

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0641549	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier Uab Ob/Gyn Research And Diagnostic Laboratory	Street Address, City, State 618 20th Street South, Ohb 365, 360, & 537, Birmingham, AL	
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
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual, validation of the Revogene Group B Streptococcus, and an interview with the Technical Supervisor, the laboratory failed to maintain a copy of the "Revogene Group B Streptococcus (GBS) Lim Broth (LB) Assay Procedure" with the date of initial use and the previous Laboratory Director's signature for review. The findings include: 1. A review of the Procedure Manual revealed the current Laboratory Director signed the Revogene Group B Streptococcus (GBS) Lim Broth (LB) Assay Procedure on 09/01/2020. 2. A review of the validation of the Revogene Group B Streptococcus revealed the previous Laboratory Director approved the validation on 11/20/2019 and patient testing started on 11/25/2019. 3. During an interview on 06/03/2021 at 4:30 PM, the Technical Supervisor stated she cleaned the Procedure Manual out before the survey and accidentally misplaced the original "Revogene Group B Streptococcus (GBS) Lim Broth (LB) Assay Procedure" which obtained the date of initial use and signature of the previous Laboratory Director.</p>