

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0984131	(X3) Date Survey Completed 05/13/2022
Name of Provider or Supplier Sudipta And Bindu Dey, Md, Inc	Street Address, City, State 127 Pines Bridge Rd, Beacon Falls, CT	
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 desk review of the 2021 and 2022 Chemistry Core proficiency testing (PT) results reported to the CLIA database by the PT provider, American Proficiency Institute (API) PT records, email communication and telephone interview with the technical consultant, the laboratory failed to successfully participate in two consecutive testing events in the specialty of Chemistry resulting in unsuccessful PT performance. Refer to citation D2097</p>
D2097	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p>

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 Proficiency Testing (PT) record review and email interview with technical consultant (TC) the laboratory failed to achieve successful performance for the same analyte in two consecutive PT events in the specialty of chemistry. Findings include:

1. Record review on 5/13/2022 of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D Report revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for two consecutive PT events for the regulated analyte # 0355 chloride (CL) as follows: Year/Event # PT Score 2021 Event 3 20% 2022 Event 1 60%
2. Record review on 6/14/2022 of the American Proficiency Institute (API) PT Chemistry Core Performance Summary revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores in two consecutive PT events for the regulated analyte # 0355 CL as evidenced below. Year /Event # PT score 2021 - Event -3 20% 2022 - Event -1 60%
3. Staff interview with the Technical Consultant on 6/7/2022 at 8:11 AM confirmed the above findings.
4. The laboratory performs 23,900 tests annually in the specialty of Chemistry.