Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0715437	(X3) Date Survey Completed 02/05/2024
Name of Provider or Supplier Care-Clinics For Abortion & Reproductive Excellenc	**Street Address, City, State** 10401 Old Georgetown Road Suite 104, Bethesda, 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) 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 review of the proficiency testing (PT) procedure, review of patient testing logs, and interview with the testing person (TP), the laboratory failed to document the PT sample results in the same manner as patient results. Findings: 1. The laboratory performed Rh typing. Patient results were recorded in a daily log. 2. The "Proficiency Testing" procedure stated that "The staff member and samples run will also be documented on a laboratory log day sheet in the same manner as patient samples." 3. The daily patient logs were reviewed for 2023. 4. The laboratory submitted PT results for three events in 2023. None of the PT results were documented on the daily patient logs as patient results were. 5. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that the PT results were not documented on the daily patient logs in 2023.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by:

	Based on review of the manufacturer's product insert (PI) and interview with the testing person (TP), the laboratory failed to follow manufacturer's instructions for using a timer for the incubation step when performing patient Rh typing. Findings: 1. The laboratory used the ALBAclone Anti-D blend slide technique for patient Rh typing. 2. The "General Information" section of the PI stated "When a test is required to be incubated for a specific time period, a timer should be used" and the "Slide Technique" section of the PI stated to "incubate the test at 18-24 C for 5 minutes with occasional mixing." 3. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that the laboratory does not use a timer to time the 5 minute incubation step.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's product insert (PI), review of the daily testing logs, and interview with the testing person (TP), the laboratory failed to document the room temperature on days when patient Rh typing was performed. Findings: 1. The laboratory used the ALBAclone Anti-D blend slide technique for patient Rh typing. 2. The "Slide Technique" section of the PI stated to "incubate the test at 18-24 C for 5 minutes with occasional mixing." 3. The laboratory recorded all Rh testing information on a daily patient testing log. Logs were reviewed for 2023 and 2024. The log form template changed after 07/29/2023. 4. The logs from 07/29/2023 and before captured the daily room temperature. After 07/29/2023, the daily room temperature was no longer recorded. 5. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that the daily room temperature was no longer recorded after 07/29/2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the procedure, review of the daily patient testing logs, and interview with the testing person (TP), the laboratory failed to document the lot number and expiration date of the patient control used for Rh typing. Findings: 1. The laboratory tested ALBAcheck BGS Monoclonal Control with every patient as a control for spontaneous agglutination. 2. The laboratory recorded all Rh testing information on a daily patient testing log. Logs were reviewed for 2023 and 2024. The log form template changed after 07/29/2023. 3. The logs from 07/29/2023 and before included a section to document the lot number and expiration date of the BGS

	Monoclonal Control. After 07/29/2023, the logs did not include this section so the lot number and expiration date were no longer recorded. 4. During the survey on 02/05 /2024 at 12:15 PM, the TP confirmed that the lot number and expiration date of the ALBAcheck BGS Monclonal Control were no longer being recorded after 07/29 /2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's product insert (PI), review of the daily patient testing logs, and interview with the testing person (TP), the laboratory failed to record the results for the patient control used for Rh typing. Findings: 1. The laboratory used the ALBAclone Anti-D blend slide technique for patient Rh typing. 2. The laboratory tested ALBAcheck BGS Monoclonal Control with every patient as a control for spontaneous agglutination. 3. The PI for the Anti-D blend stated "If a control test for spontaneous agglutination is desired, ALBAcheck - BGS Monoclonal Control ...may be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation." 4. The laboratory recorded all Rh testing information on a daily patient testing log. Logs were reviewed for 2023 and 2024. The log form template changed after 07/29/2023. 5. The logs from 07/29/2023 and before included a section to document the patient results for the BGS Monoclonal Control. After 07/29/2023, the logs did not include this section so the patient control results were no longer recorded. 6. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that the patient results for the ALBAcheck BGS Monclonal Control were no longer being recorded after 07/29/2023.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the procedure, review of proficiency testing (PT) records, and interview with the testing person (TP), there was no documentation that the laboratory director (LD) reviewed the PT results evaluations. Findings: 1. The "Laboratory Director Responsibilities" procedure stated that the LD "will review all Proficiency Testing results with testing personnel and take corrective action when necessary." 2. Records for three PT events in 2023 were reviewed. 3. The results evaluation for the

	2nd event was not printed and reviewed and the results for the 1st and 3rd events were evaluated by the TP who is not qualified to be the technical consultant (TC). 4. There was no documentation that the LD, who is also the TC, reviewed the PT results for all three 2023 events. 5. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that the LD had not reviewed the PT results evaluations.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the procedure, review of laboratory records, and interview with the testing person (TP), there was no documentation that the laboratory director (LD) was reviewing laboratory records as stated in the procedure and maintaining the quality assurance (QA) program for patient Rh typing. Findings: 1. The "Laboratory Director Responsibilities" procedure stated that the LD "will perform routine testing audits for RH typing. The results of these audits will be shared with testing personnel along with appropriate retraining", "will review control test results, temperature records, and equipment records monthly and take corrective action when required", and "will report results of Quality Assurance activities to the testing personnel." 2. The "Quality Assurance" procedure stated that the LD "is responsible for the Quality Assurance Program and will continually and periodically evaluate testing personnel for accuracy, monitor testing control results, review environment and equipment status, follow frequency and progress of deviation reports, record appropriate information, and inform staff of any problems and/or changes." 3. There was no documentation demonstrating that the LD had performed routine Rh testing audits; reviewed quality control, temperature, and equipment records; or reviewed QA activities with the TP. 4. During the survey on 02/05/2024 at 12:15 PM, the TP confirmed that there was no documentation that the LD performed the QA duties listed in the procedure.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the testing personnel (TP), the laboratory director acting as the technical consultant failed to perform a six-month competency assessment on the TP. Findings: 1. The Laboratory Personnel Report (form CMS-209) listed two TP. 2. Both TP had documentation of initial training performed in February of 2023. 3. There were no records of a six-month competency assessment performed around August 2023. 4. During the survey on 02/05/2024 at 12:

	15 PM, the TP confirmed that a six-month competency assessment had not been performed for either of the TP.