

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0925097	(X3) Date Survey Completed 12/18/2025
Name of Provider or Supplier Plano Ivf, Llc	Street Address, City, State 6300 W Parker Road Suite #G-26, Plano, TX	
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
D0000	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on December 18, 2025.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory patient worksheets, patient final reports, and interview, the laboratory failed to ensure the processing of patient samples followed the laboratory policy when no sperm is noted in the initial microscopic examination for two of two random patients reviewed in April and May 2025. The findings included: 1. Review of the laboratory policy titled "Semen Analysis", section 6 "Procedure", subsection c "Microscopic Examination" included the following instructions for specimen processing when no sperm is noted on the initial slide review: "2. If no sperm are observed in the raw sample, the sample should be centrifuged at 400 g for 10 minutes and the bottom 0.1 ml of medium/sample obtained from the tip of the centrifuged conical tube examined for the presence of individual sperm cells. Sperm Motility: Manually count the percent of motile (1 or more progressive motility) sperm as described above. Evaluate within one hour of collection ..." 2. Review of two of five random patient worksheets and final reports included the following two patients with an initial sperm count of 0: Patient ID 25-401 testing performed on 04/22/2025 Patient ID 25-451 testing performed on 05/01/2025 Review of the laboratory worksheet comments included the following annotation for each patient: 0 Sperm Centrifuge 0 Sperm Review of the patient's final report included</p>

following information under the comment section: "No sperm noted during initial analysis or after centrifugation for 10 minutes @1800xg" 3. On 12/18/2025 at 11:13 hours, in the laboratory, the surveyor asked testing personnel (TP) to show the centrifuge setting at which a semen analysis with a zero initial sperm count would be spun at. TP1 stated that the laboratory would centrifuge the specimen at 3,000 RPM for 10 minutes before attempting to perform a second count. 4. In an interview on 12/18/25 at 11:25 hours, in the office, the laboratory director confirmed the processing of patient samples with an initial sperm count of zero had not been centrifuged at 400g as outlined by the laboratory policy.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 manufacturer's instructions for use, laboratory policy, laboratory quality control records, patient testing records, and confirmed in interview, the laboratory failed to ensure quality control for manual sperm counts were acceptable before performing and resulting patient testing for 59 of 78 days reviewed in May, June, July, and September 2025 The findings included: 1. Review of the laboratory QC instructions for use (IFU) titled "accu-beads - A Quality Control Check for Automated and Manual Sperm Counting Methods", section "Manual Counting Procedures" included the following instructions: "4. Calculate the bead concentration according to the chamber manufacturer's instructions. 5. Count another aliquot of the same sample. The results should be within 10% of each other to be considered valid." 2. Review of the laboratory policy titled "Semen Analysis Quality Control (Accu-beads)", section "Quality control" stated the following: ".. When counting each side of the counting chamber, for each control, the counts must be within 10% of each other. If this does not occur, then the affected control must be repeated." 3. Review of patient test records and the laboratory "Accubeads" daily quality control log for manual sperm counts for May, June, July, and September 2025, included the following 59 days and 163 patients, with a manual sperm count performed, when one or more quality control level percent difference (% Difference) were greater than or equal to 10%: May 2025: 14 out of 21 days of testing where one or both QC level(s) were outside of a 10% difference. 05/02/2025 QC Level; Count one, Count two: % Difference QC Level 1; 34.7, 39.06: 12.56% The following patient had testing performed; 25-453 05/06/2025 QC Level; Count one, Count two: % Difference QC Level 1; 39.06, 33.6: 13.98% QC Level 2; 18.45, 20.6: 11.65% The following two patients had testing performed: 25-461, 25-463 05/07/2025 QC Level; Count one, Count two: % Difference QC Level 2; 14.1, 16.27: 15.39% The following patient had testing performed: 25-465 05/08/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.36, 15.19: 12.50% The following patient had testing performed: 25-472 05/09/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.28, 19.53: 19.96% The following four patients had testing performed: 25-476, 25-477, 25-478, 25-479 05/13/2025 QC Level; Count one, Count two: % Difference QC Level2; 19.53, 15.19: 22.22% The following four patients had testing performed: 25-487, 25-489, 25-490, 25-491 05/14/2025 QC Level; Count one, Count two, % Difference QC Level 2; 20.6, 18.44: 10.49% The following two patients had testing performed; 25-494, 25-500 05/15/2025 QC Level; Count one, Count two: % Difference QC Level 2; 18.44, 20.6: 11.71% The

following four patients had testing performed; 25-502, 25-504, 25-506, 25-508 05/20/2025 QC Level; Count one, Count two: % Difference QC Level 1; 41.2, 36.9: 10.44% QC Level 2; 17.36, 20.6: 18.66% The following three patients had testing performed: 25-518, 25-519, 25-520 05/23/2025 QC Level; Count one, Count two, % Difference QC Level 1; 32.55, 42.3: 29.95% QC Level 2; 16.2, 20.6: 27.16% The following patient had testing performed; 25-536 05/27/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.36, 19.53: 12.50% The following five patients had testing performed: 25-540, 25-541, 25-543, 25-544, 25-545 05/28/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.27, 19.53: 20.04% The following two patients had testing performed: 25-548, 25-549 05/29/2025 QC Level; Count one, Count two: % Difference QC Level 2; 20.6, 17.36: 15.73% The following three patients had testing performed: 25-550, 25-551, 25-554 June 2025 15 days of testing 20 days of testing where one or both QC level(s) were outside of a 10% difference. 06/04/2025 QC Level; Count one, Count two: % Difference QC Level 1; 39.06, 35.8: 8.35% QC Level 2; 20.6, 18.44: 10.49% The following four patients had testing performed: 25-575, 25-576, 25-578, 25-578, 25-579 06/05/2025 QC Level; Count one, Count two: % Difference QC Level 1; 37.98, 35.8: 5.74% QC Level 2; 19.53, 16.3: 16.54% The following four patients had testing performed: 25-585, 25-589, 25-587, 25-589 06/06/2025 QC Level; Count one, Count two: % Difference QC Level 1; 34.7, 41.2: 18.73% QC Level 2; 15.19, 20.6: 35.62% The following patient had testing performed: 25-591 06/09/2025 QC Level; Count one, Count two: % Difference QC Level 1; 32.55, 34.72: 6.67% QC Level 2; 16.27, 19.53: 20.04% The following five patients had testing performed: 25-594, 25-595, 25-596, 25-597, 25-598 06/10/2025 QC Level; Count one, Count two: % Difference QC Level 1; 39.06, 35.8: 8.35% QC Level 2; 20.6, 17.36: 15.73% The following four patients had testing performed: 25-600, 25-601, 25-602, 25-603 06/11/2025 QC Level; Count one, Count two: % Difference QC Level 1; 35.8, 40.1: 12.01% QC Level 2; 17.36, 19.53: 12.50% The following patient had testing performed: 25-606 06/12/2025 QC Level; Count one, Count two: % Difference QC Level 2; 20.6, 17.4: 15.53% The following four patients had testing performed: 25-609, 25-610, 25-611, 25-612 06/16/2025 QC Level; Count one, Count two: % Difference QC Level 1; 41.23, 36.9: 10.50% The following three patients had testing performed: 25-616, 25-617, 25-618 06/17/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.28, 19.5: 19.78% The following two patients had testing performed: 25-620, 25-624 06/18/2025 QC Level; Count one, Count two: % Difference QC Level 1; 35.8, 40.1: 12.01% QC Level 2; 17.36, 15.19: 12.50% The following patient had testing performed: 25-627 06/19/2025 QC Level; Count one, Count two: % Difference QC Level 1; 36.9, 41.2: 11.65 % The following three patients had testing performed: 25-629, 25-631, 25-632 06/20/2025 QC Level; Count one, Count two: % Difference QC Level 2; 20.6, 17.36: 15.73% The following patient had testing performed: 25-637 06/25/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.3, 20.6: 26.38% The following three patients had testing performed: 25-640, 25-642, 25-643 06/26/2025 QC Level; Count one, Count two: % Difference QC Level 1; 36.9, 32.6: 11.65% QC Level 2; 19.5, 15.19: 22.10% The following six patients had testing performed: 25-644, 25-645, 25-648, 25-649, 25-650, 25-651 06/30/2025 QC Level; Count one, Count two: % Difference QC Level 2; 18.4, 20.6: 11.96% The following seven patients had testing performed: 25-653, 25-654, 25-656, 25-657, 25-658, 25-660, 25-661 July 2025: 14 out of 18 days of testing where one or both QC level(s) were outside of a 10% difference. 07/01/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.4, 19.5: 12.07% The following two patients had testing performed: 25, 663, 25-664 07/02/2025 QC Level; Count one, Count two: % Difference QC Level 2; 20.6, 18.44: 10.49% The following three patients had testing performed: 25-665, 25-666, 25-670 07/07/2025 QC Level; Count one, Count two: % Difference QC Level 1; 39.06, 33.6:

13.98% The following seven patients had testing performed: 25-679, 25-680, 25-681, 25-682, 25-683, 25-684, 25-685 07/08/2025 QC Level; Count one, Count two: % Difference QC Level 2; 18.44, 15.19: 17.62% The following patient had testing performed: 25-686 07/09/2025 QC Level; Count one, Count two: % Difference QC Level 1; 40.1, 33.6: 16.21% QC Level 2; 20.6, 17.36: 15.73% The following three patients had testing performed: 25-687, 25-688, 25-689 07/10/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.4, 20.6: 18.39% The following four patients had testing performed: 25-691, 25-692, 25-693, 25-694 07/11/2025 QC Level; Count one, Count two: % Difference QC Level 1; 33.6, 37.98: 13.04% QC Level 2; 16.3, 20.6: 26.38% The following patient had testing performed: 25-697 07/14/2025 QC Level; Count one, Count two: % Difference QC Level 1; 41.2, 36.9: 10.44% The following two patients had testing performed: 25-699, 25-700 07/15/2025 QC Level; Count one, Count two: % Difference QC Level 1; 34.7, 39.06: 12.56% QC Level 2; 14.1, 17.36: 23.12% The following patient had testing performed: 25-703 07/21/2025 QC Level; Count one, Count two: % Difference QC Level 2; 20.6, 17.36: 15.73% The following five patients had testing performed: 25-719, 25-721, 25-722, 25-723, 25-724 07/24/2025 QC Level; Count one, Count two: % Difference QC Level 1; 35.8, 41.2: 15.08% The following patient had testing performed: 25-740 07/28/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.28, 19.53: 19.96% The following four patients had testing performed: 25-747, 25-748, 25-749, 25-750 07/30/2025 QC Level; Count one, Count two: % Difference QC Level 1; 40.1, 33.6: 16.21% QC Level 2; 16.27, 19.5: 19.85% The following five patients had testing performed: 25-758, 25-759, 25-760, 25-762, 25-763 07/31/2025 QC Level; Count one, Count two: % Difference QC Level 1; 42.3, 36.89: 12.79% QC Level 2; 19.5, 17.4: 10.77% The following four patients had testing performed: 25-764, 25-765, 25-766, 25-767 September 2025 16 out of days of testing where one or both QC level(s) were outside of a 10% difference. 09/03/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.3, 18.4: 12.88% The following patient had testing performed: 25-894 09/04/2025 QC Level; Count one, Count two: % Difference QC Level 1; 40.1, 33.6: 16.21% QC Level 2; 20.6, 18.4: 10.68% The following five patients had testing performed: 25-900, 25-901, 25-902, 25-903, 25-904 09/05/2025 QC Level; Count one, Count two: % Difference QC Level 1; 42.3, 36.89: 12.79% The following patient had testing performed: 25-907 09/08/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.36, 19.53: 12.50% The following three patients had testing performed: 25-912, 25-913, 25-924 09/09/2025 QC Level; Count one, Count two: % Difference QC Level 2; 16.3, 19.5: 19.63% The following five patients had testing performed: 25-915, 25-918, 25-917, 25-919, 25-920 09/10/2025 QC Level; Count one, Count two: % Difference QC Level 1; 35.8, 42.3: 18.16% QC Level 2; 20.6, 16.3: 20.87% The following three patients had testing performed: 25-923, 25-924, 25-925 09/11/2025 QC Level; Count one, Count two: % Difference QC Level 1; 41.2, 35.8: 13.11% The following two patients had testing performed: 25-928, 25-930 09/15/2025 QC Level; Count one, Count two: % Difference QC Level 2; 18, 16: 11.11% The following three patients had testing performed: 25-934, 25-935, 25-936, 25-937, 25-938 09/17/2025 QC Level; Count one, Count two: % Difference QC Level 1; 42.3, 36.59: 13.50% QC Level 2; 18.4, 21.7: 17.93% The following two patients had testing performed: 25-948, 25-949 09/18/2025 QC Level; Count one, Count two: % Difference QC Level 1; 36.9, 30.4: 17.62% QC Level 2; 18.4, 20.6: 11.96% The following patient had testing performed: 25-954 09/23/2025 QC Level; Count one, Count two: % Difference QC Level 2; 17.36, 20.6: 18.66% The following patient had testing performed: 25-963 09/24/2025 QC Level; Count one, Count two: % Difference QC Level 1; 41.2, 34.7: 15.78% QC Level 2; 14.1, 18.44: 30.78% The following three patients had testing performed: 25-969, 25-970, 25-971 09/25/2025 QC Level; Count one, Count two: % Difference QC Level 1; 36.89, 42.3: 14.67% QC

Level 2; 20.6, 16.3: 20.87% The following patient had testing performed: 25-978 09/26/2025 QC Level; Count one, Count two: % Difference QC Level 1; 40.1, 35.8: 10.72% QC Level 2; 19.5, 17.36: 10.97% The following patient had testing performed: 25-978 09/29/2025 QC Level; Count one, Count two: % Difference QC Level 1; 33.6, 39.06: 16.25% The following two patients had testing performed: 25-982, 25-983 09/30/2025 QC Level; Count one, Count two: % Difference QC Level 1; 42.3, 36.89: 12.79% QC Level 2; 17.36, 20.6: 18.66% The following four patients had testing performed: 25-985, 25-986, 25-987, 25-989 4. In an interview on 12/18/2025 at 10:55 hours, in the office, the laboratory director confirmed that testing personnel did not ensure that the duplicate counts for each QC level were within 10% of each other before accepting the quality control results, testing, and resulting patient sperm counts.