

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2110095	(X3) Date Survey Completed 07/13/2022
Name of Provider or Supplier Gondra Center For Reproductive Care And	Street Address, City, State 20940 N Tatum Blvd, Ste B210, Phoenix, AZ	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on lack of policies presented for review related to pipette calibrations and interview with the facility personnel, the laboratory failed to establish a policy in regards to pipette calibrations for pipettes used for patient testing purposes. Findings include: 1. No policy was presented for review regarding the frequency and company services utilized for the calibration of the pipettes used for patient testing purposes. 2. The facility personnel acknowledged that there was no documented policy regarding the calibration of the pipettes. 3. The laboratory performs semen analysis testing on patient specimens with an approximate annual test volume of 300.</p>