

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2170820	<b>(X3) Date Survey Completed</b> 08/24/2023
<b>Name of Provider or Supplier</b> Greenfield Labs Llc	<b>Street Address, City, State</b> 23350 Greenfield Road Suite 201, Oak Park, 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>D0000</b>	The purpose of this unannounced survey was for complaint #MI00138853. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and the following Condition: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to follow its personnel competency policies for 3 (Technical Consultant, Testing Personnel #1 and Testing Personnel #2) of 3 laboratory personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Performance Assessment" policy revealed a section stating, "All existing laboratory personnel will be appraised and evaluated at least annually." 2. A review of the laboratory's competency assessments revealed the Technical Consultant, Testing Personnel #1, and Testing Personnel #2 were last evaluated on 5/1/22. 3. An interview on 8/24/23 at 1:20 pm with Testing Personnel #1 confirmed laboratory personnel had not been assessed at least annually according to the laboratory's policy.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the laboratory failed to have written procedures for its qualitative toxicology testing for 2 (August 2021 to August 2023) of 2 years. Findings include: 1. The surveyor requested the laboratory's test procedures for its qualitative urine toxicology testing performed using the Medica Easy RA on 8/24/23 at 11:00 am and it was not made available. 2. An interview on 8/24/23 at 1:20 pm with Testing Personnel #1 confirmed test procedures were not available. \*\*\*This is a repeated deficiency from the 11/21/22 recertification survey\*\*\*

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interviews, the laboratory failed to have a director for three years and nine months (November 2019 to August 2023) since the change in laboratory director was made on 11/14/19. Findings include: 1. A review of email correspondence from the Laboratory Director to the surveyor on 8/16/23 revealed the Laboratory Director had been unaware of being listed as the laboratory director for Tox Testing Inc, stating "I have no knowledge of being a Laboratory Director or any knowledge of the following laboratories: Tox Testing located in the State of Michigan." 2. A review of the CMS laboratory database revealed a change in laboratory director to the currently listed laboratory director was effective 11/14/19. 3. The surveyor requested documentation of any contracts or agreements between the currently listed Laboratory Director and the laboratory for laboratory director services between November 2019 to present on 8/24/23 at 11:58 pm and it was not made available. 4. An interview on 8/24/23 at 11:36 am with the Laboratory Manager revealed he may have met the Laboratory Director once or twice, but the Laboratory Director had never been to the laboratory before. 5. An interview on 8/24/23 at 12:55 pm with Testing Personnel #1 revealed he had never met the Laboratory Director. 6. A review of email correspondence with the Technical Consultant on 8/28/23 revealed no documentation of contracts or agreements between the currently listed Laboratory Director and the laboratory or consulting company were available.