Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2149605	06/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Wellness Md Llc Dba Nava Labs	9755 Patuxent Woods Dr Ste 100, Columbia, MD	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of testing records and email communication with the director of laboratory operations (DLO), the laboratory failed to retain instrument data from the immunoassay analyzer for at least two years. Findings: 1. The laboratory used an Access 2 immunoassay system for patient testing. 2. The instrument results for sample ID 33084, which was received on 05/17/2021, were requested during the onsite survey on 04/14/2023 then requested via email on 04/18/2023. 3. In the email response received 05/05/2023 at 6:29 PM, the DLO stated that "We no longer have this data."
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedure manual, the manufacturer's instrument brochure, final reports, and instrument printouts from the immunoassay analyzer; interview with

	the technical consultant and testing personnel; and email communication with the director of laboratory operations, the laboratory failed to provide a client service manual with written instructions for clients to follow when transporting patient specimens (D5311 I) and failed to adhere to defined stability acceptability for multiple analytes and tested specimens beyond stated stability limits (D5311 II).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: I. Based on review of the procedure manual and interview with the testing personnel (TP), the laboratory failed to provide a client service manual with written instructions for clients to follow when transporting patient specimens. Findings: 1. Section 2 of the "Specimen Transportation" stated that "All personnel must be knowledgeable in the proper safety and packaging for specimens transported." Section 7 stated "All staff involved in handling specimens should receive training." The procedure failed to include instructions for proper safety, packaging, and training. 2. The "Specimen Transportation" procedure failed to include instructions for who would be collecting the specimens and when the specimens would be collected and transported. 3. Review of the policies and procedure manuals showed that the laboratory did not have written instructions available to their clients that included specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, specimen referral and how to maintain the patient logbook at the offices. 4. According to the TP, specimens collected on Friday afternoons at the clinic are to be sent to a reference laboratory for testing. When the TP is on vacation the specimens are to be sent to the reference laboratory for testing. The TP confirmed that these instructions are not in the laboratory's policy and procedure manuals. 5. During the survey on 04/14/2023 at 4:40 PM, the TP confirmed that the laboratory did not have written instructions available to their clients for the transportation, and training of the staff involved in the collection of the specimens to be sent to the main laboratory. 43123 II. Based on review of the procedure manual, the manufacturer's instrument brochure, final reports, and instrument printouts from the immunoassay analyzer; interview with the technical consultant (TC) and laboratory director (LD); and email communication with the director of laboratory operations (DLO), the laboratory failed to adhere to defined stability acceptability for multiple analytes and tested specimens beyond stated stability limits. Findings: 1. The TC stated that patient specimens were stored at collection sites, transported, and stored at the laboratory at refrigerated temperatures and that no specimens were frozen. 2. The laboratory's procedure manual stated that the following analytes were stable for 24 hours at refrigerated temperatures (2-8C): vitamin B-12 and prostate-specific antigen (PSA). 3. The laboratory's procedure manual stated that the following analytes were stable for 48 hours at 2-8C: dehydroepiandrosterone sulfate (DHEA-S), estradiol, free thyroxine (free T4), follicle stimulating hormone (FSH), luteinizing hormone (LH), progesterone, prolactin, testosterone, thyroid peroxidase antibody (TPO), thyroid stimulating hormone (TSH), antithyroglobulin antibody (ATA), and severe acute

	respiratory syndrome coronavirus 2 immunoglobulin G (SARS-CoV-2 IgG). 4. The laboratory's procedure manual stated that whole blood for complete blood counts (CBCs) was stable for 72 hours at refrigerated temperatures, however, the manufacturer's instrument specifications brochure stated that sample stability was 48 hours at room temperature for CBCs. 5. A total of six specimen reports were reviewed along with the requisitions and instrument printouts for each specimen. The DLO confirmed the time specimens were collected in an email received on 05/05/2023. For four of the six specimens, results were reported beyond the stated stability for at least one analyte. For one of the six specimens, the date of testing was not known because instrument printouts were missing: a. Sample ID 36334 was collected on 11/17/2021 at 9:52 AM, received on 11/17/2021, and tested on 11/20/2021 beginning at 7:42 PM, about 82 hours after collection. Results were reported for CBC, TSH, free T4, FSH, estradiol, DHEA-S, free testosterone, and vitamin B-12. b. Sample ID 37576 was collected on 01/21/2022 at 10:56 AM, received on 01/21/2022 and tested on 01/25 /2022 beginning at 2:21 PM, about 99.5 hours after collection. Results were reported for TSH, free T4, testosterone, free testosterone, estradiol, FSH, PSA, LH, DHEA-S, vitamin B-12, and SARS-CoV-2 IgG. c. Sample ID 58599 was collected on 10/13 /2022 at 10:42 AM, received on 10/13/2022, and tested on 10/14/2022 at 4:02 PM for vitamin B-12, about 29 hours after collection. Results were reported for vitamin B-12. d. Sample ID 63357 was collected on 03/09/2023 at 10:57 AM, received on 03/09 /2023, and tested on 03/13/2023 beginning at 5:48 PM about 102.5 hours after collection. Results were reported for CBC, TSH, free T4, ATA, TPO, FSH, estradiol, prolactin, DHEA-S, free testosterone, vitamin B-12, and SARS-CoV-2 IgG. e. Sample ID 33084 was collected on 05/17/2021 at 11:11 AM and received on 05/17/2021. The testing date and time is unknown because the instrument printouts were missing (cross-refer to tag D3031). The report was issued on 05/26/2021 and results were reported for CBC, TSH, free T4, ATA, TPO, testosterone, free testosterone, estradiol, FSH, LH, PSA, DHEA-S, prolactin, and vitamin B-12. f. In an email received on 06 /06/2023, the DLO confirmed that results from the CBC analyzer could not be printed. As of 06/06/2023, it was not determined when the CBC results from a., d., and e. listed above were run on the analyzer. 6. During the survey on 04/14/2023 at 4:45 PM, the TC and LD confirmed that patient results were reported for analytes received and tested beyond stability limits.
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: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey for CLIA number 21D2117103 that was completed on 06/10/2021 for not following procedures stated in the Quality Management Plan (QMP) in particularly not performing the "Process Verification" on a quarterly basis. The completion date for implementing the laboratory's plan of correction was listed as 07/01/2021. Based on review of the QMP and interview with the technical consultant (TC) and laboratory director (LD), the laboratory failed to follow procedures stated in the QMP. Findings: 1. Section 3.3.2 of the QMP stated that "The Quality Assurance Team shall, on an annual basis, determine the appropriate quality assurance monitors, including patient

	safety goals, which shall be measured and reported." 2. Section 9.1.1 of the QMP stated that "Specific, measurable indicators are developed by each department, and reported quarterly to the General Manager and Laboratory Medical Director and/or company executive as directed. These indicators shall be drawn from three phases of laboratory operations critical to patient outcome and/or effect many patients which include: Pre-analytical, Analytical, Post-Analytical." 3. Section 9.1.2 of the QMP stated that "The laboratory will documented evaluation of indicators by regularly comparing performance against available benchmarks. The benchmarks may be established based upon performance baselines from previous monitoring intervals, comparison against industry standards, or other methods as appropriate." 4. Section 9.1.4 of the QMP stated that "Indicators are reviewed that the regularly scheduled meetings of the Quality Assurance Team, or as frequently as deemed necessary. Action plans are developed as appropriate to address critical items identified during the monitoring process. Indicator review and, as needed corrective/preventative actions will be documented as part of the monthly Quality meeting." 5. Section 9.3.7 of the QMP stated that "Process Verification" would be a "quarterly review of at least 1 random accession number (from a Positive specimen) will be performed to document any deviations from established policy. This is a system whereby the entire test process can be recreated through document review for purposes of substantiating the reported test finding (see QUAL.001.FORM1)." 6. Section 9.3.8 of the QMP mentioned "Periodic (semiannually) Safety Audits. 7. During the survey on 04/14 /2023 at 4:45 PM, the TC and LD confirmed that the laboratory was not determining quality monitors/indicators on an annual basis, reporting quality monitors/indicators on a quarterly basis, or evaluating chosen quality monitors/indicators against established benchmarks. It was also confirmed that the quarterly "Process Verification" and the semiannual safety audits were not being performed.
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 the standard operating procedure (SOP) manual and interview with the testing personnel (TP), the laboratory failed to have written instructions for pipette calibration. Findings: 1. Review of the SOP showed that there were no

	instructions for calibration of the pipettes used in the laboratory. The TP stated that the pipettes were calibrated on an annual basis. 2. During the survey on 04/14/2023 at 4:40 PM the TP confirmed that the SOP failed to include instructions for the calibration and frequency of calibration of the pipettes used in the laboratory.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the maintenance charts for the Beckman AU 480 (chemistry analyzer) and interview with the testing personnel (TP), the laboratory failed to complete all required maintenance. Findings: 1. The maintenance charts from December 2022 through March 2023 for the chemistry analyzer were reviewed. 2. The monthly maintenance, which included the cleaning of the sample probe, reagent probe, mix bar wash wells, cleaning and inspection of the wash nozzle, distilled water filter, and sample probe filter, was not documented in September 2022. 3. The six-month maintenance of washing the cuvettes and cuvette wheel was last documented on 05/15/2022. The six-month maintenance had not been documented since 05/15 /2022. 4. During the survey on 04/14/2023 at 4:40 PM, the TP confirmed that the maintenance on the chemistry analyzer had not been performed as required by the manufacturer.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the technical consultant (TC), the laboratory failed to monitor room temperature and humidity in the laboratory where chemistry, endocrinology, and hematology testing was performed. Findings. 1. The laboratory performed chemistry testing using a Beckman Coulter AU480 analyzer. The manufacturer's user guide (PN B28624AA December 2013) stated an operating environmental temperature of 18 to 32C (64 to 90F) and humidity of 20 to 80% with no condensation. 2. The laboratory performed endocrinology testing using a Beckman Coulter Access 2 analyzer. The manufacturer's instructions for use (C94059-AA October 2022) stated an operating environmental temperature of 18 to 28C (64 to 82F) and humidity of 20 to 80%. 3. The laboratory performed hematology testing using a Coulter AcT 5 diff Autoloader analyzer. The manufacturer's instructions for use (PN 624026AG July 2016) stated to "Operate the

	system in a room with ambient temperature between 16 and 34C (61F to 93F), and humidity no higher than 85% without condensation." 4. The laboratory had no documentation for monitoring the room temperature and humidity. 5. During the survey on 04/14/2023 at 4:45 PM, the TC confirmed that the laboratory was not monitoring room temperature and humidity in the laboratory where chemistry, endocrinology, and hematology testing was performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records and email communication with the director of laboratory operations (DLO), the laboratory failed to perform calibration verification of the hematology analyzer at least every six months. Findings: 1. Calibration records for the hematology analyzer were reviewed for 2022. 2. Records showed that the last calibration was performed in November of 2022. 3. There were no records showing that calibration was performed around May of 2022 or earlier in that year. 4. In an email received 05/05/2023 at 6:29 PM, the DLO confirmed that the calibration from around May of 2022 "was missed."
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	I. The laboratory director failed to ensure that the Quality Management Plan was implemented and maintained. Cross-refer to tag D5401 for details. II. Based on review of the QMP, the "Report Verification" documentation, and instrument printouts from the immunoassay analyzer, and interview with the TC, LD, and director of laboratory operations (DLO), the LD failed to ensure that the QMP activities monitored the overall quality of laboratory services provided. Findings: 1. The section titled "Report Verification" of the QMP described the "Biennial review and approval by the Laboratory Medical Director of the content and format of all computer-printed reports." The procedure did not specify what "content" should be reviewed and what corrective actions should be taken if errors or deviations from laboratory policies and procedures were found. 2. The documentation for the "Report Verification" included five test reports from patient specimens collected from 05/17 /2021 through 03/09/2023. 3. In a phone conversation on 06/06/2023 at 11:00 AM, the DLO stated that the laboratory's turnaround time (TAT) from specimen receipt to issuing the final report was 7 days, but could not confirm if the TAT was stated in any written policies or procedures. 4. Each test report included the "Collected" date, the "Received" date, and the "Approval Date" which was the date the results were released. a. Sample ID 33084 was collected and received on 05/17/2021 with an approval date of 05/26/2021, 9 days after receipt of the specimen. b. Sample ID 36334 was collected and received on 11/17/2021 with an approval date of 11/29/2021, 12 days after receipt of the specimen. c. Sample 37576 was collected and received on 01 /21/2022 with an approval date of 01/26/2022, 5 days after receipt of the specimen. d. Sample 58599 was collected and received on 10/13/2022 with an approval date of 10 /21/2022, 8 days after receipt of the specimen. e. Sample 63357 was collected and received on 03/09/2023 with an approval date of 03/15/2023, 6 days after receipt of the specimen. 5. The test reports did not include the date and time the specimens were tested on each analyzer and the TAT indicated the possibility that specimens were tested beyond their stability for selected analytes. 6. Instrument printouts showed that four of the five patient specimens reported analytes that were tested beyond their stability limits and one of the five patient specimens was missing the instrument data (cross-refer to tag D5311 for details). 7. Results for sample ID 36334 were not reported until 9 days after immunoassay testing was complete. 8. The "Report Verification" review was signed by the laboratory director, but there were no notes or investigations into the extended TATs or possibility that specimens were tested beyond their stability for selected analytes. 9. During the phone conversation on 06/06 /2023 at 11:00 AM, the DLO confirmed that review of the laboratory's "Report Verification" documentation during the survey found that the laboratory had been testing specimens beyond their stability for selected analytes.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the competency assessment procedure, review of personnel records, and interview with the technical consultant (TC), the TC failed to ensure that six-month and annual competency evaluations were performed and documented as stated in the procedure. Findings: 1. The "Competency Assessment" procedure stated TCs "who perform testing on patient specimens are required to have the six (6)

	required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities." 2. The TC was also a testing person (TP). 3. The TC's personnel records showed that the six-month and annual competency evaluations as a TP were missing as well as a competency assessment based on the federal regulatory responsibilities as a TC. 4. During the survey on 04/14/2023 at 4:45 PM, the TC confirmed that six-month and annual competencies were missing for TP responsibilities as well as competency records for TC responsibilities.