

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0669482	(X3) Date Survey Completed 12/20/2022
Name of Provider or Supplier Together Women's Health	Street Address, City, State 39200 Garfield - B, Clinton Township, MI	
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 review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the sub-specialty of Bacteriology. Findings include: Review of the CMS database and the AAB proficiency testing reports showed unsatisfactory performance for 3 of 4 proficiency testing events. Refer to D2028 ***Repeat Deficiency from 5/03/2022 survey***</p>
D2028	BACTERIOLOGY

CFR(s): 493.823(e)

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 review of the CMS database and review of the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to achieve satisfactory performance for sub-specialty bacteriology throat/urine and urine culture identification in three out of four consecutive testing events. Findings include: Unsatisfactory performance for three out of four consecutive PT events constitutes a subsequent unsuccessful performance for throat/urine and urine culture identification. PT Event Score 3rd event 2021 71% 1st event 2022 68% 3rd event 2022 0%
Repeat Deficiency from 5/03/2022 survey

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

. Based on review of the CMS database and review of the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: Failure to ensure that the proficiency testing samples were tested as required under subpart H. Refer to D6089

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and review of the American Association of Bioanalysts proficiency testing reports, the director failed to ensure that the laboratory successfully participated in a proficiency testing program as required under subpart H. Findings include: The laboratory failed to achieve satisfactory performance for the sub-specialty bacteriology. Refer to D2016 and D2028.