

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2032666	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Rgi Mso Llc	Street Address, City, State 6674 Tippecanoe Rd, Suite 3, Canfield, OH	
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
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director, Testing Personnel (TP) #1 and TP#3, the Technical Supervisor (TS) failed to evaluate the competency of two out of three TP; TP#1 from 03/2022 to current and TP#3 from 07/2023 to current, to assure they were trained and maintained their competency to perform moderate and high complexity testing procedures and report test results promptly, accurately and proficiently. This deficient practice had the potential to affect all testing performed by TP#1 and TP#3 for patient sperm analysis (SA), sperm count (SC), presence/absence (p/a) of sperm in the specialty of Hematology and estradiol (E2), progesterone (P4), Lutenizing hormone (LH), follicular stimulating hormone (FSH) and serum human chorionic gonadotropin (bHCG) in the subspecialty of Endocrinology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 11/01/2023, found three individuals who were credentialed and listed as TP. 2. Review of the laboratory's "Reproductive Gynecology & Infertility Standard Operating Procedure Endocrinology Laboratory Quality Assurance" policy and procedure, approved by the Laboratory Director on 01/24/2023 (prior to the change in directorship on 10/03/2023) found the following statement: "1. Testing Personnel: Technical proficiency is monitored by proficiency testing, direct observation and annual competency assessment to objectively assess contribution to the job." 3. Review of the laboratory's "Laboratory</p>

General Standard Operating Procedures Elements of an Andrology Quality Assurance Program" policy and procedure, approved by the Laboratory Director on 09/15/2023 (prior to the change in directorship on 10/03/2023) found the following statements: "3. ...Each employee must demonstrate master, knowledge, competency and proficiency of each test before he/she is allowed to perform such test." "5. ...All personnel performing tests must demonstrate that their competency and proficiency is evaluated and documented annually for each test they perform." "8. ...All testing personnel shall undergo regular competency assessment to determine that their knowledge and technical abilities to perform assigned tests meet the laboratory's acceptable criteria."

4. Review of the laboratory's "Laboratory General Standard Operating Procedures Quality Management Plan" policy and procedure, approved by the Laboratory Director on 09/15/2023 (prior to the change in directorship on 10/03/2023) found the following statement: "2. Personnel:...All personnel are expected to and will participate in proficiency testing, both external and internal to assess their competency in testing." 5. Review of the laboratory's 2022 and 2023 competency assessment documentation, provided for the inspection, did not find that TP#1 and TP#3 had any orientation, training and competency assessments documented. 6. The Inspector requested the laboratory's documentation of orientation, training and competency assessments for TP#1 and TP#3 from the Laboratory Director, TP#1 and TP#3. TP#1 and TP#3 confirmed on 11/08/2023 at 1:10 PM and the Laboratory Director at 3:20 PM, that the laboratory did not have any orientation, training and competency assessment documentation for TP#1 and TP#3 from the time they started as TP at this laboratory location to current date and were unable to provide the requested documentation on the date of the inspection.