Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505747	03/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Austin Regional Clinic At Seton Nw	11111 Research Blvd Suite 485, Austin, 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	A validation survey was conducted at Austin Regional Clinic at Seton NW on March 17, 2026. The laboratory was found NOT to be in compliance with the following condition level deficiencies: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality control (QC), testing records, test reports, and interview the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems in Hematology. Findings included: 1. The laboratory failed to perform, in duplicate, one control each 8 hours of operation for patient testing of manual sperm counts performed for 32 out of 32 days in 2025 (refer to D5543).
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality control (QC), testing records, test reports, and interview, the laboratory failed to perform, in duplicate, one control each 8 hours of operation for patient testing of manual sperm counts performed for 32 out of 32 days in 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Control Policy, approved 06/11/2019, stated, "Quality control testing is performed to ensure the patient test results performed are accurate and can be used to diagnose and treat patients. All staff are included in the competency assessment process. Competency assessment evaluates the individual's ability to perform testing by assuring accurate and reliable laboratory results. Some or all of the following are documented to ensure quality control of results: Maintenance of microscopes annually Training Proficiency testing participation Direct Observation Competency Competency Quizzes Review of Procedure Continuing Education" There was no procedure for performing QC beads. B. QC records for testing QC beads was requested on March 17, 2025 at 1320 hours in the laboratory but not provided. C. Review of testing performed in 2025 showed the following patients were tested on the following dates of service as listed by Date of Service and Sample ID # without any controls: Date of Service Sample ID 1. 01/09 /2025 22619485 2. 01/20/2025 22665830 3. 01/31/2025 22717322 4. 02/21/2025 22813860, 22813098 5. 02/28/2025 22844002, 22845299 6. 03/04/2025 22858877 7. 03/05/2025 22865142 8. 03/11/2025 22888085 9. 03/14/2025 22906018 10. 04/15 /2025 23032202 11. 05/06/2025 23122209, 23121961 12. 06/11/2025 23268658 13. 06 /13/2025 23279794 14. 07/15/2025 23399908 15. 08/07/2025 23497352 16. 08/15 /2025 23531536 17. 08/18/2025 23540303 18. 08/25/2025 23570785 19. 08/29/2025 23593614 20. 09/08/2025 23627876 21. 09/25/2025 23705635 22. 10/08/2025 23760165 23. 10/14/2025 23784481 24. 10/17/2025 23801957 25. 11/04/2025 23878514 26. 11/06/2025 23888731 27. 11/10/2025 23902275 28. 11/14/2025 23926963 29. 11/17/2025 23933941 30. 11/18/2025 23939182 31. 11/21/2025 23957960 32. 12/12/2025 24041544 D. Random review of six patient test reports from the list verified sperm counts were reported as listed by Date of Service and Sample ID #: 1. 01/09/2025 22619485 2. 02/28/2025 22845299 3. 05/06/2025 23121961 4. 08/25/2025 23570785 5. 11/04/2025 23878514 6. 12/12/2025 24041544 E. Interview with the General Supervisor (on the CMS form 209) on March 17, 2025 at 1320 hours in the laboratory confirmed they did not perform QC on manual sperm counts. Interview with the Administrative Laboratory Director for Austin Regional Clinic on March 17, 2025 at 1330 hours in the conference room confirmed they were unaware QC beads were available for manual sperm counts.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical consultant failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for two of two providers performing the provider performed microscopy procedure (PPMP) fern testing. Findings follow. A. Review of the laboratory's policy

	and procedure titled ARC Competency Program, effective 07/03/2017, stated, "All laboratory staff is included in the competency assessment process, ranging from personnel involved in specimen collection and processing to those responsible for supervision and compliance. Competency assessments should occur every six months for the first year and annually thereafter for all testing personnel, supervisors, and technical consultants." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #7 & 8 (as listed on the CMS form 209) began testing 10/01/2024. C. Semi-annual competency evaluations for testing personnel #7 & 8 were requested on March 17, 2026 at 1045 hours but not provided. D. Interview with Technical Supervisor on March 17, 2026 at 1045 hours confirmed semi-annual competency evaluations were not performed in the first year.