

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2240452	<b>(X3) Date Survey Completed</b> 01/24/2023
<b>Name of Provider or Supplier</b> Westlake Ivf Andrology/North	<b>Street Address, City, State</b> 7700 Cat Hollow Dr Suite 105, Round Rock, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies and procedures, observation, and interview, the laboratory failed to follow manufacturer's instructions using the Makler Counting Chamber used to perform Semen Analysis for one of one sample observed. Findings follow. A. Review of the Makler Counting Chamber package insert, no revision date, under Method of Performing Semen Analysis stated, "Mix the specimen well, taking care to avoid formation of bubbles. With the aid of a wooden rod or a pipette, place a small drop in the center of the disc area. Grasp the cover glass with your fingers opposite the black dots and immediately place the cover glass on the four pins. Press gently, looking again for the appearance of the color fringes. The drop will spread on the entire area of the disc into a thickness of 10 microns. Some surplus does not interfere with proper analysis as long as the tips are not flooded. Once the cover glass is in place, avoid touching, lifting and covering again, as this may change the uniform spread of sperm within the Chamber." And under Special Cases stated, "Bubbles: If bubbles appear in the grid area, it is recommended that the drop be replaced by another one, unless the bubbles are too small to interfere with the analysis..." B. The laboratory's policy and procedure titled Andrology Protocols Semen Analysis, Revision 11/25/22, did not address recovering</p>

the chamber. C. Surveyor observed on January 24, 2023, at 1430 hours in the laboratory testing personnel #2, as listed on the CMS form 209, perform a semen analysis on chart #24063. Testing personnel #2 looked at the counting chamber under the microscope with the sample, removed the chamber from the microscope and reset the cover glass. D. Interview on January 24, 2023, at 1435 hours in the laboratory with testing personnel#2 acknowledged she reset the coverslip to remove a bubble [on the counting chamber]. Interview on January 24, 2023, at 1445 hours in the laboratory with the Laboratory Director confirmed that they should not be doing that.