Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1002114	05/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Center Of Reproductive Medicine	2344 Dowlen Road, Beaumont, TX	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: . Based on review of laboratory competency verification documents and staff interview, the laboratory failed to document competency verification for the technical consultant, technical supervisors 1 and 2, and general supervisors 1 and 2 (CMS form 209). Findings: 1. Personnel training and competency verification documentation was reviewed. Education materials and evidence of training were present for the technical consultant, technical supervisors 1 and 2, and general supervisors 1 and 2. (Note: the technical consultant, technical supervisor 2 and general supervisor 2 are the same person) Competency verification materials based on position responsiblities were not included. 2. In an interview at the site on 05-08-2019, technical supervisor 1 stated that no such documentation was present or could be made available during the survey. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	. Based on review of laboratory quality assessment (QA) documents for 2018 and 2019 and staff interview, the laboratory failed to follow its procedure for monthly documentation of quality parameter monitoring. 1. Laboratory QA documents were reviewed. Monthly logs of items monitored were present for all of 2018 and January of 2019. No log entries were found for February, March or April of 2019. 2. In an interview at the site on 05-08-2019, technical supervisor 1 stated that the monthly logs for 2019 had not been maintained due to an oversight by laboratory personnel. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on review of method verification documentation for the Roche E411 chemistry analyzer and staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the facility's patient population. Findings: 1. Method verification documentation for the Roche E411 analyzer was reviewed. In studies provided principally by the manufacturer's field service representative dated 09-12-2016, accuracy, precision and reportable range were addressed. 2. No evidence of reference range verification was included. In an interview at the site on 05-08-2019, technical supervisor 1 stated he was not aware that such a study had not been performed.