

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1089837	(X3) Date Survey Completed 10/21/2020
Name of Provider or Supplier Savannah River Dermatology Llc	Street Address, City, State 575 Furrys Ferry Road, Martinez, GA	
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
D0000	Based on an initial CLIA certification survey performed on October 21, 2020, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all TP receive the appropriate training for the type and complexity of the services offered as required. Findings include: 1. TP document review revealed the lack of initial training documentation available at the time of survey for the following TP: Staff #1; Staff #3 - Staff #6 (CMS 209) for 2019. 2. An interview with Staff #2 (CMS 209) in the office manager's office on 10/21/2020 at approximately 5:00 p.m. confirmed the aforementioned lack of initial TP competencies.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the</p>

performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical supervisor (TS) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least semiannually during the first year the TP tests patient specimens as required. Findings include: 1. TP document review revealed the lack of semiannual competency documentation available at the time of survey for the following TP: Staff #1; Staff #3 - Staff #6 (CMS 209) for 2020. 2. An interview with Staff #2 (CMS 209) in the office manager's office on 10/21/2020 at approximately 5:00 p.m. confirmed the aforementioned lack of semiannual TP competencies.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical supervisor (TS) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least annually after the first year the TP tests patient specimens as required. Findings include: 1. TP document review revealed the lack of annual competency documentation available at the time of survey for the following TP: Staff #1; Staff #3 - Staff #6 (CMS 209) for 2020. 2. An interview with Staff #2 (CMS 209) in the office manager's office on 10/21/2020 at approximately 5:00 p.m. confirmed the aforementioned lack of annual TP competencies.