| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2164222 | 11/30/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Life Ivf Center Los Angeles | 289 W Huntington Dr Ste 400, Arcadia, CA | |

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** |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) College of American Pathologists (CAP) records and policy and interview with the testing personnel, the laboratory failed to document the handling, preparation, processing, examination, and each step in the testing, reporting, testing failures, and corrective action of results for all proficiency testing samples. The laboratory failed to maintain a copy of all records including; a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing, the attestation statement provided by the PT program signed by the analyst performing the tests and the laboratory director, documentation that proficiency testing samples were tested in the same manner as patient specimens and kept available for a minimum of two years from the date of the proficiency testing event. Findings included: 1. The laboratory was unable to produce 2021 and 2022 proficiency testing attestation sheets with the testing personnel signatures and the laboratory director signatures, PT testing records, preventive maintenance, function checks, quality control, and competency of staff performing PT samples testing. 2. The laboratory could not locate the proficiency testing worksheets, |

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| | or the results review forms signed off by the laboratory director or designee. 3. On November 30, 2022, at approximately 11:30 a.m. the testing personnel confirmed by interview these findings described in 1 and 2 above. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of documentation, review of testing personnel competency assessment records, and interview with the testing personnel (TP) on November 30, 2022, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the TP competency for the years 2021 and 2022. Findings include: 1. Based on review of the laboratory's policies and procedure and competency evaluations' records the laboratory failed to establish and follow written policies and procedures for competency assessment of the TP. 2. The laboratory fail to provide documentation of training and competency assessment for the TP performing Endocrinology moderate complexity sample processing and testing at the laboratory for the years 2021 and 2022. 4. This deficient practice was affirmed by interview with the TP on November 30, 2022, at approximately 12:15 p.m. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation on the lack of calibrated thermometers in the refrigerator and freezer to verify digital temperature readings and interviews with the testing personnel (TP), it was determined that the laboratory failed to monitor the digital temperature readings of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, November 30, 2022, based on observation and interview with the TP the laboratory failed to have calibrated thermometers on the refrigerator and freezer that verify accurate digital thermometers readings which affect reagents and patients' samples testing. 2. The TP confirmed on 11/30/2022, at approximately 12:00 p.m. that the laboratory has no calibrated thermometers in the refrigerator and freezer to verify digital temperature readings. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 5,934 samples annually. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1407(e)(4)(i)<br><br>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory's proficiency testing (PT) records, and interview with the laboratory testing personnel on November 30, 2022, at approximately 11:30 a.m. it was determined that the laboratory director failed to ensure that PT samples were tested as required under subpart H. of this part. The findings include: D2015. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of all laboratory personnel competency evaluations for the years 2021 and 2022, the lack of signed and dated laboratory written policies and procedures for proficiency testing, lack of calibrated thermometers to verify digital temperature readings, and interview with the testing personnel; the laboratory director failed to ensure that policies and procedures are established and followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D2015, D5209, D5413, and D6046. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on lack of documentation for competency assessments for the year 2021 and 2022 and interview with the testing personnel; it was determined that the technical consultant/director failed to perform and document the performance evaluation of all testing personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: see D5209. |