

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2170820	(X3) Date Survey Completed 11/21/2022
Name of Provider or Supplier Greenfield Labs Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure all testing data from proficiency testing events was retained for at least two years for 1 (2020 Chemistry Event #2) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute proficiency testing records revealed a lack of testing data generated from the 2nd event of 2020 with the review date of 11/24/20. 2. The surveyor requested testing data for the proficiency testing samples from the 2nd event of 2020 on 11/21/22 at 11:34 am and they were not made available. 3. An interview on 11/21/22 at 12:58 pm with TP1 confirmed the laboratory had not retained the testing data from the 2nd event of 2020.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL 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 record review, observation, and interview with Testing Personnel #1 (TP1),</p>

the laboratory failed to ensure its specimen labeling policy was followed for 1 of 1 specimen observed. Findings include: 1. A review of the laboratory's "Specimen Handling Policy" revealed a section stating, "All specimens received must have a permanently attached label with a unique identifier (such as patient name or ID number). TWO Patient ID required for collection." 2. The surveyor observed Testing Personnel #2 (TP2) perform urine qualitative toxicology testing on 11/21/22 at 12:37 pm revealed the specimen being tested was labeled with the patient first name only and did not include a last name or second identifier. 3. An interview on 11/21/22 at 12:58 pm with TP1 confirmed TP2 had not followed the laboratory's specimen labeling policy as established.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks 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 a lack of procedures and an interview with Testing Personnel #1 (TP1), the laboratory failed to have written procedures for its qualitative toxicology testing performed on the Easy RA analyzer for 2 (November 2020 to November 2022) of 2 years. Findings include: 1. The surveyor requested the laboratory's testing procedures for its qualitative urine toxicology testing using the Easy RA analyzer on 11/21/22 at 11:36 am and none were provided. 2. An interview on 11/22/22 at 12:58 pm with TP1 confirmed the laboratory did not have procedures for the performance of qualitative urine toxicology testing using the Easy RA analyzer.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform quality control testing at least each date of patient testing for its urine qualitative toxicology testing for 2 (11/19/20 and 11/25/20) of 13 patient testing dates reviewed. Findings include: 1. A review of the laboratory's quality control documentation for its urine qualitative toxicology testing using the Easy RA analyzer revealed a lack of documentation for 11/19/20 and 11/25/20. 2. A review of patient test reports revealed 7 patients received testing on 11/19/20 and 3 patients

received testing on 11/25/20. 3. An interview on 11/21/22 at 12:22 pm with TP1 confirmed the laboratory did not have documentation of quality control performed on the dates listed above when patient testing was reported.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
. Based on a lack of documentation and an interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure a quality assessment program was established and performed for 2 (November 2020 to November 2022) of 2 years reviewed. Findings include: 1. The surveyor requested the laboratory's quality assessment policies and records on 11/21/22 at 11:36 am and they were not made available. 2. An interview on 11/21/22 at 12:58 pm with TP1 confirmed the laboratory had no quality assessment policies or records of quality assessments performed between November 2020 and November 2022.