

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0504798	(X3) Date Survey Completed 10/19/2018
Name of Provider or Supplier Amg Seton Women's Health-Central Lamar	Street Address, City, State 1004 West 32nd St Suite 100, 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	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
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 a review of patient records and interview with facility personnel, the laboratory failed to include the name and address of the laboratory location where the test was performed on 10 of 10 randomly reviewed patient specimens. The findings included: 1. The following patient final reports were reviewed: Patient - Date specimen was collected PT: 602209 - 4/23/2018 PT: 583262 - 4/30/2018 PT: 629742 - 4/2/2018 PT: 12267 - 7/30/2018 PT: 639438 - 7/11/2018 PT: 7184 - 7/9/2018 PT: 628863 - 9/6/2018 PT: 618850 - 8/16/2018 PT: 627034 - 8/15/2018 The patient final reports listed above had the statement "In-house testing" and the results for testing on the BD Affirm in the boxes below this text. At the top of the page, an address that did not match the location of the laboratory was printed. 2. In an in interview at 10:53 hours on 10/19/2018 in the office, the Technical Consultant stated the patient reports</p>

did not have the name and address of the laboratory that performed the testing and that the address printed at the top of the result form belonged to an affiliated facility that did not perform laboratory testing.