

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0986052	(X3) Date Survey Completed 02/15/2022
Name of Provider or Supplier Dr Elvin R Garcia Md Pa	Street Address, City, State 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 laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director Note: The laboratory ceased testing of the specialty of Endocrinology; the specialty will be removed from the laboratory's CLIA certificate.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and confirmed in interview of laboratory personnel, the laboratory did not successfully participate in a proficiency testing</p>

	<p>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 for the analyte Anti-streptolysin O (refer to D2084).</p>
<p>D2075</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and confirmed in interview of laboratory personnel, the laboratory did not successfully participate 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 for the analyte Anti-streptolysin O (ASO). The findings included: 1. Review of the laboratory's proficiency testing records from API for Immunology 2020 and 2021 (events 1, 2, and 3) found the following unsatisfactory score: ASO (2020 event 2) Score of 0% (cross refer to D2077) ASO (2020 event 3) Score of 60% 2. An interview with the technical consultant on February 15, 2022 at 10:15 hours in the patient exam room confirmed the finding. He agreed that he was aware that the laboratory had an initial PT failure for ASO.</p>
<p>D2076</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and confirmed in interview of laboratory personnel, the laboratory failed to attain an overall score of at least 80% for each testing event in the specialty of general immunology. The findings included: 1. Review of the laboratory's proficiency testing records from API for Immunology 2020 and 2021 (events 1, 2, and 3) found the laboratory failed to attain an overall event score of at least 80%: ASO (2020 event 2) Score of 0% (failure to submit) 2. An interview with the technical consultant on February 15, 2022 at 10:15 hours in the patient exam room confirmed the finding. He agreed that he was aware that the laboratory had an initial PT failure for ASO.</p>
<p>D2077</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program</p>

within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and confirmed in interview of laboratory personnel, the laboratory failed to participate in 1 of 6 testing events reviewed for general immunology resulting in a score of 0%. The findings included: 1. Review of the laboratory's proficiency testing records from API for Immunology 2020 and 2021 (events 1, 2, and 3) found the laboratory failed to participate in the following event resulting in score of 0%: ASO (2020 event 2) Score of 0% 2. An interview with the technical consultant on February 15, 2022 at 10:15 hours in the patient exam room confirmed the finding. He agreed that he was aware that the laboratory had an initial PT failure for ASO.

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 the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and confirmed in interview of laboratory personnel, the laboratory failed to achieve satisfactory performance (80% or greater) for Antistreptolysin (ASO) in the specialty of immunology in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings included: 1. Review of the laboratory's proficiency testing records from API for Immunology 2020 and 2021 (events 1, 2, and 3) found the following unsatisfactory scores: ASO (2020 event 2) Score of 0% (cross refer to D2077) ASO (2020 event 3) Score of 60% 2. An interview with the technical consultant on February 15, 2022 at 10:15 hours in the patient exam room confirmed the finding. He agreed that he was aware that the laboratory had an initial PT failure for ASO.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on surveyor observation, review of manufacturer's instructions, review of patient test records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for test performance of Rheumatoid

Factor for 1 of 1 test performance event observed. The findings included: 1. Surveyor observation made on February 15, 2022 at 10:45 in the laboratory found testing personnel 2 (as listed on Form CMS-209) beginning patient test run for Rheumatoid Factor using Teco Diagnostics test kit. She did not spread controls or patient samples to the edge of the testing area. 2. Review of manufacturer's instructions for Teco Diagnostics Rheumatoid Factor test kit (RF/2018) under "Procedure", it stated, "Qualitative Test: 1. Bring reagents and specimens to room temperature before use. 2. Place one drop (50 l) of the RF Positive Control on field #1 of the glass slide. Place one drop (50 l) of the RF Negative Control on field #2. The remaining fields are used for test specimens. Using a pipette, place one drop of the undiluted specimens on successive fields. 3. Gently resuspend the RF Latex Reagent and add one drop to each test field. Use stir stick to spread reaction mixture over entire test field. 4. Rotate the slide manually or with a mechanical rotor at 80-100 rpm for 2 minutes and read immediately under direct light. 5. Presence of agglutination of the latex particle is a positive result (see figure 1). Agglutination indicates a RF concentration of equal or more than 8 IU/ml. Sera with positive agglutination should be run again with the Semi-Quantitative Test. 3. Review of patient test records for Specimen #51456 tested during the observed patient run found the result was negative. 4. The laboratory was asked to provide documentation of following the manufacturer's instructions for test performance on the Teco Diagnostics Rheumatoid Factor. No documentation was provided. 5. The findings were confirmed in interview with the laboratory director and technical consultant during the exit conference on February 15, 2022 at 13:00 hours in the patient exam room. Key: CMS - Centers for Medicare and Medicaid Services RF - Rheumatoid Factor IU/ml - international units per milliliter rpm - rotations per minute ul - microliter

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 surveyor observation, review of laboratory specimen and quality control worklist, review of patient records, and confirmed in interview of laboratory personnel, the laboratory's quality assurance program failed to identify and correct that the laboratory was resulting patient results using wrong lot numbers of quality control and latex reagent for 18 of 18 Rheumatoid Factor patient tests reviewed from February 7, 2022 through February 15, 2022 (the date of the survey). The findings included: 1. Surveyor observation performed on February 15, 2022 at 10:45 hours in the laboratory found testing personnel #2 (as listed on CMS-Form 209) performing a patient run of Rheumatoid Factor using the Teco Diagnostics test kit. Review of the kit contents opened on 02-07-2022): Positive Control: Lot 13735 (expiration date: 1-31-2024) Negative Control: Lot 89555 (expiration date: 12-23-2023) Latex Reagent: Lot 11183 (expiration date: 07-31-2023) 2. Review of the laboratory's specimen and quality control worklist for February 15, 2022 found the laboratory resulted patient results using a pre-filled worksheet. Review of the worksheet found the following lot numbers did not match those currently in use: Negative Control: Lot 86791 (expiration date: 03-17-2023) Latex Reagent: Lot 10961 (expiration date: 11-30-2022)

3. Review of patient records found the following patients were tested when the laboratory had not correctly documented the current lot number in use from February 7, 2022 through February 15, 2022: Sample ID: Date: Result: 51456 02-15-2022 Negative 51361 02-07-2022 Negative 51362 02-07-2022 Positive 51365 02-07-2022 Negative 51366 02-07-2022 Negative 51368 02-07-2022 Negative 51369 02-07-2022 Negative 51373 02-07-2022 Positive 51380 02-08-2022 Negative 51384 02-08-2022 Negative 51387 02-08-2022 Positive 51388 02-08-2022 Negative 51389 02-08-2022 Negative 51392 02-09-2022 Negative 51413 02-10-2022 Negative 51416 02-10-2022 Positive 51417 02-10-2022 Negative 51418 02-10-2022 Negative 4. The laboratory was asked to provide documentation of ensuring patient testing was performed using current lot numbers in use. No documentation was provided. 5. An interview with the technical consultant after his review of the records on February 15, 2022 at 11:45 hours in the patient exam room confirmed the findings.

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 performance, 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 proficiency testing results and confirmed in interview of laboratory 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)