Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1075668	08/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rockville Gynecology Llc	15204 Omega Drive, Suite 200, Rockville, MD	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory failed to ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory had seven TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209) which was collected on the day of the survey who perform testing for Chlamydia trachomatis and Neisseria gonorrhoeae on the Cepheid GeneXpert system. 2. A review of microbiology PT attestation worksheets from six PT events from 2023 through 2025 showed that PT was performed by the same TP (TP #1) in six of six events. 3. During an interview on 07/25/2025 at 1:40 PM, the laboratory staff confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	Based on procedure manual review and interview with laboratory staff, the laboratory failed to ensure that the written procedure manual had one, consistent and accurate procedure which instructed testing personnel (TP) how to perform quality control (QC) on the Cepheid GeneXpert system. Findings: 1. The laboratory performs testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) on the Cepheid GeneXpert system. 2. Procedure manual review showed that there were two versions of the "Cepheid GeneXpert CT/NG Procedure" in the procedure manual. One version stated, "External controls are run (per IQCP) [Individualized Quality Control Plan]: Weekly" and the other version stated, "External negative [and positive] CT/NG control - run daily" There was one signature page showing that the laboratory director (LD) reviewed the procedure on 01/03/2025. 3. A review of the IQCP (signed by the LD on 03/08/2022) showed that QC for CT/NG were to be run "Weekly, for each new lot, for each new shipment, and each time a new operator performs test"; however a document titled, "Quality Control Procedure Review" (signed by the LD on 11/11 /2021) stated that "GeneXpert controls are to be run daily for Neisseria gonorrhoeae and Chlamydia trachomatis." 4. Further review showed that a document titled, "Quality Control Procedure Review" (signed by the LD on 11/11/2021) stated that "GeneXpert controls are to be run daily for Neisseria gonorrhoeae and Chlamydia trachomatis" and the "Quality Assurance" procedure listed "Run and record quality control" under "Daily" tasks. 5. During an interview on 07/25/2025 at 10:15 AM, TP #1 stated that QC is run monthly. A document/letter was found, signed on 10/19/2023 by the LD that stated that CT/NG controls were to be run "Once a month for each new lot for each new shipment." 6. Review of QC records from January through May 2024 and January through June 2025 showed that the laboratory was running QC monthly. 7. During an interview on 07/25/2025 at 1:40 PM, the laboratory staff confirmed that the procedure manual did not have one consistent procedure instructing the laboratory staff on how frequently to run QC on the Cepheid GeneXpert system.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of microbiology PT records from 2023 to 2025 showed that PT results (scores) received from the PT provider were not reviewed and signed by the LD for five out of six events. 2. During an interview on 07 /25/2025 at 1:40 PM TP #1 stated that they sent the LD a message when the laboratory passed their PT, however there was no documentation that the LD had personally reviewed microbiology PT results to evaluate the laboratory's performance. This was confirmed by the laboratory staff.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory director (LD) acting as the technical consultant (TC) failed to perform and document the competency assessment reviews on all testing personnel (TP) to ensure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings: 1. The laboratory had seven TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209) which was collected on the day of the survey. Five of seven TP had been performing testing in the laboratory for more than six months. 2. A review of competency assessment records from 2023 to 2025 showed that there were no annual competency records available for TP #1 for 2023. 3. The six month and annual competency assessments performed on four of four TP (TP #2, TP # 3, TP # 4, and TP #5) were performed and signed by TP #1. A review of TP's credentials showed that TP #1 did not qualify as a TC and could not perform the competency assessments. 4. During an interview on 07/25/2025 at 1:40 PM, the laboratory staff confirmed that the LD acting as the TC failed to personally evaluate the competency of all TP.