

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1038900	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Birth N' Beyond Llp	Street Address, City, State 600 Fitch Street, Suite 206, Elmira, NY	
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 Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) data and American Proficiency Institute (API) PT summary reports, the laboratory failed to successfully perform in the CMS approved PT program for the bacteriology test analyte. FINDINGS: The following scores were assigned: Bacteriology Test Analyte: 2023 Third Event = 60% 2024 First Event = 0% This is considered repeatedly unsuccessful PT performance.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</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 CMS PT data and API PT summary reports, the laboratory failed to achieve satisfactory performance for the bacteriology test analyte in two out of three consecutive testing events. FINDINGS: The following scores were assigned: Bacteriology Test Analyte: 2023 Third Event = 60% 2024 First Event = 0%

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 CMS PT data and API PT summary reports, the laboratory director (LD) failed to fulfill LD responsibilities and ensure that the laboratory achieved a satisfactory performance for the bacteriology test analyte as well as successfully participate in the CMS approved PT program. FINDINGS: The following scores were assigned: Bacteriology Test Analyte: 2023 Third Event = 60% 2024 First Event = 0%

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on CMS PT data and API PT summary reports, the LD failed to test the bacteriology test analyte as required as well as achieve a satisfactory performance in the CMS approved PT program. FINDINGS: The following scores were assigned: Bacteriology Test Analyte: 2023 Third Event = 60% 2024 First Event = 0%