

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0933357	(X3) Date Survey Completed 07/14/2025
Name of Provider or Supplier Guajira Family Clinic & Diabetes Care	Street Address, City, State 1900 S Jackson Rd Ste 9, 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	Based on a proficiency testing desk review survey performed on July 14, 2025, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute's proficiency reports, the laboratory failed to achieve satisfactory

	performance in two of two testing events for the specialty of endocrinology (refer to D2108) and the analyte of thyroid stimulating hormone (refer to D2107) resulting in an initial unsuccessful performance.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute's proficiency reports, the laboratory failed to achieve satisfactory performance for two of two events in 2025 for the analyte of thyroid stimulating hormone. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, the laboratory received the following unsatisfactory performances for thyroid stimulating hormone in two of two events: 2025 API 1st event 40% 2025 API 2nd event 20% 2. Based on review of the American Proficiency Institute's proficiency reports, the laboratory received the following unsatisfactory performances for thyroid stimulating hormone in two of two events: 2025 API 1st event 40% 2025 API 2nd event 20%
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) (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 the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute's proficiency reports, the laboratory failed to achieve satisfactory performance for two of two events in 2025 for the specialty endocrinology. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, the laboratory received the following unsatisfactory performances for the specialty of endocrinology in two of two events: 2025 API 1st event 40% 2025 API 2nd event 20% 2. Based on review of the American Proficiency Institute's proficiency reports, the laboratory received the following unsatisfactory performances for specialty endocrinology in two of two events: 2025 API 1st event 40% 2025 API 2nd event 20%
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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute's proficiency reports, 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)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute's proficiency reports, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for the specialty endocrinology (refer to D2108) and the analyte of thyroid stimulating hormone (refer to D2107) for two of two events in 2025, resulting in an initial unsuccessful performance.