Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0717691	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sovereign Medical Group, Llc	15-01 Broadway Route -Suite #31 B - Route 4 West, Fair Lawn, 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
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 surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from August 2018 to the date of survey. The LD confirmed on 3/21 /19 at 11:00 am that a BA procedure was not established.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the Laboratory Director (LD), the laboratory failed to ensure that information from TR was transcribed accurately into the LIS for all tests from August 2018 to the date of the survey. The LD confirmed on 3/21/19 at 1:15 pm that the laboratory did not ensure information was transcribed accurately.

D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to established a written procedure on how transcribed information from test requisition into the laboratory information system will be monitored from August 2018 to the date of survey. The LD confirmed on 3/21/19 at 1:00 pm that the laboratory did not have the procedure mentioned above.
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 surveyor review of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to perform Hematoxylin and Eosin (H&E) stain Quality Control (QC) slide from August 2018 to the date of the survey. The LD confirmed on 3/21/19 at 11:25 am that the laboratory did not prepare H&E stain QC slide.
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 surveyor review of the Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the Test Report Date (TRD) was accurate into the MD Vision Laboratory Information System (LIS) of the facility from April 2017 to the date of survey. The LD confirmed on 3/21/19 at 1:55 pm that the TRD was not on correct on the FR of facility LIS.