

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2081515	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Southwest Texas Two Medical Group, PLLC	Street Address, City, State 1509 Town Center Dr, Pflugerville, 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	Based on an announced validation inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of the test reports, interview, and pre-survey paperwork, the laboratory failed to ensure the name of the facility and report date were on the test reports for eight of eight reports reviewed from Oct 2021 - Feb 2023 for 16 of 16 months reviewed. Findings follow. A. Random review of eight testosterone test reports from Oct 2021 - Feb 2023 showed no facility name or report date on the test reports as listed by date of service and Medical Record Number (MRN): Date MRN 1. 02/21/23 43868 2. 12/26/22 253371 3. 10/28/22 186055 4. 08/15/22 241670 5. 07/05/22 238357 6. 03/23/22 229622 7. 01/19/22 225112 8. 10/15/21 218800 B. Interview with the Operation's Manager on April 26, 2023 at 1610 hours in the patient room confirmed the findings. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed the laboratory performed approximately 3000 testosterone tests annually.</p>