

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2169802	<b>(X3) Date Survey Completed</b>  02/04/2022
<b>Name of Provider or Supplier</b>  Ringfeil Advanced Dermatology	<b>Street Address, City, State</b>  569 W Lancaster Ave, Haverford, PA	
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>D8103</b>	<p><b>BASIC INSPECTION REQUIREMENTS</b> CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the office manager (OM), The laboratory failed to provide the required documents during the course of the inspection on 02/04/2022 Findings Include: 1. On the day of survey 02/04/2022 at 11: 10 a.m, the laboratory could not provide the following documents upon request for Mohs Microscopic examinations: - Written statements for personnel responsibilities. - Competency assement procedures. - Preanalytical procedures: Patient Identification, Patient preparation, specimen collection, specimen labeling. - Testing Procedures: Processing tissues, Mohs procedure, Frozen section procedure, Hematoxylin and Eosin Staining procedure, Slide labeling procedure, Cover slipping procedure, storage</p>

of slides, specimen acceptance or rejection, Corrective action procedures, quality control procedures. - Proficiency testing procedures. - Quality Assessment Procedures. - Postanalytical procedures: Method of reporting results 2. The OM confirmed the findings above on 02/04/2022 at 11:30 a.m.