

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0380673	(X3) Date Survey Completed 12/18/2023
Name of Provider or Supplier Born Clinic, P C	Street Address, City, State 3700 52nd Street Se, Grand Rapids, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to follow its direct wet mount preparation testing policy for 1 (Testing Personnel #7) of 9 testing personnel listed on Form CMS-209. Findings include: 1. The surveyor observed a bottle of Sternheimer-Malbin stain near the microscope on 12/18/23 at 9:49 am. 2. A review of the laboratory's "Vaginal Wet Prep and KOH Mount" procedure revealed a lack of use of the Sternheimer-Malbin stain. 3. An interview on 12/18/23 at 11:43 am with the Laboratory Director revealed Testing Personnel #7 had been using the Sternheimer-Malbin stain to visualize bacteria when performing direct wet mount preparation testing.</p>