

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2033427	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Ms Diagnostic Laboratory	Street Address, City, State 128 W Olive Ave, Monrovia, CA	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, lack of quality assessment records from 2021 and 2022, and interview with the laboratory technical supervisor on April 18, 2023, at 11:20 am, the laboratory failed to have records of review of the effectiveness of corrective actions taken to resolve problems in the general laboratory systems. The findings include: 1. The laboratory had established the general laboratory systems quality assessment program by creating a QA screen - yearly log sheet which include various problem indicators throughout the laboratory operations. However, the laboratory did not use the log sheet in 2021 and 2022 and was not evaluating and monitoring the effectiveness of corrective actions taken for continuous improvement in preventing the recurrence. Moreover, the laboratory's information system had lots of pending samples and thus it was difficult to assess its turn-around times. The problem correction process involves investigation, identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken has prevented recurrence of the original problem. The laboratory did not have documentation of monitoring and its efforts to reduce the recurrence of the problems. Therefore, the patient may have harmed by the repeat of the same type of problems in the laboratory's operation. 2. The laboratory technical</p>

supervisor on April 18, 2023, at 11:20 am, affirmed that the laboratory did not monitor the effectiveness of the corrective actions taken in the recurrence of the problems by keeping the yearly screen log sheet records. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/6/2023, stated that the laboratory performed approximately 2,78,047 tests, annually.

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:

Based on Surveyor review of laboratory's policy and procedure, quality assessment records and interview with the laboratory technical supervisor on April 18, 2023, at 11:20 am, the laboratory director failed to ensure that the laboratory maintained quality assessment programs. The findings include: See D5293.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's personnel records and interview with the laboratory technical supervisor on April 18, 2023, at 11:00 am, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. The findings include: The laboratory did not have any records showing that the director had assigned the duties and responsibilities to each laboratory personnel engaged in the process. The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.