Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0921612	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mariano D Cibran Md Corp D/B/A	2701 54th Ave S, Saint Petersburg, 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	Mariano D Cibran MD Corp DBA St Petersburg Pediatric clinical laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories. Validation survey was conducted on 02/21/19. The following Condition was not met: D2016 Successful Participation 493.803(a)(b)(c).
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing and interview with the Technical Consultant the laboratory failed to have a satisfactory

	performance for 2 consecutive testing events (2nd and 3rd testing event in 2017) out of 6 testing events reviewed (1st, 2nd, 3rd in 2017 and 2018) in WBC diff (white blood cell differential). (See D2131).
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing and interview with the Technical Consultant the laboratory failed to score at least 80% in 1 testing events (3rd testing event in 2017) out of 6 testing events reviewed (1st, 2nd, 3rd in 2017 and 2018) in WBC (white blood cell). Findings Included: Review of the MLE proficiency testing revealed a score of 60% for WBC the 3rd testing event in 2017. Interview on 02/21/19 at 10:00 AM the Technical Consultant confirmed the proficiency testing failure.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing and interview with the Technical Consultant the laboratory failed to have a satisfactory performance for 2 consecutive testing events (2nd and 3rd testing event in 2017) out of 6 testing events reviewed (1st, 2nd, 3rd in 2017 and 2018) in WBC diff (white blood cell differential). Findings Included: Review of MLE proficiency testing revealed a score of 73% in the 2nd event in 2017 and a score of 66% in the 3rd testing event in 2017 for WBC diff. Interview on 02/21/19 at 10:00 AM with the Technical Consultant confirmed the proficiency testing failures.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of MLE (Medical Laboratory Evaluation) proficiency testing and interview with the Technical Consultant the laboratory failed to retain proficiency testing records for 1 testing events (1st testing event in 2017) out of 6 testing events reviewed (1st, 2nd, 3rd in 2017 and 2018). Findings Included: Review of MLE proficiency testing records revealed there was no attestation statement or the raw data printouts from the CBC (Complete Blood Count) analyzer. During an interview on 02 /21/19 at 11:00 AM, the Technical Consultant confirmed that the proficiency testing records were missing.

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 record review and interview with the Technical Consultant the laboratory failed to perform calibration verification on the CBC (complete blood count) analyzer at least every 6 months for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of the manufacturer's instructions (April 2012 version) for the CBC analyzer indicated that calibration verifications should be done at least every six months. Review of the calibration verifications revealed it was performed 02/14/17, 11/29/17 (9 months), and 03/06/18 (new CBC analyzer and the only calibration verification performed in 2018). Interview on 02/21/19 at 12:30 PM with the Technical Consultant confirmed that the calibration verification was not performed every 6 months per the manufacturer's instructions.