Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0674230	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Brookside Women's Medical Services	1902 S Ih 35 Frontage Rd, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, observation and interview, the laboratory failed to label their Saline vial, used to test Wet Prep solutions for the identification of clue cells, yeast, and trichomonas, to include lot number, pour over date and expiration date, as applicable. Findings follow. Review of the laboratory's Wet Mount (Prep) procedure on page 2 stated, "Normal saline and KOH solutions must be replaced monthly. Each new bottle must be labeled with the name of the solution and the expiration date." Surveyor observed on March 9, 2021 at 1030 hours in the laboratory a vial labeled "Saline" on the counter next to the microscope. Interview with testing personnel #1, on the CMS form 209, on March 9, 2021 at 1030 hours in the laboratory confirmed the Saline was used for Wet Preps and was missing any additional information.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, patient test reports and interview, the laboratory failed to include all the results of the Wet Prep used for the identification of clue cells, yeast, and trichomonas for 1 of 3 test reports reviewed. Findings follow. Review of the laboratory procedure Wet Mount (Prep) stated, "a wet mount test provides a fast and convenient method for screening for vaginal infections such as yeast, trichomonas, and bacterial vaginosis." Review of the Wet Prep patient test reports showed a test report from 03/09/2021 was missing the results of "Monilla" for yeast and Clue Cells. Interview with testing personnel #1, on the CMS form 209, on March 9, 2021 at 1145 hours in the office confirmed the results were missing on the test report.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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: Review of the CMS report 209 Laboratory Personnel Report, personnel files and interview of facility personnel found that the technical consultant failed to perform competency assessments at least semiannually during the first year of patient testing for one of 11 testing personnel performing Rh testing. Findings were as follows: 1. Review of the The CMS report 209 Laboratory Personnel Report found the laboratory listed 11 testing personnel performing non-waived testing. 2. Review of personnel files found that testing person four had an initial hire date of 09/04/2019. Testing person 4 completed initial training for Rh testing on 09/04/2019. One competency assessment dated 04/02/2020 was included in the personnel file with no other competency assessments available for review 2. Interview of testing person one conducted on March 9, 2021 at 10:30 AM confirmed that competency assessments for testing persons 4 were not performed at least semiannually during the first year of patient testing.