Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0668268	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wendover Ob/Gyn & Infertility, Inc	1908 Lendew Street, Greensboro, NC	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 API proficiency testing records and interview with the TC (technical consultant) on 2/28/24, the laboratory failed to evaluate ungraded and unacceptable proficiency testing results for 9 of 17 test events reviewed. Findings: Review of 2021, 2022, and 2023 API proficiency testing records revealed the laboratory failed to evaluate ungraded and unacceptable proficiency testing results on the following test events to ensure corrective action was taken and documented as needed: 1. 2022 2nd Chemistry Core - no evaluation of 3 ungraded quantitative hCG (humun chorionic gonadotropin) responses for samples HCG-07, HCG-09, HCG-10. 2. 2022 3rd Chemistry Core - no evaluation of 3 ungraded quantitative hCG responses for samples HCG-11, HCG-13, HCG-15. 3. 2022 2nd Hematology - no evaluation of ungraded wet prep response for sample VA-02. 4. 2022 3rd Hematology - no evaluation of unacceptable response for wet prep sample VA-03. 5. 2023 1st Chemistry Core - no evaluation of 3 ungraded quantitative hCG responses for samples HCG-01, HCG-02, HCG-05. 6. 2023 2nd Chemistry Core - no evaluation of 3 ungraded quantitative hCG responses for samples HCG-06, HCG-08, HCG-09. 7. 2023 3rd Chemistry Core - no evaluation of 3 ungraded quantitative hCG responses for samples HCG-12, HCG-14, HCG-15. 8. 2023 3rd Hematology - no evaluation of ungraded response for wet prep sample VA-03. 9. 2024 1st Chemistry Core - no evaluation of 3 ungraded quantitative hCG responses for samples HCG-02, HCG-03, HCG-04.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TC 2/28/24, the laboratory director failed to ensure that testing personnel competency evaluations were performed by personnel who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. Findings: Review of personnel records revealed that 2023 competency evaluations for 10 of 15 testing personnel (TP #5, TP #6, TP #7, TP #8, TP #9, TP #11, TP #12, TP #13, TP #14, TP #15) were performed by TP #10. Review of personnel records for TP #10 revealed that TP #10 has a high school diploma and does not meet the qualification requirements to serve as a technical consultant in a moderate complexity laboratory. During interview at approximately 12:45 p.m., the TC confirmed that competency evaluations for TP #5, TP #6, TP #7, TP #8, TP #9, TP #11, TP #12, TP #13, TP #14, and TP #15 were performed by TP #10.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 API proficiency testing records, review of 2022 email communication, review of 2021, 2022, and 2023 patient records, and interview with the TC 2/28/24, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for 2022 and 2023 for the molecular Neisseria gonorrhoeae and Chlamydia testing performed on the BD Max analyzer. Findings: 1. Review of 2021 API enrollment confirmation records revealed the laboratory was enrolled in proficiency testing for the molecular Neisseria gonorrhoeae and Chlamydia testing performed on the BD Max analyzer for the 3rd Microbiology event of 2021. 2. Review of 2022 API enrollment confirmation records revealed the laboratory had enrolled in proficiency testing for 2022 for the Vaginal Panel performed on the BD Max analyzer. Review of an email sent to API by the former TC revealed a request to cancel enrollment for the Vaginal Panel, stating the test was no longer performed by the laboratory. The laboratory did not participate in proficiency testing for the molecular Neisseria gonorrhoeae and Chlamydia testing performed on the BD Max analyzer in 2022. 3. Review of 2023 API enrollment confirmation

	records revealed the laboratory was not enrolled in proficiency testing for the molecular Neisseria gonorrhoeae and Chlamydia testing performed on the BD Max analyzer for 2023. 4. Review of 2021, 2022, and 2023 patient records revealed the laboratory performed patient Neisseria gonorrhoeae and Chlamydia testing on the BD Max analyzer during 2021, 2022, and 2023. During interview at approximately 9:00 a. m., the TC confirmed the laboratory did not receive proficiency samples for the molecular Neisseria gonorrhoeae and Chlamydia testing, and was not enrolled in proficiency testing for the molecular Neisseria gonorrhoeae and Chlamydia testing performed on the BD Max analyzer during 2023.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TC 2/28/24, the laboratory director failed to ensure that prior to testing patient specimens, 1 of 15 testing personnel (TP #13) had received appropriate training and had demonstrated the ability to perform all testing operations reliably to provide accurate patient test results. Findings: Review of personnel records revealed TP #13 was hired in September 2021. There were no training records for TP #13 available for review at the time of the survey. During interview at approximately 4:55 p.m., the TC confirmed there were no training records available for TP #13.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TC 2/28/24, the TC failed to perform and document an annual competency evaluation for 1 of 15 testing personnel (TP #10) during 2022. Findings: Review of personnel records records for TP #10 revealed TP #10 had competency evaluations in May 2021 and September 2023. There was no documentation of a competency evaluation in 2022 for TP #10. During interview at approximately 12:45 p.m., the TC confirmed that they were not able to find a 2022 competency evaluation for TP #10.