

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2095249	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Agape Pain Management & Anesthesia Llc	Street Address, City, State 2170 E Lohman Ave Suite C, Las Cruces, NM	
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	An onsite recertification survey conducted on May 14, 2025, at Agape Pain Management & Anesthesia found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements.
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 the laboratory's "Specimen Rejection Criteria" and "Laboratory Record Retention" policies, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to follow its own policy to maintain a log for rejected specimens in 2024 and 2025. Findings include: 1. Review of the laboratory's "Specimen Rejection Criteria" policy stated, "All rejected specimens will have the reason for rejection documented in the specific laboratory log." 2. Review of the laboratory's "Laboratory Record Retention" policy stated lab logs and worksheets are "stored and readily accessible for 2 (two) years". 3. A request was made for documentation showing records of rejected specimens, none was provided. 4. An interview on 05/14/2025 at 2:11 pm with TC confirmed the above findings. 5. The laboratory reports 2700 toxicology tests annually.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) 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</p>

within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

I. Based on review of Immunalysis Methamphetamine Urine HEIA (MUH) manufacturer's instructions (MI), Immunalysis SEFRIA Fentanyl Urine (SFU) MI, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to follow the manufacturer's instructions to centrifuge highly turbid urine specimens before toxicology testing in 2024 and 2025. Findings include: 1. Review of MUH MI and SFU MI indicated "Highly turbid specimens should be centrifuged before analysis." 2. The laboratory was asked to provide a policy that covers processing highly turbid urine specimens for methamphetamine and fentanyl testing, none was provided. 3. The laboratory was asked to provide evidence that highly turbid urine specimens are centrifuged before analysis, none was provided. 4. During an interview on 05/14/2025 at 2:03 pm, the TC stated the laboratory "does not have a low-speed centrifuge for processing turbid specimens", which confirms the above findings. 5. The laboratory reports 2,700 toxicology tests annually. II. Based on review of IMMTOX 270 manufacturer's instructions, the laboratory's "Laboratory Maintenance" policy, the laboratory's temperatures and humidity log, and interview with the Technical Consultant (TC) the laboratory failed to follow manufacturer's instructions by failing to maintain humidity requirements for the IMMTOX 270 for three of three months reviewed in 2024. Findings Include: 1. Review of IMMTOX 270 manufacturer's instructions stated, "Room humidity should be 35-80%RH, and no condensation." 2. Review of the laboratory's "Laboratory Maintenance" policy indicated a room humidity requirement of 15-85% 3. A random review of the laboratory's temperature and humidity log showed the room humidity was below 35% for 15 of 15 recorded days in February 2024, 11 of 11 recorded days in June 2024, and 17 of 17 days in November 2024. 4. Interview on 05/14/2025 at 10:20 am with the TC confirmed the above findings. 5. The laboratory reports 2,700 toxicology tests annually.