Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2046630	01/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Maiden Lane Medical Pllcr	90 Maiden Lane, Third Floor, New York, NY	

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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, Quality Assessment (QA) & Quality Control (QC) procedures, lack of QA & sperm analysis QC records for the calendar years 2021 and 2022, and interview with the technical consultant and the primary testing person, the laboratory failed to retain the following documents and records for the calendar years 2021 and 2022. FINDINGS: 1. The laboratory failed to retain the QA records to include a review of the following records and documentation: Patient Test Management Relationship of Patient Information to Patient Test Results Procedure Manual Quality Control (QC) and Calibration Personnel Assessment Proficiency Testing (PT) Enrollment and Assessment and Comparison of Test Results Communication and Complaints Quality Assessment Review and Records 2. The laboratory failed to identify & take corrective action when the Quick Dip stain used for sperm morphology had expired on 3/22/2021. 3. Failure to enroll in an approved Proficiency testing (PT) program in 2021 and 2022 4. The technical consultant and primary laboratory testing person confirmed on January 13, 2023, at approximately 10: 00 AM the surveyor's findings regarding the lack of QA to retain the documents and records for the calendar years 2021 and 2022.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on review of the current laboratory procedure manual, 2023 QA records and an interview with the technical consultant and the primary testing person, the laboratory failed to follow the established QA policy and perform a monthly QA review for the calendar years 2021 and 2022. FINDINGS: 1. The Written QA policy states that a monthly review of all records & documents pertaining to the following is performed monthly: Patient Test Management Relationship of Patient Information to Patient Test Results Procedure Manual Quality Control (QC) and Calibration Personnel Assessment Proficiency Testing (PT) Enrollment and Assessment and Comparison of Test Results Communication and Complaints Quality Assessment Review and Records 2. Surveyor reviewed the 1/6/2023 QA reviewed but do to the lack of QA records for the calendar years 2021 and 2022 could not determine if the laboratory identified problems, issues and performed corrective action. 3. The primary testing confirmed that the laboratory failed to record the stains quality for the Rapid Differential stain used for sperm morphology for 2021, 2022 through survey date. 3. The technical consultant and the primary testing person, confirmed on January 13, 2023, at approximately 10:30 AM, that the laboratory failed to follow established QA policy and perform a monthly QA review for the calendar years 2021 and 2022.
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 direct observation of the Rapid Differential Stain bottles and confirmation with the technical consultant and primary testing, the laboratory failed to ensure that stain used for sperm morphology did not exceed the expiration dates. FINDINGS: 1. Fixative Lot #9080 Expiration date 3/21/2021 2. Dye Lot#9079 Expiration date 3/20 /2021 3. Wright -Geimsa Lot#9081 Expiration date 3/22/2021 4. The laboratory tested and reported 822 patient samples for sperm morphology using the expired Rapid Quick stain from 3/23/2021 through survey date.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory procedure manual manual, QC records, QA documentation and confirmed in an interview with technical consultant and primary testing person, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. maintain the QC program for sperm morphology, refer to D6020; 2.

	maintained their written QA policy for all phases of laboratory testing, refer to D6021; 3. take all necessary remedial & corrective actions when issues & problems are identified, refer to D6024.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of sperm analysis procedure, lack of QC record for sperm morphology and and confirmed in an interview with the technical consultant and primary testing person, at the time of this survey, the laboratory director failed to ensure that the QC program for sperm morphology was maintained to assure the quality of laboratory services. Refer to D3039 and D5417
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 laboratory's QA policy, lack of QA documentation for 2021 & 2022 and confirmed in an interview with the technical consultant and primary testing person, the laboratory director failed to follow the establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D3039, D5291, and D5417.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by:

	Based on the review of laboratory QC, calibration records and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D 3039, D5291 and D5417.