

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2224791	<b>(X3) Date Survey Completed</b>  02/27/2023
<b>Name of Provider or Supplier</b>  Sc Medical Inc	<b>Street Address, City, State</b>  27550 Newhall Ranch Rd Unit 203, Valencia, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) and corrective actions records, and interview with the laboratory testing person on February 27, 2023, at 2:00 pm, the laboratory failed to retain QC records. The findings include: 1. The laboratory performed QC run on January 19, 2022, on the Medonic CBC instrument. The low-level QC failed and was out of range, so it repeated the run which was acceptable. However, the laboratory did not save the failed QC results. Without any record it cannot be determined how many times QC was run and failed, and if the reported patients' results were accurate. Therefore, the accuracy of the patients' test results cannot be assured and may have harmed patient. 2. The laboratory testing person on February 27, 2023, at 2:00 pm, affirmed that the laboratory did not save the failed QC records. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/20/2023, stated that the laboratory performs approximately 2,700 CBC tests, annually.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's corrective actions records for the quality control (QC) material, and interview with the laboratory testing person on February 27, 2023, at 2:00 pm, the laboratory failed to document corrective action taken when the QC run was out of range. The findings include: 1. The laboratory performed QC run on January 19, 2022, on the Medonic CBC instrument. The low-level QC failed and was out of range, so it repeated the run which was acceptable. However, the laboratory did not save the failed QC results together with any corrective actions taken. If the QC failure affected the patients' results can not be determined. Therefore, the accuracy of the patients' CBC test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory testing person on February 27, 2023, at 2:00 pm, affirmed that the laboratory did not document any corrective actions taken after QC was out of range. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/20/2023, stated that the laboratory performs approximately 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 quality control (QC) and corrective actions records, and interview with the laboratory testing person on February 27, 2023, at 2:00 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3031, D5781 and D6024.

**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 quality control (QC) and corrective actions records, and interview with the laboratory testing person on February 27, 2023, at 2:00 pm, the laboratory failed to document any corrective actions taken when QC failed. The findings include: See D5781.