

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2002949	(X3) Date Survey Completed 05/12/2023
Name of Provider or Supplier Boston Ivf, Llc	Street Address, City, State 778 Main Street, So Portland, ME	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the Laboratory Director (LD) had not signed the procedure manual. Findings include: 1. Record review of the laboratory procedure manual on 5/12/2023 revealed no signature since 2012 by the LD. 2. Record review of the laboratory "Quality Management Policy" on 5/12/2023 revealed: "The lab director will review and approve new policies and procedures and substantial changes prior to implementation.", "All protocols... are reviewed by the appropriate supervisory staff and lab director every year." and, "Annual procedure review... GS, TS with LD sign off". 3. Staff interview with Technical Supervisor (TS) on 5/12/2023 at 10:00 AM confirmed the LD had not signed subsequent updates in the procedure manual since 2012. 4. The laboratory performs 4600 tests annually in the specialty of Chemistry and 400 tests annually in the specialty of Hematology.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Technical Supervisor #1 (TS1),</p>

the laboratory failed to document routine maintenance and function checks on the Roche Cobas E411 Chemistry analyzer. Findings include: 1. Record review of the E411 "Weekly/Monthly Maintenance Record" on 5/12/2023 revealed the manufacturer's "Bi-Weekly" maintenance incomplete for 5 months between April 2021 and April 2023. 2. Interview with TS1 on 5/12/2023 at 9:30AM confirmed the above findings. 3. The laboratory performs 4600 tests per year in the specialty of Chemistry.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to evaluate the competency of one of two new testing personnel (TP) semiannually during the first year of patient testing. Findings include: 1. Record review on 5/12/2023 of the laboratory's 2021, 2022 and 2023 TP competency records revealed, TP#1 hired on 3/1/2021 had only 1 competency evaluation completed on 12/15/2022. 2. Staff interview with the Technical Supervisor on 5/12/2023 at 11:00 AM confirmed the above findings. 3. The laboratory performs 4600 tests annually in the specialty of Chemistry and 400 tests annually in the specialty of Hematology.