

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2037621	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Radiant Complexions Dermatology Clinic	Street Address, City, State 2913 5th Avenue South, Fort Dodge, IA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual volume form and confirmed by the Chief Operating Officer at approximately 11:10 am on 05/24/2022, the laboratory failed to verify the accuracy for performing potassium hydroxide (KOH) examinations twice annually for five out of five time periods from 01/01/2020 - 05/24/2022. At the time of the survey, the laboratory did not enroll in proficiency testing for KOH examinations and did not verify the accuracy of the testing by another method from 01/01/2020 - 05/24/2022. THIS IS A REPEAT DEFICIENCY.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test logs, patient electronic health records (EHR), and</p>

confirmed by the laboratory's Chief Operating Officer at approximately 11:10 am on 05/24/2022, the laboratory failed to have a system in place to ensure the accurate and reliable transcription of manual test results into the laboratory's EHR for two out of two patients (patient identifier A & B) having potassium hydroxide (KOH) examination testing performed in October 2021. The findings include: 1. Review of the laboratory's KOH log indicated that patient A had a KOH examination performed on 10/01/2021 with a negative result. 2. Patient A's EHR chart showed a result of "positive/negative" for the KOH performed on 10/01/2021. 3. Review of the laboratory's KOH log indicated that patient B had a KOH examination performed on 10/14/2021 with a negative result. 2. Patient B's EHR chart did not include a record of the KOH examination performed on 10/14/2021. 4. At the time of the survey, the laboratory's Chief Operating Officer confirmed that the laboratory did not have a system in place to ensure the accurate and reliable transcription of KOH testing into the EHR.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality assurance (QA) policy, lack of QA records, and confirmed by the Chief Operating Officer at approximately 11:30 am on 05/24/2022, the laboratory director failed to ensure that the laboratory established and followed a QA policy that describes the system or process for monitoring the general, pre-analytic, analytic, and post-analytic quality systems as well as define the frequency of QA monitoring. At the time of the survey, the Chief Operating Officer confirmed that the QA policy did not include the process for monitoring the quality systems or the frequency with which they would be monitored.