

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2088100	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Gamma Healthcare Tyler	Street Address, City, State 2211 Roy Road Suite A, Tyler, 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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the Center of Medicare Services (CMS) national database and verified with the American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation for the CLIA program. The following Conditions of Participation were found to be out of compliance: 493.803 Successful participation (proficiency testing) .
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 an Individual Laboratory Profile (CASPER Report 0155D) dated 02-06-2020, confirmed by proficiency testing (PT) results provided by the American</p>

Proficiency Institute, the laboratory failed to successfully participate in an approved PT program for the specialty of diagnostic immunology in the second and third testing events of 2019. Refer to D2084. .

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 an Individual Laboratory Profile dated 02-06-2020, confirmed by API PT results, the laboratory failed to achieve satisfactory performance for two consecutive testing events in 2019 in the specialty of general immunology. Findings:
1. Review of the Individual Laboratory Profile report showed the following scores for the second and third testing events of 2019: Specialty: General Immunology Analyte Event Score Rheumatoid Factor 2019 2nd 60% Rheumatoid Factor (titer) 2019 2nd 20% Rheumatoid Factor 2019 3rd 40% Rheumatoid Factor (titer) 2019 3rd 0% 2. The above scores were confirmed by API.