Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2178760	10/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Whole Woman's Health Of South Bend	3511 Lincoln Way West, South Bend, IN	

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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on document review, the laboratory failed to successfully participate in the American Proficiency Institute (API) proficiency testing (PT) program for one analyte (D (Rho) Type) tested under one of one subspecialty (ABO Group and Resus Factor (Rh) Group) during PT testing event 1 in 2021 and testing event 2 in 2021. (Refer to D2162).
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)

	Failure to achieve satisfactory performance for the same analyte 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 document review, the laboratory failed to achieve a proficiency test (PT) score of 100% or higher for one of one analyte (D (Rho) Type) tested under one of one subspecialty (ABO Group and Resus Factor (Rh) Group) during two consecutive PT events (Events 1, 2021 and Event 2, 2021), resulting in unsatisfactory performance. Findings include: 1. Review of "CASPER Report 0155D" indicated the laboratory received unsatisfactory scores for the subspecialty of ABO Group and RH Group and the analyte D (RHO) Type in 2021: a) Event 1, 2021 = 80% b) Event 2, 2021 = 80% 2. Review of proficiency testing scores from American Proficiency Institute (API), indicated the laboratory performing PT for one analyte and received the following failing scores for 2021: a) D (Rho) Type Event 1, 2021 = 80% b) D (Rho) Type Event 2, 2021= 80%