

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0901468	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Alma S Rigonan Md Pa	Street Address, City, State 3318 S Alameda Street, Corpus Christi, 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	An announced validation survey was performed on February 6, 2024. 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	<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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) evaluation reports, and confirmed in interview with laboratory personnel, the laboratory failed to achieve satisfactory performance in two</p>

of two consecutive overall testing events for the subspecialty of Bacteriology in 2023, resulting in an initial unsuccessful performance (refer to D2028).

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

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, the laboratory's American Proficiency Institute (API) evaluation reports, and confirmed in interview with laboratory personnel, the laboratory failed to achieve satisfactory performance in two of two consecutive overall testing events for the subspecialty of Bacteriology in 2023. 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 subspecialty of Bacteriology in two of two consecutive events: 2023 API Bacteriology 1st event 0% 2023 API Bacteriology 2nd event 71% 2. Based on review of the laboratory's American Proficiency Institute (API) Comparative Evaluations, the laboratory received the following unsatisfactory performances for the subspecialty of Bacteriology in two of two consecutive events: 2023 API Bacteriology 1st event 0% 2023 API Bacteriology 2nd event 71% 3. In an interview at 11:22 hours on February 6, 2024, in the conference room, the technical consultant stated the laboratory was aware of the failures, had ceased testing for *Mycoplasma pneumoniae* for six months, performed two offsite successful events, and had reinstated testing about 1 week prior to the validation survey.

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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) evaluation reports, and confirmed in interview with laboratory personnel, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the subspecialty of Bacteriology in 2023 (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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory's American Proficiency Institute (API) evaluation reports, and confirmed in interview with laboratory personnel, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the subspecialty of Bacteriology in 2023, resulting in an initial unsuccessful performance (refer to D2028).