did not have an approved QA plan for the assessment of the daily, weekly and monthly records generated by the laboratory to ensure the accuracy and reliability of the patient testing. 2. The current TS documented monthly evaluations and stated that the documentation was emailed to the LD on a monthly basis. The monthly evaluations for May through December 2019 were electronically evaluated by the LD on the day of the survey, 01/15/2020, and printed by the current TS for review by the surveyor. 3. There were no monthly QA evaluations documented since the previous survey conducted on 08/01/2018 until May of 2019. 4. During the survey on 01/15/2020 at 1:30 PM the current TS confirmed that the SOPM did not have any written QA policies and procedures for the laboratory staff to follow. II. Based on record review and interview with the current TS, the laboratory director failed to ensure that the policies for monitoring the laboratory staff included the TS. Findings: 1. The laboratory's training and evaluation records were reviewed for 2018 and 2019. The documentation showed that the previous TS had an evaluation in March 2018 and did not have an evaluation in March 2019. The previous TS left the laboratory at the end of April 2019. 2. The current TS started in the laboratory in April 2019. At the time of the survey there was no documentation showing that an evaluation had been performed on the current TS. 3. During the survey on 01/15/2020 at 1:30 PM the current TS confirmed that the laboratory records did not include documentation of an evaluation of the previous TS and the current TS and the laboratory policy and procedure manual did not include a protocol for the evaluation of the TS on an annual basis. III. Based on review of the "Director Visitation Log" binder and interview current TS, the laboratory director failed to the laboratory was visited each month and document the findings in the "Director Visitation Log." Findings: 1. The laboratory's records included a binder with worksheets titled "Director Visitation Log." The log included monthly evaluations and comments from August 2018 through November 16, 2018. 2. The current TS started in the laboratory in April 2019 and was not aware of the required monthly visits on the "Director Visitation Log" until the binder was found on the shelf. 3. During the exit survey on 01/31/2020 at 12:30 PM the TS confirmed that the laboratory records did not include documentation of monthly visitation by the laboratory director in the "Director Visitation Log."

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on review of the "Annual thermometer, Hygrometer, Timer and Eyewash

Pressure worksheet" and interview with the current TS, the laboratory director failed to ensure that the annual maintenance was performed in 2019. Findings: 1. Review of the "Annual thermometer, Hygrometer, Timer and Eyewash Pressure worksheet" showed that the last time these annual checks were performed was on 07/31/2018. 2. During the survey on 01/15/2020 at 1:30 PM the TS confirmed that the annual checks had not been performed and documented in 2019.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on review of the computer verification records and interview with the current technical supervisor (TS), the previous TS did not ensure that the verification of the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer included accurate and reliable documentation. Findings: 1. The laboratory records show that the LC/MS/MS analyzer was not functioning properly from 02/15/2019 through 02/28/2019 and patient test results were not reported. Records do not clearly identify when maintenance was performed but the patients and proficiency testing samples were saved until the analyzer verification procedures were performed on 03/05/2019. 2. The current TS explained that the verification records in the computer showed that the previous TS tested the "Old" and "New" stock solutions along with the calibrators and quality control materials. 3. The computer records did not include documentation of the preparation and expiration dates of the solutions used during the verification of the LC/MS/MS after the maintenance was performed. 4. The current TS could not provide a written policy for the modified verification that had been performed after the maintenance. 5. There were no records in the computer or written documentation stating that the verification had been successfully completed and that the LC/MS/MS was capable of providing accurate and reliable patient test results. 6. During the survey on 01/15/2020 at 1:30 PM the current TS confirmed that the documentation for the verification did not include preparation and expiration dates of the solutions used during the verification and there was no documentation stating that the LC/MS had successfully been re-verified.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the worksheet for stock solution preparation and interview with the testing person, the testing person did not follow the laboratory's procedures for documenting the preparation of the new stock solution on 07/04/2019. Findings: 1. According to the worksheet for stock solution preparation the testing person is required to document the date of preparation of the stock solution along with the preparation of the other solutions. 2. When interviewed the testing person confirmed

that a worksheet for stock preparation was not used to document the preparation of the stock solution prepared on 07/04/2019. 3. During the survey on 01/15/2020 at 1:30 PM the testing person confirmed that the worksheet for stock solution preparation had not been used for documenting the preparation of the new stock solution on 07/04/2019.