

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1020051	(X3) Date Survey Completed 08/15/2022
Name of Provider or Supplier Rm Lab Llc Dbc Express Lab	Street Address, City, State 7988 W Marigold St Ste 100, Boise, ID	
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
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 an off-site Proficiency Testing (PT) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (0155D), graded results from the College of American Pathologists (CAP) and a telephone interview with testing personnel on 8/10 /2022, the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) consecutive testing events for the specialty of General Immunology. See D2077, D2085</p>
D2077	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</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 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 an off-site Proficiency Testing (PT) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D), graded PT results from the College of American Pathologists (CAP) and a telephone interview with testing personnel on 8/10/2022, the laboratory failed to participate in two (2) of three (3) testing events in 2021 and 2022 for the specialty of general immunology. The findings include: 1. An off-site PT desk review of Report 155D and graded PT results from CAP identified that the laboratory failed to participate in testing for events three (3) in 2021 and one (1) in 2022 for the specialty of general immunology for the analyte Rubella. 2. A telephone interview with testing personnel on 8/10/2022 at 11:13 am confirmed the above findings.

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 an off-site Proficiency Testing (PT) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D), graded PT results from the College of American Pathologists (CAP) and a telephone interview with testing personnel on 8/10/2022, the laboratory failed to participate in two (2) of three (3) testing events in 2021 and 2022 for the specialty of general immunology. The findings include: 1. An off-site PT desk review of Report 155D and graded PT results from CAP identified that the laboratory failed to achieve overall satisfactory scores for events one (1) and three (3) in 2021 for the specialty general immunology analyte rubella. Analyte Year Event Score rubella 2021 3 0% rubella 2022 1 0% 2. A telephone interview with testing personnel on 8/10/2022 at 11:13 am confirmed the above findings.