

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0984131	(X3) Date Survey Completed 09/21/2022
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
D0000	A proficiency testing desk review of the Sudipta and Bindu Dey, MD Inc Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 Proficiency Testing (PT) data report (Report 155) and graded results from American Proficiency Institute (API), the laboratory failed to successfully participate in the regulated analyte chloride. The laboratory had unsatisfactory scores for the 3rd event 2021, the 1st event 2022 and the 2nd event 2022. Refer to D2096</p>

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(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 the Proficiency Testing (PT) data report (Report 155), graded results from American Proficiency Institute (API), and phone interview with the technical consultant, the laboratory failed to achieve satisfactory performance in three consecutive testing events for the chloride analyte and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings include: 1. API 2021 Event #3 for Chloride the score of 20% and was unsatisfactory. 2. API 2022 Event #1 for Chloride the score of 60% and was unsatisfactory. 3. API 2022 Event # 2 for Chloride the score of 20% and was unsatisfactory. 4. Phone interview on 09/21/2022 at 02:02 PM with the technical consultant(TC) confirmed the laboratory failed to achieve satisfactory performance for the chloride analyte in the last event 2021 and the first and second PT events in 2022. The TC further stated, " The laboratory is not testing the chloride analyte, and has not resumed testing since the failure of Event # 1 2022."

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 record review of 2021 Event #3 and 2022 Events # 1 & 2 of the American Proficiency Institute (API) proficiency testing (PT) results (3 testing events), the laboratory director failed to ensure effective remedial action was instituted in response to unsatisfactory PT results resulting in the second unsuccessful performance for the analyte chloride. Refer to D2016 & D2096