

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2176775	(X3) Date Survey Completed 08/10/2020
Name of Provider or Supplier Conceptions Fertility Laboratories Llc	Street Address, City, State 2750 Sw 145th Ave Suite 103, Miramar, FL	
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
D0000	An initial certification survey conducted on 08/10/2020 found that Conceptions Fertility Laboratories LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document the initial competency assessment for 1 out of 1 Technical Supervisor (TS), 1 out of 1 General Supervisor (GS) and 2 out of 2 Testing Personnel (TP) after the laboratory started operations since March 2020. Findings include: 1) A review of CMS 209 form, Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 08/07/2020; revealed that: -The Laboratory Director and Clinical Consultant was the same person, the laboratory has 1 TS, 1 GS and 2 TP (A and B). - GS was also testing personnel (TP) A. 2) Review of employee folders revealed that they were missing the initial competency for TS, GS, and TP (A and B) after laboratory started operations on March 2020. During an interview on 08/07/202 at 11:30 AM, with TS, she confirmed that the laboratory failed to document the initial competency assessment for the positions listed above.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and</p>

identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's Semen Analysis Report failed to list the correct location, CLIA number and laboratory director, for the semen morphological evaluation performed for 2 out of 2 (# 1 and 2) patients report examined since the laboratory started operations in March 2020. Findings Include: Review of the Semen Analysis Report for patients # 1 (date 3/16/2020) and #2 (date 7/14/2020), showed that the address, CLIA number and laboratory director listed corresponded with the information for another facility, operated by the same group. During an interview on 8/10/2019 at 11:30 am, with Technical Supervisor, she confirmed that the Semen Analysis report failed to include the correct address, CLIA number and laboratory director.