

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1106147	<b>(X3) Date Survey Completed</b>  06/11/2019
<b>Name of Provider or Supplier</b>  Beautiful Baby Conception Inc	<b>Street Address, City, State</b>  500 E Colorado Ave 4th Floor, Glendale, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on reviews and the lack of documentation for corrected action for a proficiency testing result from College of American Pathologist (CAP), and interview with the laboratory personnel, it was determined that the laboratory failed to all proficiency testing evaluation and verification activities must be documented. The findings included: a. Q1-2017, specimen SEM-02 CAP reported a result code 27 (Lack of participant or reference consensus) which the program indicated under "Actions Laboratories Should Take when a PT Result is Not Graded." CAP has a requirement under Actions Laboratories Should Take when a PT Result is Not Graded: "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (i.e., split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." b. For ten (10) out of ten (10) random patient test results reviewed covering the period from 1/4/2017 to 5/30/2019, the laboratory analyzed and reported approximately 75 qualitative (presence or absence of sperm) tests and the accuracy could not be assured. c. The laboratory personnel confirmed (6/11/2019, 1300) that the laboratory has no documentation of corrective action and has not established, or followed written policies and procedures to monitor and correct problems that may occur.</p>