

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1007218	<b>(X3) Date Survey Completed</b>  03/06/2024
<b>Name of Provider or Supplier</b>  Jona K Gill, Md, Pc	<b>Street Address, City, State</b>  14650 E Old Us 12, Chelsea, MI	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #3, the laboratory failed to follow specimen labeling policies and procedures for 1 (Patient "GE") of 1 patient tissue specimen observed. Findings include: 1. The surveyor observed testing personnel drop off a tissue specimen in a petri dish with a post-it note with "GE" set on top on 3/6/24 at 9:08 am. 2. A review of the laboratory's "Specimen Acceptance or Rejection" policy revealed a section stating, "When the specimen is received in the laboratory, it must be received accordingly: 1. It must be transported in a secondary container. 2. It must be labeled with the patient's name, date, specimen site, corresponding map with stage number." 3. An interview on 3/6/24 at 11:15 am with Testing Personnel #3 confirmed the laboratory had not followed it's specimen labeling policy.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #3, the laboratory failed to ensure histopathology procedures were approved, signed, and dated by the Laboratory Director for 1 (March 2023 to March 2024) of 1 year since the laboratory started testing. Findings include: 1. A review of the laboratory's procedure manual revealed a page titled "Policies and Procedures" stating, "The above policies and procedures have been reviewed and are effective as of open date. Updated as procedures change. Reviewed yearly." The section below this left a space for a signature with "Laboratory Director's Approval" and "Date" written underneath. No signature or date was present. 2. An interview on 3/6/24 at 9:40 am with Testing Personnel #3 confirmed the policies and procedures had not been approved by the Laboratory Director.