

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2105179	(X3) Date Survey Completed 03/29/2021
Name of Provider or Supplier Specialty Laboratories	Street Address, City, State 13530 Michigan Ave Suite L11, Dearborn, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to follow a written policy to assess testing personnel and consultant competency for 2 (March 2019 to March 2021) of 2 years reviewed. Findings include: 1. A record review of the laboratory's policies and procedures revealed a policy stating, "Training verification must be documented for all lab staff. Examples would be performing proficiency testing. All training for each employee will be indicated in the "Employee's Competency and Proficiency Evaluations Manual" and the employee's department file." 2. A record review of personnel records revealed the following personnel listed on the CMS-209 did not have documented competency assessments: a. Clinical Consultant also performing the duties of the Technical Supervisor and Technical Consultant b. Testing Personnel #3 performing high complexity toxicology testing 3. An interview on 3/29/21 at 12:30 pm with the GS confirmed the two personnel listed above did not have documented competency assessments. **This is a repeated deficiency from the 12/20/16 recertification survey**</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. A. Based on observation, record review, and interview with the Testing Personnel #3, the laboratory failed to label reagents with the expiration dates for 4 of 4 toxicology reagent bottles in use. Findings include: 1. The surveyor observed four bottles attached to the AB Sciex Triple Quad 4500 MD toxicology analyzer with a lack of expiration dates indicated on the containers on 3/29/21 at 9:22 am. 2. A review of the laboratory's "Reagent Storage and Handling Procedure" revealed a section stating, "Laboratory generated solutions and secondary containers require the same information on them. Anything generated in the laboratory must have the full chemical name, the hazard, the date processed, and expiration date suggested by manufacturer or other literature sources." 3. An interview on 3/29/21 at 9:22 am with Testing Personnel #3 confirmed the laboratory did not have the expiration date on the toxicology reagent containers. B. Based on observation, record review, and interview with the General Supervisor (GS), the laboratory failed to label hematology stain coplin jars with the identity of the contents and expiration dates for the current containers in use. Findings include: 1. The surveyor observed three unlabeled coplin jars with purple contents during a tour of the laboratory on 3/29/21 at 9:22 am. 2. A review of the laboratory's "Reagent Storage and Handling Procedure" revealed a section stating, "Laboratory generated solutions and secondary containers require the same information on them. Anything generated in the laboratory must have the full chemical name, the hazard, the date processed, and expiration date suggested by manufacturer or other literature sources." 3. An interview on 3/29/21 at 11:55 am with the GS confirmed the coplin jars were used in staining for hematology manual differentials and were not labeled with the identity of the contents and expiration dates. **This is a repeated deficiency from the 8/20/18 recertification survey**

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 observation, record review, and interview with the General Supervisor (GS), the laboratory failed to ensure stain for hematology manual differential counts did not exceed the expiration date for the current stain in use. Findings include: 1. The surveyor observed a bottle of QuickLink I Wright-Giemsa stain next to the hematology slide staining station with the expiration date of 11/29/2020 during a tour of the laboratory on 3/29/21 at 9:22 am. 2. A review of the laboratory's "General Quality Control" procedure revealed a section titled "Labels" stating, "All reagents, probes, antibodies are used within their indicated expiration dates. Outdated reagents are discarded." 4. A review of manual differential test records revealed the following dates when expired stain was used: a. 12/15/20 b. 1/18/21 c. 2/15/21 d. 3/16/21 3. An interview on 3/29/21 at 11:55 am with the GS confirmed the laboratory used the bottle of stain beyond its expiration date.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with the General Supervisor, the laboratory failed to ensure microscope annual maintenance was performed for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's maintenance records revealed an invoice for annual maintenance performed on the microscope on 12/23/19 and the next service was due 1/22/21. There was a lack of documentation for microscope service performed after 12/23/19. 2. A review of the laboratory's "General Quality Control" procedure revealed a section stating, "Microscopes are inspected and cleaned annually by qualified service representative. Documentation is kept in the "Instrument Maintenance Logbook." 3. An interview on 3/29/21 at 12:12 pm with the GS confirmed the laboratory did not have microscope maintenance performed. B. Based on record review and interview with the General Supervisor, the laboratory failed to ensure pipettes used in toxicology testing were calibrated for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's maintenance records revealed an invoice for annual calibration and repair for the seven pipettes used in toxicology testing dated 9/26/19. There was a lack of documentation for pipette calibration and repair performed after 9/26/19. 2. A review of the laboratory's "Pipette Calibration" procedure stating, "After initial verification, pipettes that are designed to deliver a preset volume and/or adjustable volumes must be calibrated annually, when they become contaminated, after major maintenance, and/or when proper operation is in question." 3. An interview on 3/29/21 at 12:12 pm with the GS confirmed the laboratory did not have pipette calibration and repair performed.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor (GS), the Laboratory Director failed to ensure corrective action was performed for 3 (2020 2nd and 3rd events and 2020 toxicology 2nd event) of 11 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed the following unacceptable proficiency testing results without documentation of corrective action: a. American Proficiency Institute (API) 2020 2nd Event Hematology/Coagulation i. Prothrombin Time (PT): 80% ii. Activated Partial Thromboplastin Time (APTT): 80% iii. Mean Corpuscular Hemoglobin Concentration (MCHC): 80% b. API 2020 Event 3 Hematology/Coagulation 2020 3rd Event Hematology/Coagulation i. APTT: 80% c. College of American Pathologists' (CAP) 2020 2nd Event Drug Monitoring for Pain Management i.

Methylenedioxyamphetamine (MDA): Unacceptable 2. A review of the laboratory's "Policy for Laboratory Director Responsibilities" revealed a section stating, "It is the policy of APG medical Laboratory that the responsibility of signing off discipline specific documentation is delegated by the Medical Laboratory Director to Lab manger and charge medical scientists as deemed appropriate...Review proficiency test reports and approve remedial action: Director/ Lab Manager." 3. The surveyor confirmed the proficiency testing events listed above did not have corrective action documented with the GS during the exit conference on 3/29/21 at 2:29 pm.