

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2244426	<b>(X3) Date Survey Completed</b>  11/21/2022
<b>Name of Provider or Supplier</b>  Radiant Complexions Dermatology Clinic	<b>Street Address, City, State</b>  2420 4th Street Sw, Mason City, IA	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during the survey and confirmed by the Chief Operating Officer at approximately 1:30 pm on 11/21/2022, the laboratory failed to ensure that stains used for Mohs surgery frozen sections were not used beyond their expiration date for five out of six months of patient testing from 06/01/2022- 11/21/2022. The findings include: 1. Observations made during the survey revealed that the laboratory had in use the following expired stain: Gill 3 Hematoxylin- lot 112909, expiration 06 /30/2022. 2. At the time of the survey, the Chief Operating Officer confirmed that the laboratory had expired reagents in use.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:

Based on review of the Clinical Laboratory Improvement Amendment (CLIA) application (Form CMS-116), patient test reports, and confirmed by the Chief Operating Officer at approximately 1:30 pm on 11/21/2022, the laboratory failed to indicate the name and address of the testing facility for four out of six patient test reports reviewed from July 2022- October 2022. the findings include: 1. Patient identifiers A and B had Mohs surgery frozen section testing performed on 10/14/2022. 2. Patient identifiers C and D had Mohs surgery frozen section testing performed on 10/28/2022. 3. The CLIA application listed the name and address of the facility as Radiant Complexions Dermatology Clinic, 2420 4th Street SW, Mason City, IA 50401. 4. The test reports for the four patients listed above recorded the name and address of the testing facility as Iowa Dermatology Clinic, 6000 University, Suite 230, West Des Moines, IA 50266- 8206.