

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0994325	<b>(X3) Date Survey Completed</b>  07/17/2019
<b>Name of Provider or Supplier</b>  Advanced Reproductive Health Center Ltd	<b>Street Address, City, State</b>  3310 W Main St, Ste 175, Saint Charles, IL	
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>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies, procedures manuals, patient test records and interview with the technical supervisor; the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, correct problems identified in the postanalytic systems specified in 493.1291. Findings include: 1. Laboratory policies and procedures instruct personnel to do the following when reporting patients' test result: a. Front Desk staff will scan the original hard copies of report, semen preparation worksheet, Semen Acceptance Form, SIP form, doctor's referral, and copy of Driver's License into eIVF. b. Lab staff will verify that all records are scanned completely and accurately c. All reports will be verified against handwritten reports by the Laboratory Director or designee prior to release. d. Hard copy of records destroyed after Lab Staff verification. 2. At 2:30 PM on July 17, 2019, the technical supervisor stated that patients' records are scanned into eIVF, and personnel off site at one of their other laboratory locations verifies the information scanned into eIVF at the laboratory location being surveyed. 3. Review of 5 patients' records revealed, that there was an error in the patients first name on the final report for 1 of 5 patients' test records reviewed. 4. At 3:00 PM on July 17, 2019, the technical supervisor confirmed the surveyor's findings</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are</p>

established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, procedures manuals, patient's test records, quality assessment (QA) records and interview with the technical supervisor (TS); the laboratory director failed to ensure that the QA programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The laboratory's policy states, "The Technical Supervisor or Testing Personnel will print and audit five random IUI reports every month." 2. Review of QA records revealed that there was no documentation to show QAs were performed for 15 months, from October 2017 through January 2019. 3. At 3:00 PM on July 17, 2019, the TS confirmed the surveyor's findings.