Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2196276	06/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Denver Recovery Group Labs	56 E Arapahoe Rd, Suite A, Littleton, CO	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory ' s proficiency testing (PT) records, and an interview with the laboratory's office manager (not listed on CMS-209 form), the laboratory failed to evaluate and document the evaluation of PT results received from the PT provider, since the laboratory ' s last survey on 02/15/2022. The laboratory performs approximately 2,124,000 tests annually. Findings include: 1. A review of the laboratory's PT records showed that no evaluation or documentation of PT results review were recorded when the laboratory received a score of less than 100% for an analyte. 2. An interview with the laboratory's office manager (not on CMS-209 form) on 06/02/2024 at approximately 4:00 P.M. confirmed that the laboratory did not document any evaluation or corrective action of PT scores received from the PT provider of analytes with scores of less than 100%.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory ' s records, and an interview with the laboratory's office manager (not listed on CMS-209 form), the laboratory failed to have a written

	and approved policy or procedure for: investigating laboratory errors, evaluating the effectiveness of corrective actions, assessing the competency of laboratory staff, and handling laboratory communications and complaints, since the laboratory's last survey on 02/15/2022. The laboratory performs approximately 2,124,000 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that there were no written and approved policies or procedures for investigating laboratory errors, evaluating the effectiveness of corrective actions, assessing the competency of laboratory staff, and handling laboratory communications and complaints. 2. An interview with the laboratory's office manager (not on CMS-209 form) on 06/02/2024 at approximately 4:00 P.M. confirmed that the laboratory did not have written and approved policies or procedures for investigating laboratory errors, evaluating the effectiveness of corrective actions, assessing the competency of laboratory staff, and handling laboratory communications and complaints.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of laboratory ' s policy and procedure manual, and an interview with the laboratory's general supervisor (GS), and office manager (not listed on CMS-209 form), the laboratory failed to have a written and approved policy for, and perform comparison studies between the laboratory's two SCIEX Liquid Chromatography Mass Spectrometry (LC-MS) instruments used for clinical testing, since the laboratory ' s last survey on 02/15/2022. The laboratory performs approximately 2,124,000 tests annually, roughly split between the two LC-MS instruments. Findings include: 1. A review of the laboratory's policy and procedure manual revealed there was not a written and approved policy or procedure to compare the laboratory's two SCIEX LC-MS instruments used for clinical testing at least once every 6 months. 2. An interview with the laboratory's GS on 06/02/2024 at approximately 2:30 P.M. confirmed that the laboratory failed to have a written and approved policy or procedure for comparing the two LC-MS instruments, and had not performed any comparison studies between the two instruments. 3. An interview with the laboratory's office manager (not on CMS-209 form) on 06/02/2024 at approximately 4:00 P.M. confirmed that the laboratory had failed to have a written and approved policy for comparing the two LC-MS instruments, and had not performed any comparison studies between the two instruments.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory ' s records, policy and procedure manual, and an interview with the laboratory's office manager (not listed on CMS-209 form), the laboratory failed to document corrective actions to laboratory errors, have a written and approved policy or procedure for investigating laboratory errors, documenting corrective actions, and evaluating the effectiveness of the corrective actions taken, since the laboratory ' s last survey on 02/15/2022. The laboratory performs approximately 2,124,000 tests annually. Findings include: 1. A review of the laboratory's corrective action logs showed that laboratory errors were documented, but did not contain documentation of the corrective actions taken and any review of their effectiveness. 2. A review of the laboratory's policies and procedures manual revealed that there was no written and approved policy or procedure for investigating laboratory errors, documenting corrective actions, or evaluating their effectiveness. 3. An interview with the laboratory's office manager (not on CMS-209 form) on 06/02 /2024 at approximately 4:00 P.M. confirmed that the laboratory did not have a written and approved policy or procedure for investigating laboratory errors, documenting corrective actions, and has not been evaluating their effectiveness.