Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2156058	02/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pelican Medical Group Llc	3706 Crondall Lane Suite 105b, Owings Mills, 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**
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 the alternate proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory did not ensure that the documentation of the alternate PT records included the date of testing, who performed the tests, the source of the samples sent for analysis and the name of the laboratory that performed the alternate PT. Findings: 1. According to the TS the alternate PT procedure requires the laboratory to retest 5 patient specimens along with 5 standards used for calibration of the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. These results are compared to the in-house testing 2. The alternate PT records from one event in 2019 were reviewed. The records did not include the date the specimens were tested in-house. The records did not included who performed the tests in-house. The source of the patient samples and standards tested in-house were not identified on any of the alternate PT records in ensure authenticity of the results that were compared. The worksheets did not include the name of the laboratory performing the PT. 3. During the survey on 01/28/2020 at 2:30 PM the TS confirmed that alternate PT records did not include the date of testing, name of the laboratory, who performed

	the tests, the source of the samples used for the alternate PT testing on the LC/MS /MS.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory's quality assessment system did not differentiate between the two laboratories using one liquid chromatography with tandem mass spectrometry (LC/MS /MS) analyzer. Findings: 1. According to the memo titled "Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group" Ref: QSO-18-20-CLIA dated July 20, 2018. Clarification of the Operation of Multiple Laboratories at the Same Location. "All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently." 2. The following laboratory records that were reviewed did not differentiate between the two laboratories: temperature charts, pipette calibration, maintenance records, personnel training and evaluations, alternated proficiency testing, and quality control results were printed separately but not labeled with the name of the laboratory. 3. During a phone conversation on 02/11/2020 at 2:11 PM the TS confirmed that the laboratory records listed above did not differentiate between the two laboratories sharing the same refrigerators, LC/MS/MS analyzer, personnel and space.
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 procedure manual and interview with the technical supervisor (TS), the laboratory's standard operating procedure manual (SOPM) did not include written instructions for all activities performed by the testing personnel. Findings: 1. After review of the SOPM and discussion with the TS the following procedures were not available in the SOPM: 2. The procedures labeled "8.3 Batch Acceptance Criteria" and "8.4 Analyte Identification Criteria" did not include written instructions for what to do when the testing failed to provide the acceptable results. There were no written directions to following when the criteria was not met by the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. 3. The procedure manual does not include written instructions for documenting when one or two of the negative calibrators are dropped from a daily run (calibration point exclusions). The documentation would provide the laboratory with information to investigate problems when the negative calibrators are dropped multiple times in a week or month. 4. The procedure manual does not have written instructions for how to identify and save daily computer analysis by the LC/MS/MS analyzer of the calibrators, quality control and patient results in the laboratory information system. 5. The procedure for corrected report did not include written instructions to print the original report, corrected report and save the documentation along with the investigation of the error found in reporting the result. 6. The procedure manual did not include written instructions for the documentation of the testing person who loads the sample onto the LC/MS/MS analyzer. 7. The laboratory's procedure manual includes a worksheet labeled "Monthly Report Check." The worksheet was reviewed and according to the TS the worksheet is used to document random review of patient resorts in the computer system. The worksheet did not identify what elements were being reviewed. 8. According to the TS this facility has multiple laboratories at the same physical location. The laboratory personnel competency records did not include the identify the laboratory being surveyed. 9. During the survey on 01/28/2020 at 2:30 PM the TS confirmed that the policy and procedure manual did not contain all the required written instructions for the laboratory staff.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the technical supervisor (TS), the laboratory did not ensure that the function checks for the digital balance was performed at the frequency required by the manufacture to provide quality laboratory services. Findings: 1. The laboratory records that were reviewed for November and December 2019 showed that there were no initial function checks performed on the digital balance. The operators manual was not available for reference. 2. The TS contacted the manufacturer of the digital balance on 01/31/2020 and they stated that the balance was to be checked each day of use with a weight to ensure it was functioning properly and when ever there were temperature changes. 3. During the phone conversation on 01/31/2020 at 4:03 PM the TS confirmed that the function checks were not being performed on the digital balance as required by the manufacture.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM), quality assurance (QA) records and interview with technical supervisor (TS), the laboratory did not establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. Findings: 1. The TS stated that the laboratory started reporting patient results on 11/04/2019. The TS provided documented QA reviews for the months of November and December 2019. The single page QA review included several topics discussed but did not clearly identify the specific records reviewed and found acceptable, e.g., temperature, maintenance, quality control... This QA review is shared during a meeting with the testing personnel and later reviewed and signed by the laboratory director. 2. During the survey on 01/28/2020 at 2:30 PM, the TS confirmed that the QA program did not specifically identify all the elements to be monitored and reviewed for the assessment of the post analytic systems in the laboratory.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM), worksheets and interview with the technical supervisor (TS), the laboratory director did not ensure that the written verification procedures included all the steps necessary for the completion of the verification of the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The SOPM instructions from the computer for the verification of the LC/MS/MS included worksheets for three days of testing. 2. The worksheets did not include written instructions for how to perform and document the verification of the LC/MS/MS analyzer. 3. The worksheets did not include the documentation of the testing person who performed testing on each of the three days of the verification of the LC/MS/MS analyzer. 4. The analyzer printouts from the computer for the LC/MS/MS indicated that the all the verification testing was performed on 07/03/2019. According to the TS the verification testing on the LC /MS/MS was performed on three consecutive days- 07/03, 07/04 and 07/05/2019. The records did not include accurate dates for testing. 5. According to the TS this facility has multiple laboratories at the same physical location. The verification records did not include the identify the laboratory being surveyed. 6. During the survey on 01/28 /2020 at 2:30 PM the TS confirmed that the SOPM worksheets did not include written instructions for how to perform and document the verification of the LC/MS/MS analyzer and that the records were missing testing personnel identity, dates of testing and the name of the laboratory being surveyed.

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 record review and interview with the technical supervisor, the laboratory director did not specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the the surrey on 01/28/2020 at 2:30 PM the technical supervisor confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the laboratory clinical consultant.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 initial training records, competency evaluations, laboratory records, and interview with the technical supervisor (TS), the TS did not ensure that the laboratory personnel competency records included the identify the laboratory being surveyed. Findings: 1. According to the TS this facility has multiple laboratories that operate at the same physical location and use the same testing personnel and equipment. 2. The laboratory personnel competency records did not identify the name of the laboratory being surveyed. 3. During the survey on 01/28/2020 at 2:30 PM the TS confirmed that the competency records did not identify the name of the laboratory being surveyed.