Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0986052	01/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Elvin R Garcia Md Pa	811 E Fern Ave Suite 1, Mcallen, TX	

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	The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director
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 the laboratory's API (American Proficiency Institute) proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) and confirmed in interview of facility personnel, it was determine that the laboratory had

	not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of Immunology. (refer to D2084 and D2085)
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 the laboratory's API (American Proficiency Institute) proficiency testing records and confirmed in interview with facility personnel, the laboratory failed to attain a score of at least 80% for each regulated analyte in the specialty of Immunology. The findings were: 1. Review of the laboratory's API records from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) revealed the laboratory received the following unacceptable scores: API 2017 - event 1, lab received a score of 60% for Anti-Streptolysin O API 2017 - event 1, lab received a score of 60% for Antinuclear Antibody API 2017 - event 3, lab received a score of 60% for Antinuclear Antibody API 2017 - event 3, lab received a score of 40% for Rheumatoid Factor 2. An interview with the technical consultant on 01/23/2018 at 1100 hours in the office manager's office confirmed the findings.
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) Failure to achieve satisfactory performance for the same analyte or test in 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 laboratory policy, the laboratory's API (American Proficiency Institute) proficiency testing records from 2016 (events 1,2, and 3) and 2017 (events 1, 2, and 3) and confirmed in interview of facility personnel, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance for Immunology. NOTE: Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings were: 1. API 2017-1st event lab received a score of 60% for ANA. 2. API 2017-3rd event lab received a score of 60% for ANA. 3. An interview with the technical consultant on 01/23/2018 at 1100 in the office manager's office confirmed the above scores.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(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 laboratory policy, the laboratory's API (American Proficiency Institute) proficiency testing records from 2016 (events 1,2, and 3) and 2017 (events 1, 2, and 3) and confirmed in interview of facility personnel, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance for Immunology. NOTE: Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing," approved by the laboratory director on 10/16 /2013, stated, "For the initial unsuccessful performance, when 2 out of 3 failures exist, the laboratory will follow all corrective action necessary to resolve the failure through appropriate training and/or technical assistance." 2. 2017 - 1st event laboratory received an unsatisfactory score of 73% for Immunology. 3. 2017 - 3rd event laboratory received an unsatisfactory score of 66% 4. An interview with the technical consultant on 01/23/2018 at 1100 hours in the office manager's office confirmed the findings.
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 the laboratory's API (American Proficiency Institute) proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing self-grading for proficiency testing results when the agency did not score the proficiency testing. The findings were: NOTE: The laboratory performed self-grading for the ungraded analytes on 10/23/2018 during the onsite survey. 1. Review of the laboratory's API proficiency testing records revealed the following scores: Immunology 2017 (event 3) Anti-SSA/SSB ANA11 - Not Graded (2) ANA14 - Not Graded (2) ANA15 - Not Graded (2) Antinuclear Antibody ANA114 - Not Graded (2) Immunology 2017 (event 2) Anti-RNP/Sm ANA07 - Not Graded (2) Anti-SSA/SSB ANA06 - Not Graded (2) ANA08 - Not Graded (2) ANA09 - Not Graded (2) Antinuclear Antibody ANA10 - Not Graded (2) Immunology 2017 (event 1) Anti-ds DNA ANA01 - Not Graded (2) Anti-RNP/Sm ANA02 - Not Graded (2) Immunology 2016 (event 2) Anti-RNP/SM ANA06 - Not Graded (2) Immunology 2016 (event 2) Antinuclear Antibody ANA08 - Not Graded (2) ANA10 - Not Graded (2) Immunology 2016 (event 3) Anti-RNP/Sm ANA14 - Not Graded (2) Immunology 2016 (event 3) Antinuclear Antibody ANA11 - Not Graded (2) ANA13 - Not Graded (2) 2. Further review of the proficiency testing records revealed, "2-No Consensus." The laboratory must perform self-grading. 3. The laboratory was asked to provide documentation of performing self-grading for the ungraded analytes. No documentation was provided. 4. An interview with the technical consultant on 01/23/2018 at 1100 hours in the office manager's office confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, review of the laboratory's quality control records, patient reports, and confirmed in interview of facility personnel, the laboratory failed to run at least two levels of quantitative controls each day of patient testing for Vitamin D and TSH (thyroid stimulating hormone) performed on the NanoEnTek FREND analyzer (Serial Number FAP170401-010). The findings were: 1. Review of the laboratory's policy, "Control Policy," approved by the laboratory director on 08/25/2008, stated, "For quantitative testing, two levels of control shall be run for every procedure on each day of use or for every eight hours of operation ..." 2. Review of the manufacturer's instructions for the Frend analyzer NESPI-FVAP-002EN(V.0.0) stated under, "External Quality Control Testing," " ...It is recommended that a minimum of two (2) levels of controls be run once per day on days when assaying patient samples ..." And; " ...Or another option may be adopted - Individualized Quality Control Plan (IQCP) is an all-inclusive approach to assuring the quality of the entire testing process." 3. Review of the laboratory's quality control records revealed external quality control testing was performed on the following dates: 10/23/2017 11/03/2017 12/29/2017 4. Review of patient results from 10/01/2017 (the date patient testing began) to 01/23/2018 (the date of the onsite survey) revealed the laboratory performed 31 patient TSH tests (see "TSH Patient Alias Report"). 5. Review of patient results from 10/01/2017 (the date patient testing began) to 01/23/2018 (the date of the onsite survey) revealed the laboratory performed 91 patient Vitamin D tests (see "Vitamin D Patient Alias Report"). 6. The laboratory was asked to provide documentation of performing at least 2 levels of quantitative controls each day of patient testing or an IQCP that would allow the laboratory to decrease the frequency of quality control testing. No documentation was provided. 7. An interview with the technical consultant on 01/23 /2018 at 1215 hours in the office manager's office confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, quality control records, patient results, and confirmed in interview of facility personnel, the laboratory's quality assurance policy failed to identify quality control testing for TSH and Vitamin D was being performed at an incorrect frequency (refer to D5447).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory services. (refer to D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and confirmed in interview of facility personnel, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. (refer to D2084)