Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2224194	(X3) Date Survey Completed 04/05/2023
Name of Provider or Supplier Sovereign Medical Group, Llc	**Street Address, City, State** 631 Grand Street, Jersey City, NJ	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the lack of an Accession Log (AL), Histopathology Slides (HS) and Cytology Slides (CS) and interview with the Chief Operations Officer (COO), the laboratory failed to retain HS and CS from 5/12/21 to the date of survey. The finding includes: 1. Review of five patient records revealed five out of five patient slides were not available at the time of the survey. 2. The COO confirmed on 4/5/23 at 1:00 pm the slides were not retained.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the lack of Quality Control records (QC), Procedure Manual (PM) and interview with the Chief Operations Officer (COO), the laboratory failed to ensure that quality systems for the pre-analytical, analytic and post-analytical phases of

	Histopathology testing were monitored from 5/12/21 to the date of survey. 1. The laboratory failed to verify the accuracy of Histopathology. Cross Refer to D5217. 2. The laboratory failed to establish a detailed procedure for Biannual Assessment (BA) for Histopathology. Cross refer to D5291. 3. The laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing. Cross Refer to D5601.
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 the lack of Biannual Assessment (BA) records and interview with the Chief Operation Officer (COO), the laboratory failed to verify the accuracy of Histopathology, Cytology, Cytogenetics and Semen Analysis testing from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:00 pm that the laboratory did not perform BA for aforementioned sub-specialties.
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 the lack of a Procedure Manual and interview with the Chief Operation Officer (COO) the laboratory failed to establish detailed procedures for Biannual Assessment (BA) for Histopathology, Cytology, Cytogenetics and Semen Analysis from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:15 pm that the laboratory did not have BA procedures.
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 the lack of Laboratory Temperature Logs (DLL) and interview with the Chief Operations Officer (COO), the laboratory failed to monitor and document Room temperature, where Histopathology, Cytology, Cytogenetics and Semen Analysis tests

	are performed from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1: 35 pm that Room temperature was not documented .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of maintenance records and interview with the Chief Operations Officer (COO), the laboratory failed to perform and document annual maintenance on microscopes used in Histopathology, Cytology, Cytogenetics and Semen Analysis Testing from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:00 pm there was no documented evidence maintenance was performed on the microscopes.
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 the lack of Quality Control (QC) records and interview with the Chief Operations Officer (COO), the laboratory failed to perform and document QC on each day of patient Semen Analysis testing from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:10 pm that the laboratory did not perform QC on each day of patient Semen Analysis testing.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Chief Operations Officer (COO), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing from 5/12/21 to the date of

	the survey. The findings include: 1. The laboratory did not document H&E stain QC reactions during the time period stated above. 2. The laboratory read and reported approximately 2000 patients in the above time period. 3. The COO confirmed on 4/5 /23 at 1:30 pm that the laboratory did not document H&E QC stain reactions.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of Histopathology slides and interview with the Chief Operations Officer (COO), the laboratory failed to retain Quality Control (QC) Histology Slides (HS) from 5/12/21 to the date of the survey The COO confirmed on 4/5/23 at 1:15 pm that QC HS were not retained.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, lack of laboratory records and interview with the Chief Operations Officer (COO) the laboratory Director (LD), failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology from 5/12/21 to the date of the survey. Findings include: 1. The laboratory failed to provide written policies and procedures for an annual statistical evaluation of three required statistics for nongynecologic specimens. 2. The laboratory failed to provide an evaluation of three of three required statistics. Statistics include: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis to include unsatisfactory. 3. The COO confirmed on 4/5/23 at 1:50 pm the laboratory did not have the above procedures.
D5643	CYTOLOGY

	CFR(s): 493.1274(d)(2)(iii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM), Work Load log and interview with the Chief Operations Officer (COO), the laboratory failed to establish workload limits for personnel reading nongynecology slides from 5/12/21 to the day of the survey. The COO confirmed on 4/5/23 at 1:00 pm that workload limits were not established.
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 the lack of a Procedure Manual (PM), of Quality Control (QC) records, and interview with the Chief Operations Officer (COO) the laboratory failed to have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports on the date of survey. The COO confirmed on 4/5/23 at 1:00 pm that the laboratory failed to have available CA procedures.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the lack of an Accession Log (AL), Test Report (TR) and interview with the Chief Operations Officer (COO), the laboratory failed to maintain an accurate information system for Histopathology, Cytology, Cytogenetics and Semen Anaylsis tests from 5/21/21 to the date of survey. The COO confirmed at 1:30 pm on 4/5/23 that the laboratory did not maintain an accurate information system.
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 the lack of a the Procedure Manual (PM) and interview with the Chief Operations Officer (COO), the laboratory failed to establish written policies and procedures to monitor, assess and correct problems identified in the analytic system quality assessment from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:10 pm that they have no written policy for the above mentioned procedures and policies.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR), and interview with the Chief Operations Officer (COO), the laboratory failed to have accurate Reference Interval (RI) for Semen Analysis from 5/12/21 to the date of survey. The findings include: 1. A review of the FR revealed the RI for Motility, pH, and Sperm concentration was 1.5 - 5.0 ML 2. The COO confirmed on 4/5/23 at 1:00 pm that laboratory failed to have accurate RI.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 5/12/21 to the date of the survey. 1. The LD failed to ensure Biannual Assessment (BA) was performed to evaluate the laboratory's performance accurately. Cross refer to D6091. 2. The LD failed to ensure that the laboratory maintained a QC program. Cross refer to D6093. 3. the LD failed to ensure a Quality Assurance (QA) program was established. Cross refer to D6094. 4. The LD failed to ensure that the education and training records were available. Cross refer to D6102. 5. The LD failed to have an approved Procedure Manual. Cross refer to D6106. 6. The LD failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Cross Refer to D6107.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the lack of the Biannual Assessment (BA) records and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure BA was performed to evaluate the laboratory's performance accurately from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:00 pm the BA was not performed to evaluate the laboratory's performance accurately.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure that the laboratory maintained a QC program from 5/12/21 to the date of the survey. The findings include: 1. There was no documented evidence that a control slide was observed on each day of patient testing for histopathology testing. 2. There was no documented evidence cytology statistics were being monitored. 3. There was no documented evidence that a control slide was observed on each day of patient testing for Semen Morphology testing 4. The COO confirmed on 4/5/23 at 1:00 pm the laboratory did not ensure a QC program was maintained.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of a laboratory Procedure Manual (PM) and interview with the Chief Operations Officer (COO) , the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services for Histopathology, Cytology, Cytogenetics and Semen Analysis tests provided from 5/21/21 to the date of the survey. The COO confirmed on 4/5/23 at 1: 45 pm that a QA program was not established.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the lack of Personnel Records (PR) and interview with the Chief Operations Officer (COO), the Laboratory Director (LD) failed to ensure that the education and training records were available on the date of the survey. The COO confirmed on 4/5 /23 at 1:39 pm that the education and training records were not available.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Chief Operations Officer (COO), Laboratory Director (LD) failed to have an approved PM for Histopathology, Cytology, Cytogenetics and Semen Analysis testing from 5/12/21 to the date of the survey. The COO confirmed on 4/5/23 at 1:10 pm that the LD did not ensure an approved PM was available.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Chief Operations Officer (COO) the Laboratory Director (LD) failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, from 5/12/21 to the date of the survey. The COO confirmed on 4/5 /23 at 1:20 pm that the LD failed to specify in writing the responsibilities and duties of the aforementioned staff.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and

	(c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual and interview with the Chief Operations Officer (COO), the Technical Supervisor failed to establish the work load limit for examining slides and to reassess the work load limit every six months from 5/12/21 to the date of survey. The COO confirmed on 4/5/23 at 1:30 pm that work load limits were not established.