Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2023227	02/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Robinhood Integrative Health, Pllc	3288 Robinhood Rd, Winston Salem, NC	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 American Proficiency Institute (API) proficiency testing (PT) records and interview with the off-site consultant 2/22/23, the laboratory failed to verify the accuracy of their carbon dioxide (CO2) testing at least twice a year in 2021 and 2022. Findings: Review of 2021 and 2022 API PT records revealed graded results for the Chemistry Core module did not include results for CO2. There was no documentation available to indicate that the laboratory performed any other activity to verify the accuracy of the CO2 testing performed during 2021 or 2022. During interview at approximately 1:30 p.m., the off-site consultant stated that the laboratory was enrolled in proficiency testing for CO2 and the samples were tested as part of the panel, but the results were not submitted to API.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 API PT records, and interview with testing personnel (TP) #1 on 2/22/23, proficiency samples were not tested in the same manner as patient specimens for 10 of 11 testing events in 2022. Findings: Review of the laboratory's "Proficiency Testing Policy" revealed "... Analyze samples within the time provided by the testing agency treating all PT samples in the same manner as a patient sample. ..." Review of the laboratory's "General Laboratory Systems Quality Management Policy" revealed "... Proficiency Testing PT samples are handled and tested exactly like patient specimens. ..." Review of 2022 API PT records revealed proficiency samples were tested multiple times and on multiple days for 10 of 11 testing events. Patient samples were routinely tested only once. Examples: 1. 2022 1st Chemistry Core - routine chemistry samples tested 1/14/22, 1/18/22, 1/19/22. 2. 2022 1st Hematology test event - hematology samples tested 3/10/22, 3/11/22, 3/14/22. 3. 2022 2nd Hematology test event - hematology samples tested 3 times on 7/20/22. 4. 2022 2nd Immunology test event - C-Reactive Protein (CRP) samples tested 8/8/22, 8/9/22, 8/10/22. 5. 2022 2nd Chemistry Miscellaneous test event - testosterone samples tested 2 times on 10/13/22 and 1 time on 10/14/22. During interview at approximately 12:40 p.m., TP #1 confirmed the proficiency samples were tested multiple times. She stated she repeats the testing of proficiency samples if results are abnormal. She stated she also wants to make sure precision is there before reporting.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of laboratory verification of performance records and interview with laboratory manager 2/22/23, the laboratory failed to retain documentation of the verification of performance of the laboratory information system (LIS) Lab -Trak when testing began in August of 2020 and when the laboratory changed locations in November of 2022. The laboratory also failed to retain documentation of the verification of performance for the testing performed on the Medica Easy RA and the Tosoh A1A 2000 analyzers when the laboratory changed locations in November of 2022. 1. The laboratory failed to retain documentation of the verification of performance of the LIS Lab-Trak when testing began in August of 2020 and when the laboratory changed location in November of 2022. Findings: Review of laboratory procedure "LIS Data and Result Transfer Verification" revealed "Policy: Data such as patient demographics, test name, units of measure, and normal ranges will be confirmed for accuracy when said information is transferred electronically from the analyzers to the LIS....Audits will be performed at: Installation of the LIS. Six(6) month intervals for the first year. Annually each yearly following. When any major change occurs with testing procedures or LIS updates.". Review of laboratory verification of performance records revealed no documentation the LIS Lab-Trak was verified when the laboratory began testing in August of 2020 and when the laboratory changed locations in November of 2022. Interview with laboratory manager at approximately 2:00 p.m. confirmed the laboratory failed to retain the

	documentation of the verification of the LIS Lab-Trak performed in August of 2020 and November of 2022. She stated the verification was performed but the laboratory was unable to locate the documentation. 2. The laboratory failed to retain documentation of the verification of performance for the testing performed on the Medica Easy RA and the Tosoh A1A analyzers when the laboratory changed locations in November of 2022. Findings: Review of laboratory procedure "Quality Control and Calibrations Procedure" revealed "All calibrations must be documented as to when they were performed, who performed them, and whether they were acceptable or not.". Interview with laboratory manager at approximately 1:30 p.m. confirmed the laboratory failed to retain documentation of the verification of performance for the testing performed on the Medica Easy RA and the Tosoh A1A analyzers when the laboratory moved to a new location in November of 2022. She stated calibrations were performed after the analyzers were moved but they were unaware documentation of the calibrations should be retained.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure and interview with laboratory manager 2/22 /23, the procedure manual failed to include the type (name) and levels of quality control (QC) and calibration reagent used for the testing performed on the Medica Easy RA, the Tosoh A1A 2000 and the Tosoh G8 HPLC analyzers. Findings: Review of laboratory procedure "Quality Control and Calibrations Procedure" revealed "Procedure: Reagents, Controls, Calibrators, and Supplies...All quality control materials utilized are recommended by the instrument, system, and method manufacturers and/or have established assayed values for the methods being performed.". The laboratory procedure failed to include the type (name) and levels of QC and calibration reagent used for the testing performed on the Medica Easy RA, the Tosoh A1A 2000 and the Tosoh G8 HPLC analyzers. Interview with laboratory manager at approximately 3:00 p.m. confirmed the procedure manual failed to include the type (name) and levels of quality control (QC) and calibration reagent used for the testing performed on the Medica Easy RA, the Tosoh A1A 2000 and the Tosoh G8 HPLC analyzers. She stated they use the manufacturer's QC and calibration reagents.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of laboratory verification of performance specifications records, interview with laboratory manager 2/22/23, and email correspondence with laboratory manager 3/1/23, the laboratory failed to verify the performance specifications for high-sensitivity C-reactive protein (Hs-CRP), approximately 4,043 patients were tested since testing began on 3/23/21. Findings: Review of laboratory procedure "Verification of Performance Specification Policy" revealed "Policy: Each analyzer or testing method categorized as moderate complexity will be tested and evaluated to verify that it can perform to the manufacturer's specifications.". Review of laboratory verification of performance specification records revealed no documentation the laboratory verified the performance specifications for Hs-CRP testing since testing began on 3/23/21. Interview with laboratory manager at approximately 1:00 p.m. confirmed the laboratory failed to verify the performance specifications for Hs-CRP testing. Email correspondence with laboratory manager on 3/1/23 confirmed approximately 4,043 patients were tested since Hs-CRP testing began 3/23/21.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: A. Based on review of laboratory procedure, review of 2020, 2021, 2022, 2023 laboratory calibration records for the Medica Easy RA and Tosoh A1A 2000 analyzers and interview with off-site consultant and laboratory manager 2/22/23, the laboratory failed to maintain documentation of the calibrations for all testing performed on the Medica Easy RA and Tosoh A1A 2000 analyzers since testing began in August of 2020, approximately 30 months in which documentation was not maintained. Findings: Review of laboratory procedure "Quality Control and Calibrations Procedure" revealed "All calibrations must be documented as to when

	they were performed, who performed them, and whether they were acceptable or not.". Review of 2020, 2021, 2022 and 2023 laboratory calibration records stored on a Universal Serial Bus (USB) for the Medica Easy RA and Tosoh A1A 2000 analyzers revealed the laboratory could not reproduce the calibrations in a format that could demonstrate an acceptable performance of calibration. Review of 2023 calibrations maintained on the Medica Easy RA analyzer revealed documentation of the last two calibrations performed for each analyte. Review of 2023 calibrations maintained on the Tosoh A1A 2000 analyzers revealed documentation of the last three calibrations performed for each analyte. Interview with off-site consultant at approximately 1:30 p. m. confirmed the calibration records maintained on the USB failed to demonstrate an acceptable performance of calibration. Interview with laboratory manager at approximately 1:30 p.m. confirmed the Medica Easy RA maintained documentation of the last two calibrations performed for each analyte in 2023 and the Tosoh A1A 2000 maintained documentation of the last three calibrations performed for each analyte in 2023. B. Based on review of manufacturer's instructions, review of 2020, 2021, and 2022 Medonic M Series calibration records, and interview with the off-site consultant 2/22/23, the laboratory failed to perform and document calibration for the Medonic M Series at least once every 6 months during 2021 and 2022. Review of the Medonic M Series Operator's Manual revealed "Section 7: Calibration ... It is recommended to calibrate the instrument every 6 months. ... It is recommended that calibration reports be printed and archived in case it may be needed for future reference. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ..." Review of the laboratory's Medonic M Series calibration records revealed a calibration was performed when the instrument was installed, 6/30/20. Additional calibrations were performed 8/6/21, 3/3/22, and 11 /15/22. There were no other records available for review, and documentation of quality control testing was not included in the calibration records from 8/6/21 and 11 /15/22. During interview at approximately 1:55 p.m., the off-site consultant verified that some of the documentation was missing. He stated the analyzer was also calibrated in January 2021 and September 2022. Review of a "Hemo Calibration" file provided by the off-site consultant revealed the following handwritten information on the front of the file: "1-26-2021 - missing Calibration Documented - Listed on PreCal done 8-6-2021". "9-16-2022 - missing documents. Printer not working."
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of reagent package insert, review of random patient test reports and interview with off-site consultant 2/22/23, the laboratory director (LD) failed to ensure reports for Prostate-specific antigen (PSA) test results included the assay method. Findings: Review of reagent package insert for PSA revealed "Caution: ... Because of the differences in reagent specificity and assay methods, the concentration of PSA in a given specimen may vary with devices from different manufacturers. Values obtained with different assay methods cannot be used interchangeably. It is

	mandatory that results reported by the laboratory to the physician include the identity of the assay used.". Review of random patient test reports, Sample #116505 and #116516, revealed the PSA results failed to include the assay method. Interview with off-site consultant at approximately 2:00 p.m. confirmed the PSA test results failed to include the assay method. The off-site consultant updated the test reports to include the assay method of PSA at time of survey.