Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2115146	02/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Assisted Reproductive Labs	9817 N 95th St, Bldg I, Ste 107, Scottsdale, AZ	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review, direct observation of patient specimens and interview with the facility personnel, the laboratory failed to establish policies and procedures for specimen labeling. Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry, with an approximate annual test volume of 4,000. 2. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures regarding specimen labeling. The laboratory uses an electronically generated specimen label which is placed on each blood tube tested by the laboratory. The specimen label contains only the patient name and date of birth. 3. During the survey conducted on February 3, 2022, direct observation of patient specimens revealed the laboratory failed to include the unique 4-digit patient ID on the specimen tube label. The facility personnel stated that a unique 4-digit patient ID is manually entered into the Tosoh analyzer as each specimen is placed on the analyzer for testing. This unique patient ID is also included on each patient test report. 4. Direct observation of the electronically generated label on each patient specimen revealed the specimen label failed to include the date and time of specimen collection. This information was not maintained in any other laboratory record, including the EMR (Electronic Medical Record). 5. The

	facility personnel confirmed the laboratory did not have policies and procedures regarding specimen labeling in place at the time of the survey conducted on February 3, 2022.
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 laboratory's temperature logs and interview with the laboratory personnel, (A) the laboratory failed to establish an acceptable range for the room temperature, humidity and refrigerators used by the laboratory and (B) failed to document the humidity of the laboratory during 2021. Findings include: 1. The laboratory performs testing in the specialty of Chemistry with an approximate annual test volume of 4,000. The laboratory utilizes the Tosoh AIA-360 analyzer to perform patient testing. A1. No documentation was presented for review during the survey conducted on February 3, 2022 to indicate the laboratory established acceptable temperature ranges for the room temperature where patient testing is conducted, the refrigerator where test reagents are stored and the humidity of the laboratory, as required by the instrument manufacturer. A2. The manufacturer's system specifications for the Tosoh AIA-360 instrument reviewed during the survey indicates a required room temperature of 15 to 30 degrees Celsius and a humidity range of 40-80%. A3. The facility personnel confirmed that the laboratory failed to establish a policy or maintain a log that indicates the acceptable room temperature range, refrigerator temperature range and humidity range for the area where patient is performed. B1. No records were presented for review during the survey to indicate the laboratory monitored the humidity of the laboratory where patient testing occurred from August 2021 through the date of the survey conducted on February 3, 2022. B2. The facility personnel acknowledged that the laboratory failed to monitor and document the humidity of the room where patient testing occurred from August 2021 through February 3, 2022.