

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0419924	<b>(X3) Date Survey Completed</b>  09/14/2022
<b>Name of Provider or Supplier</b>  Doctors General Laboratory	<b>Street Address, City, State</b>  59 Ogden Ave, Clarendon Hills, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 CASPER Report 0155D and interview with an American Association of Bioanalysts (AAB) representative the laboratory failed to successfully participate in proficiency testing (PT) for the routine chemistry analyte amylase during event three of 2021 and event one of 2022 (See D2096) and the endocrinology analyte thyroxine during events one and two of 2021 (See D2107).</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p>

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 CASPER Report 0155D and interview with an American Association of Bioanalysts (AAB) representative; the laboratory failed to successfully participate in proficiency testing (PT) for the routine chemistry analyte amylase during event three of 2021 and event one of 2022. Findings include: 1. Review of the CASPER Report 0155D ran on 9-1-2022 identified the initial unsuccessful PT performance for the specialty of chemistry for the analyte amylase. ROUTINE CHEMISTRY Amylase- EVENT-3, 2021 = 0% - Unsatisfactory Amylase- EVENT-1, 2022 = 0% - Unsatisfactory 2. A phone interview with the AAB PT representative on 09/01/2022, at 9:43 AM, confirmed the unsuccessful PT performance for amylase during event three of 2021 and event one of 2022.

**D2107**

**ENDOCRINOLOGY**

CFR(s): 493.843(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 CASPER Report 0155D and interview with an American Association of Bioanalysts (AAB) representative; the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte thyroxine (TT4) during events one and two of 2021. Findings include: 1. Review of the CASPER Report 0155D ran on 9-1-2022 identified the initial unsuccessful PT performance for the subspecialty of endocrinology analyte thyroxine (TT4). ENDOCRINOLOGY Thyroxine (TT4) - EVENT-1, 2021 = 0% - Unsatisfactory Thyroxine (TT4) - EVENT-2, 2021 = 0% - Unsatisfactory 2. A phone interview with the AAB PT representative on 09/01/2022, at 9:43 AM, confirmed the unsuccessful PT performance for thyroxine (TT4) during events one and two of 2021.