

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0669482	(X3) Date Survey Completed 08/14/2019
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) final proficiency testing reports, it was determined that the laboratory failed to successfully participate in a CMS approved proficiency testing program for the chemistry analyte alanine aminotransferase (ALT). Findings include: Review of the CMS database and the AAB proficiency testing reports showed unsatisfactory performance for two of three proficiency testing events for the chemistry analyte: ALT. Refer to D2087 and D2096.</p>
D2087	ROUTINE CHEMISTRY

CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to attain a score of at least 80% of acceptable responses for the alanine aminotransferase (ALT) analyte, which is unsatisfactory performance for the testing events. Findings include: Unsatisfactory performance for two of three consecutive proficiency testing events constituting unsuccessful performance for ALT: PT event Score 3rd event 2018 60% 2nd event 2019 20%

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 CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the chemistry analyte alanine aminotransferase (ALT) in two of three consecutive testing events. Findings include: Unsatisfactory performance for two of three consecutive proficiency testing events constituting unsuccessful performance for ALT: PT event Score 3rd event 2018 60% 2nd event 2019 20%