

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2170383	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Radiant Complexions	Street Address, City, State 311 S Clark Street, Suite 280, Carroll, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and patient test reports, lack of cryostat temperature logs, and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/18/2023, the laboratory failed to document cryostat temperatures for one out of one day of records reviewed in February 2023. The findings include: 1. The Mohs procedure states that the cryostat must be at a minimum of -20 degree Celcius to cut tissues for Mohs specimens. 2. On 2/27/2023, the laboratory performed Mohs testing on two patients. 3. At the time of the survey, the laboratory did not have documentation of the cryostat temperature for the specimens cut on 2/27/2023.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on lack of quality control records, review of patient test reports, and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/18/2023, the laboratory failed to document the Hematoxylin and Eosin (H&E) stain quality each day of patient testing for one out of one day of records reviewed in February 2023. The findings include: 1. On 2/27/2023 the laboratory performed Mohs testing on 2 patients. 2. At the time of the survey, the laboratory did not have documentation of H&E stain quality from 2/27/2023.