

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0557525	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Omid S Shaye Md	Street Address, City, State 7320 Woodlake Ave Ste 330, West Hills, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on February 15, 2023, at 11:45 am, the laboratory failed to successfully participate in the proficiency testing program for the WBC differential test. The findings include: 1. The laboratory participated in the AAB PT testing program for the specialty of hematology in the year 2022. However, it received an unsatisfactory score of 47% at the Q2 and Q3 events for WBC differential test, resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical consultant on February 15, 2023, at 11:45 am,</p>

	<p>affirmed that the laboratory did not receive a satisfactory score for the WBC differential test at the Q2 and Q3 events of PT in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/27/2022, stated that the laboratory performs approximately 8,802 tests, annually.</p>
<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on February 15, 2023, at 11:55 am, the laboratory failed to attain a score of at least 80 percent of acceptable responses for the bicarbonate analyte at Q3 testing event in 2022. The findings include: 1. The laboratory participated in AAB PT testing program for the specialty of chemistry in the year 2022. It received a score of 0% at the Q3 event for the analyte bicarbonate. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured and may have harmed patient. 2. The laboratory technical consultant on February 15, 2023, at 11:55 am, affirmed that the laboratory received 0% score for the analyte bicarbonate at the Q3 PT event in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/27/2022, stated that the laboratory performs approximately 7,476 bicarbonate tests, annually.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on February 15, 2023, at 11:45 am, the laboratory failed to achieve satisfactory performance for the WBC differential test in two consecutive testing events. The findings include: 1. The laboratory participated in AAB PT testing program for the specialty of hematology in the year 2022. However, it received an unsatisfactory score of 47% at the Q2 and Q3 events for WBC differential test that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two consecutive events resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical consultant on February 15, 2023, at 11:45 am, affirmed that the laboratory did not receive a satisfactory score for the WBC differential test at the Q2 and Q3 events of PT in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/27/2022, stated that the laboratory performs approximately 8,802 tests, annually.</p>
<p>D5779</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p>

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's CBC test records, and interview with the laboratory technical consultant and testing person on February 15, 2023, at 12:35 pm, the laboratory failed to follow corrective action procedures when patients' CBC results flagged by the instrument. The findings include: 1. The laboratory performed CBC test using Micros-60 instrument. The instrument flags the test results if the sample has problems which makes the results unreliable. Corrective actions must be taken for an accurate result. The laboratory did not have any records showing that it had taken any corrective actions for flagged samples. The laboratory did not save instrument test records with flags and affected sample can not be identified. The testing person #1 was unaware of the flag when interviewed. Therefore, the accuracy of the patients' CBC test results rendered by the laboratory during that time cannot be assured and might have harmed patients. 2. The laboratory technical consultant on February 15, 2023, at 12:35 pm, affirmed that the laboratory did not document any corrective action for flagged CBC test results. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/27/2022, stated that the laboratory performs approximately 8,802 tests, annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on Surveyor review of laboratory 's proficiency testing (PT) and patient sample testing records, and interview with the laboratory technical consultant and testing person during an onsite survey of the laboratory on February 15, 2023, at 12:35 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing moderate complexity testing; laboratory director was not met. The laboratory director 's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. (See D6004) 2. The laboratory director failed to ensure the maintenance of an acceptable levels of analytical performance for CBC and bicarbonate tests. (See D6023) 3. The laboratory director failed to ensure that all necessary remedial actions are taken and documented. (See D6024)

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory technical consultant on February 15, 2023, at 11:45 am, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harm patients. The findings include: See D2087, D2130 and D5779.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) 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 Surveyor review of laboratory's proficiency testing (PT) results from AAB, and interview with the laboratory technical consultant on February 15, 2023, at 11:45 am, the laboratory failed to achieve satisfactory performance for the WBC differential test in two consecutive testing events and attain a score of at least 80 percent of acceptable responses for the bicarbonate analyte at Q3 testing event in 2022. The findings include: See D2087 and D2130.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's CBC test records, and interview with the laboratory technical consultant and testing person on February 15, 2023, at 12:35 pm, the laboratory failed to follow the corrective action procedure and document when patients' CBC results flagged by the instrument. The findings include: See D5779.