

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2044073	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Sc Medical Inc	Street Address, City, State 19042 Soledad Canyon Rd, Santa Clarita, 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
D2121	<p>HEMATOLOGY CFR(s): 493.851(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) evaluation from American Proficiency Institute (API), PT sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit at the 2nd event of 2021. The findings include: 1. The laboratory performed complete blood count (CBC) using an automated CDS Medonic instrument. To verify its test accuracy, the laboratory participated in API PT testing for the year of 2021. However, it received a score of 20% at the 2nd event for the following analytes: Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit, resulting in an unsatisfactory analyte performance for the event. Therefore, the failure in the PT event suggesting that the patients' results reported during the PT event period might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on November 3, 2021 at 12:48 pm, affirmed that the laboratory had received a score of 20% at the 2nd event for the following analytes: Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/01 /2021, stated that the laboratory performs 2,700 CBC tests, annually.</p>
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training</p>

and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) evaluation from American Proficiency Institute (API), PT sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48 pm, the laboratory failed to take any remedial action and re-train its testing person #1 after receiving an unsatisfactory score of 20 percent for Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit at the 2nd event of 2021. The findings include: 1. The laboratory performed complete blood count (CBC) test for PT samples using an automated CDS Medonic instrument. The laboratory investigated the PT failure, however, was not able to find out the reason. Instrument print out, ran on 7/24/2021, showed "AL" flag next to the RBC and HGB results for the PT samples HSY-06, HSY-07 and HSY-09. The laboratory's procedure instructs to dilute the sample and rerun, but the testing person #1 failed to do so. That could be the reason of the PT failure. However, laboratory's failure to find out the problem resulted lack of any remedial action or re-training the testing person involved. Therefore, the testing person #1's failure to follow the laboratory procedure suggesting that the patients' results reported by the testing person #1 might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on November 3, 2021 at 12:48 pm, affirmed that the laboratory testing person #1 did not follow the laboratory's procedure to run PT samples and the lab did not take any remedial action due to the failure to identify the problem. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/01/2021, stated that the laboratory performs 2,700 CBC tests, annually.

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 reappoints 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) evaluation from American Proficiency Institute (API), PT sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48 pm, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2121 and D2128.

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 laboratory's proficiency testing (PT) evaluation from American Proficiency Institute (API), PT sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48 pm, the laboratory failed to take any remedial action and re-train its testing person #1 after receiving an unsatisfactory score of 20 percent for Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit at the 2nd event of 2021. The findings include: The laboratory did not follow an approved corrective action plan to take any remedial action after receiving unacceptable Proficiency testing evaluations from API for Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit at the 2nd event of 2021. See D2128.

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) evaluation from American Proficiency Institute (API), PT sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Leukocyte count, Erythrocyte count, Hemoglobin and Hematocrit at the 2nd event of 2021 and received an unsatisfactory analyte performance evaluation for the testing event. The findings include: See D2121.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate 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 Surveyor review of laboratory's proficiency testing (PT) sample test records and interview with the laboratory technical consultant on November 3, 2021 at 12:48

pm, the laboratory testing person #1 failed to follow the laboratory's procedure for RBC and HGB tests analyses which might have caused PT failure at the 2nd event of 2021. The findings include: 1. The laboratory performed complete blood count (CBC) test for PT samples using an automated CDS Medonic instrument. Instrument print out showed "AL" flag next to the RBC and HGB results for the PT samples HSY-06, HSY-07 and HSY-09. The laboratory's procedure instructs to dilute the sample and rerun, however, the testing person #1 failed to do so. Therefore, the testing person #1's failure to follow the laboratory procedure suggesting that the patients' results reported by the testing person #1 might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on November 3, 2021 at 12:48 pm, affirmed that the laboratory testing person #1 did not follow the laboratory's procedure to run PT samples. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/01/2021, stated that the laboratory performs 2,700 CBC tests, annually.