

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0546234	<b>(X3) Date Survey Completed</b> 11/03/2020
<b>Name of Provider or Supplier</b> Scrc Medical Group Pc	<b>Street Address, City, State</b> 450 N Roxbury Dr Ste 101, Beverly Hills, 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 policy &amp; procedure, random patient and quality control (QC) testing records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant (TC) on November 3, 2020 at 12:30 pm, the laboratory failed to retain patient testing records for 1 sample out of 8 samples, reviewed. The findings include: 1. The laboratory received and reported a patient sample however, it failed to retain patient's testing records. Therefore, it can not be assured that the laboratory had tested the sample. a. The laboratory had received an order for CBC on 12/05/2018 via its EMR system (# 59638) and reported the testing results in the EMR. b. The laboratory has an automated CBC analyzer, ACT Diff2 which was not interphased with the laboratory's LIS system, LabDaq. Moreover, the analyzer saves only limited numbers of past testing records, and did not have above patient testing records saved. c. The laboratory did not have any printout from the CBC analyzer for the above patient testing. 2. The laboratory TC on November 3, 2020 at 12:30 pm, affirmed that the laboratory did not have the above patient testing records. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/01/2020, stated that the laboratory performs 2,500 CBC tests, annually.</p>
<b>D6004</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 reappropriates 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 policy & procedure, random patient, QC and PT testing records for the years of 2018, 2019 and 2020, and interview with the laboratory technical consultant (TC) on November 3, 2020 at 12:30 pm, it was determined that the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D3031.