Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2177660	03/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mainstream Diagnostic Laboratory Llc	5354 Gulf Dr, New Port Richey, FL	

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
D0000	An announced CLIA recertification survey was conducted at Mainstream Diagnostic Laboratory LLC on 02/06/2023 - 03/31/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 Analytic Systems 493.1250
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) documents and interview with the Technical Supervisor, the laboratory failed to maintain complete proficiency testing records to include instrument printouts, completed American Proficiency Institute (API) worksheets, and signed attestation statements for 16 (Chemistry Core 3rd Testing Event 2021, 1st and 2nd Testing Event 2022, Chemistry Miscellaneous 1st and 2nd Testing Event 2021 and 1st Testing Event 2022, Hematology 1st, 2nd, and 3rd Testing Event 2021, and 1st Testing Event 2022, Microbiology 1st Testing Event 2021, 1st and 2nd Testing Event 2022, and Immunology/Immunohematology 1st and 2nd Testing Event 2021 and 1st Testing Event 2022) of 21 (Chemistry Core 1st, 2nd, and 3rd Testing Event 2022, Chemistry Miscellaneous 1st and 2nd Testing

	Event 2021, and 1st Testing Event 2022, Hematology 1st, 2nd, and 3rd Testing Event Hematology, and 1st and 2nd Testing Event 2022, Microbiology 1st, 2nd, and 3rd Testing Event 2021, and 1st and 2nd Testing Event 2022, and Immunology /Immunohematology 1st, 2nd, and 3rd Testing Event 2021, and 1st and 2nd Testing Event 2022) events reviewed from 2021 - 2022. Findings included: Review of API Chemistry Core, Chemistry Miscellaneous, and Hematology proficiency records revealed 10 (Chemistry Core 3rd 2021, Chemistry 1st and 2nd 2022, Chemistry Miscellaneous 1st and 2nd 2021, and 1st 2022, and Hematology 1st, 2nd, and 3rd 2021, and 1st 2022) proficiency events out of 14 (Chemistry Core 1st, 2nd, and 3rd 2021 and 1st, 2nd, and 3rd 2022, Chemistry Miscellaneous 1st and 2nd 2021 and 1st 2022, and Hematology 1st, 2nd, and 3rd, and 1st and 2nd 2022) events did not have instrument printouts for the chemistry analyzers and hematology analyzers. Record review of API proficiency testing records revealed 5 (Microbiology 1st 2021 and 1st and 2nd 2022, and Immunology/Immunohematology 1st and 2nd 2021) proficiency testing events out of 8 (Microbiology 1st, 2nd, and 3rd 2021, and Immunology /Immunohematology 1st, 2nd, and 3rd 2021, and 1st and 2nd 2022) proficiency testing events did not have completed worksheets Record review of the API proficiency testing records revealed 13 (Chemistry Core 3rd 2021, 1st and 2nd 2022, Chemistry Miscellaneous 1st 2022, Hematology 1st and 3rd 2021, 1st and 2nd 2022, Microbiology 1st and 3rd, and 1st 2022, and Immunology/Immunohematology 1st 2021 and 1st 2022) proficiency testing events out of 21 (Chemistry Core 1st, 2nd, and 3rd 2022, Chemistry Miscellaneous 1st and 2nd 2021, and 1st 2022, Hematology 1st, 2nd, and 3rd Hematology, and 1st and 2nd 2022, Microbiology 1st, 2nd, and 3rd 2021, and 1st and 2nd 2022, and Immunology/Immunohematology 1st, 2nd, and 3rd, and 1st and 2nd 2022) proficiency testing did not include signed attestation statements. On 02/07/2023 at 5:00 PM, the Technical Supervisor confirmed the laboratory did not keep all proficiency records in the API binder.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) and interview with the Technical Supervisor, the laboratory failed to evaluate ungraded results in routine chemistry, endocrinology, and toxicology proficiency testing for 8 (Chemistry Core proficiency testing 1st, 2nd, and 3rd events in 2021, 1st, 2nd, and 3rd events in 2022, and Hematology proficiency testing 1st event in 2021 and 1st Event in 2022) out of 11 (Chemistry Core proficiency testing 1st, 2nd, and 3rd events for 2021, 1st, 2nd, and 3rd events in 2022 and Hematology 1st, 2nd, 3rd events for 2021, and 1st and 2nd events for 2022). Findings Included: Record review of API proficiency testing revealed the laboratory had not performed a self evaluation for ungraded results for the following: Chemistry Core 1st, 2nd, and 3rd Events 2021 - Amylase: Code 1 (less than 10 participants) Chemistry Core 1st, 2nd, and 3rd Events 2021 and 2022 - T-Uptake (percent): Code 1 Chemistry Core 2nd and 3rd Events 2022 - Estradiol - specimens IA 08-10 and IA 13-15: Code 1 Hematology -1st Event 2021 - nucleated Red Blood Cell: Code 3 (See Data Summary) Hematology 1st Event 2022 - nucleated Red Blood Cell - COU-01: Code 1; COU-02: Code 3 Record review of the laboratory's procedure "Proficiency Testing Program" signed by the previous

	Laboratory Director on 01/06/2020 revealed "7. Ungraded PT results will be evaluated to assess grade." On 02/07/2023 at 5:00 PM, the Technical Supervisor confirmed the laboratory had not performed self evaluations of results that were ungraded by API.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing and interview with the Technical Supervisor, the laboratory failed to evaluate proficiency testing that received a "0%" score for two (2021 Chemistry Miscellaneous 1st event and 2022 Hematology/Coagulation 2nd Event) out of 8 (Chemistry Miscellaneous 2021 1st and 2nd Events and 2022 1st Event and Hematology/Coagulation 2021 1st, 2nd, and 3rd and 2022 1st and 2nd Events) testing events reviewed. Findings Included: Review of API proficiency testing results revealed the laboratory had received a "0%" score but failed to evaluate the proficiency testing for 2021 Chemistry Miscellaneous 1st Event for urine chemistry and toxicology and 2022 Hematology 2nd Event for automated differential, sedimentation rate, coagulation, urinalysis and urine pregnancy, microscopy, and blood cell identification 2nd Event). Record review of the laboratory's procedure "Proficiency Testing Program" signed by previous laboratory director on 01/06/2020 revealed "Ungraded PT challenges will be evaluated to assess the grade." On 02/07/23 at 5:00 PM, the Technical Supervisor confirmed the laboratory had not documented the evaluation of the proficiency testing when the laboratory received a "0%" score.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of urine creatinine testing at least twice a year (2021). Findings included: Record review of the American Proficiency Institute (API) 2021 Chemistry - Miscellaneous 1st event dated 6/1/2021 revealed the laboratory failed to participate resulting in a "0%" proficiency testing score for urine creatinine. Record review of the API Chemistry - Miscellaneous 2nd event dated 11/19/2021 revealed a 0% proficiency testing score. The 2nd event comparative evaluation showed unacceptable results for UC-04, UC-05, and UC-06. On 02/07/2023 at 5:00 PM, the Technical Supervisor confirmed the laboratory had unsuccessful proficiency testing scores.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a policy of platelet poor plasma (See D5401), failed to have the Laboratory Director sign and approve the policies (See D5407), failed to maintain room temperature, maintenance, and humidity logs (See D5413), failed to label jars (See D5415), failed to calibrate the Coagulation analyzer (See D5437), failed to have acceptable Quality Control or correct International Sensitivity Index for Coagulation (See D5545), and failed to establish a Quality Assurance program (See D5791).
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 record review and staff interview, the laboratory failed to follow their procedure "Determination of Platelet Poor Plasma for Coagulation Specimens" for two out of two years (2021-2022) reviewed. Findings included: A review of the laboratory's procedure titled "Determination of Platelet Poor Plasma for Coagulation Specimens" signed by the previous Laboratory Director on 01/06/2020 revealed "This procedure will be done annually and reviewed by the Hematology Supervisor." Record review of coagulation records revealed a lack of documentation of the "Determination of Platelet Poor Plasma for Coagulation Specimens" procedures. On 02/07/23 at 11:00 AM., the Technical Supervisor confirmed that the laboratory had not performed the "Determination of Platelet Poor Plasma for Coagulation Specimens" for 2021 and 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on interview and review of policies, the Laboratory Director failed to sign and approve the policies before use beginning on 04/08/2021 through the start of survey on 02/06/2023. Findings included: Review of the policies and procedures revealed signatures of the original Laboratory Director on 01/06/2020. On 04/08/2021 and 11 /07/2022 there were Laboratory Director changes. Neither Laboratory Director

	approved or signed the policies when they became the Laboratory Director. During an interview on 02/06/2023 at 11:30 AM, the Technical Supervisor confirmed that the policies had not been signed by either of the new Laboratory Directors.
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 record review and interview with the Technical Supervisor, the laboratory failed to monitor and document conditions for proper storage of reagents and specimens as evidenced by 1) lack of documentation of room temperature and humidity where patient testing was performed from 04/01/2020 to the last day of patient testing on 09/12/2022, 2) lack of refrigerator temperature documentation where storage of coagulation and chemistry reagents, quality controls, and patient specimens were held from 04/01/2020 to the last day of patient testing on 9/12/2022, and 3) lack of documentation to ensure deionized (DI) water quality from 12/14/2021 to the last day of patient testing on 9/12/2022. Findings included: Review of the laboratory's policy titled "Refrigerator and Ambient Room Temperatures and Humidity" revealed the ambient temperature reading should not exceed the range of 18-30 degrees Celsius or 64-86 degrees Fahrenheit. The acceptable refrigerator temperature for storing reagents and patients specimens was between 2 and 8 degrees Celsius. The relative humidity range for analyzers was 20 -80%. Record review to the laboratory's "Room Temperature log" revealed the laboratory had not documented room temperature and humidity from 04/01/2020 - 09/12/2022. An attempt was made to review the refrigerator logs, but no such logs were present. Interview with the Technical Supervisor on 02/7/2023 at 11:05 AM confirmed she could not find any other refrigerator, room temperature and humidity logs. Record review of the laboratory's "DI Water System Log" logs revealed the laboratory had not documented the service light or Ultraviolet (UV) light from 12/14/21 to the last day of patient testing on 09/12/2022. In addition, no documentation of monthly microbiological analysis of the laboratory's water quality was present for 2021 and 2022. Record review of the laboratory's policy titled "Water Analysis/Distilled Water" with an effective of 11/1/19 but not signed by the Laboratory Director revealed "3 DI-Water tanks must be verified functional with daily light checks for the color green meaning the system is operational. A quantitative culture of the water system must be performed and documented monthly, on each spigot to test for bacterial contamination." On 02/07/23 at 11:30 AM, the Technical Supervisor confirmed the laboratory had not documented the water quality daily from 12/14/21 to the last day of patient testing on 09/12/2022 and had not documented the monthly microbiological analysis.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the Technical Supervisor, the laboratory failed to label 3 glass jars used for staining slides for hematology manual differential with identity of the solutions, preparation dates, and expiration dates. Findings included: On 02/07/2023 at 10:35 AM, observation revealed 3 glass jars containing solutions that were not labeled with the identity of the solutions, preparation dates, and expiration dates. On 02/07/2023 at 10:55 AM, the Technical Supervisor confirmed the three glass jars were not labeled. Photographic evidence was obtained.
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: Based on record review of Manufacturer's Instructions (MI), lack of calibration documentation, and interview with the Technical Supervisor, the laboratory failed to perform LED calibrations on the Sysmex CA1500 Coagulation analyzer from 02/22/2021 through the start of the survey on 02/06/2023. Findings included: Review of the MI on the Sysmex CA1500 revealed the "LED calibration is performed every 3 months." No documentation of this calibration could be located. During an interview on 02/07/2023 at 3:00 PM, the Technical Supervisor confirmed there were no calibrations performed on the Coagulation analyzer.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, review of Prothrombin Time (PT) quality control (QC), and staff interview, the laboratory failed to have documentation of acceptable QC from 01

	/02/2021 to the last day of patient testing on 09/12/2022. Findings Included: Review of the PT QC policy showed controls 1 and 3 were to be run once during each 8 hour shift, when a new bottle of reagent was opened, or when maintenance procedures had been completed. Review of Levy Jennings reports dated 01/02/2021 to 09/12/2022 revealed for Level 1 there was 1 day (08/29/2022) the QC was acceptable out of 108 days QC was ran and for Level 3 there were 3 days (08/26/2022, 08/29/2022, and 08 /30/2022) the QC was acceptable out of 96 days QC was ran. There were no instrument print outs of QC being ran. Review of the Dade Innovin Thromboplastin reagent, used on the Sysmex CA1500 Coagulation instrument, showed Lot #549783 being used with an ISI (International Sensitivity Index) of 1.07. Observation on 02/07 /2023 at 4:30 PM of the Sysmex CA1500 Coagulation instrument said that the current lot since 12/23/2021 was Lot#549797 with an ISI of 1.03. During an interview on 02 /07/2023 at 4:30 PM, the Technical Supervisor confirmed that the ISI value was not correctly put into the machine. She also confirmed that the Levy Jennings charts printed from 01/01/2021 to 09/12/2022 were not acceptable and patients should not have been reported. She confirmed that there were 206 Patients reported during this timeframe.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to have a Quality Assurance (QA) plan or any QA documents in place since 02/22/2021. Findings included: Review of the laboratory's policies and procedures revealed no policy was present for QA, and no documentation could be located to show that any QA had been performed. During an interview on 02/07/2023 at 3:00 PM, the Technical Supervisor confirmed there were no QA documents.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Patient reports and interview, the laboratory failed to have accurate test reports in 22 out of 85 test reports reviewed. Findings included: Review of Patient reports revealed that Patient #13, 14, 15, 16, 17, 34, 39, 41, 44, 45, 46, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, and 60 had an incorrect name and address of the

	laboratory where the testing was performed. Electronic correspondence on 03/31/2023 at 11:05 AM with the Technical Supervisor revealed the accurate name and location where the testing was performed and confirmed that the Patient reports were incorrect.