Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0674230	11/04/2022
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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, observation, interview, and patient testing logs, the laboratory failed to perform the Osom Trichomonas Rapid Test correctly when they failed to use the rayon cotton swabs from the test kit for three of three Trichomonas patient tests performed in 2022. Findings follow. A. Review of the package insert for the Sekisui Osom Trichomonas Rapid Test, 11/2021, under Specimen Collection and Preparation stated, "Collect specimens from the vaginal cavity with a sterile rayon swab from the test kit. Use of the swabs supplied in the kit or BD BBL CultureSwab (sterile or with Liquid Stuarts Media) is recommended. Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended." B. Surveyor observed on October 21, 2022, at 1600 hours in the laboratory the Sekisui Osom Trichomonas Test kit had 25 rayon swabs in the kit, but only 22 test tubes. The kit was Lot 221122, expiration

	07/31/2023. C. Interview with testing personnel #2 on the CMS form 209, on October 21, 2022, at 1600 hours in the laboratory acknowledged they ordered swabs in bulk for the clinic and used those for the test. She presented the surveyor with the swabs used for the test, a Puritan Sterile Cotton Tipped Applicator with a wooden shaft. D. Review of the patient testing logs from Jan - Oct 2022 showed three patient tests were performed on 08/04/2022 and 08/31/2022. II. Based on review of the manufacturer's instructions, observation, quality control (QC) records, and interview, the laboratory failed to perform external quality control for the Sekisui Osom Trichomonas Rapid Test for one of one open test kits in 2022. Findings follow. A. Review of the package insert for the Sekisui Osom Trichomonas Rapid Test, 11/2021, under External Quality Control stated, "Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, and with each new untrained operator." B. Surveyor observed on October 21, 2022, at 1600 in the laboratory the Sekisui Osom Trichomonas Test kit had 22 tests remaining out of a kit of 25 tests, and the positive control swab was still in the kit (a rayon swab served as the negative control). The kit was Lot 221122, expiration 07/31/2023, and had no QC information on the box. C. Review of the patient testing logs that included the controls run for various tests from Jan - Oct 2022 showed QC was not performed on the kit. The three patient tests were performed on 08/04/2022 and 08/31/2022. D. Interview with testing personnel #2 on October 21, 2022, at 1615 hours in the counseling room confirmed they only ordered one box at a time, and QC was not performed on the kit. III. Based on review of the manufacturer's instructions, observation, and interview, the laboratory failed to follow manufacturer's instructions for the urinalysis and hCG quality control (QC) testing and use a separate set of vials for the urinalysis and hCG QC. Findings follow. A. Review of the package insert for the Quantimetrix Dipper Urinalysis Dipstick Control Level 1 & 2, under Procedure for Dipstick Testing stated, "Caution Once control fluid is removed for hCG or confirmatory testing that control tube must not be used for dipstick immersion testing. Once a control tube is used for dipstick immersion testing, it must not be used for hCG or confirmatory testing." B. Surveyor observed on October 21, 2022, at 1520 hours in the laboratory two sets of unlabeled QC vials in the box. C. Interview with testing personnel #2 on October 21, 2022, at 1520 hours in the laboratory confirmed they used the same vials for urinalysis and hCG testing. KEY: hCG = human Chorionic Gonadotropin
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, test reports, pre-survey documents, observation, and interview, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast. Findings follow. A. Review of the laboratory's textbook procedure from Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd Edition, 1990, Chapter 179, Tests on Vaginal Discharge, under Technique stated, "Place the sample in 1 ml of saline and agitate to mix. Take a drop of this mixture and place it on a slide... cover with a cover slip.... The slide may be warmed briefly (to increase motility of trichomonas) and should be

	looked at promptly. A careful search of several fields should be made at both medium and high power for trichomonas, clue cells, and yeast. Trichomonas are motile flagellated organisms about the size of a white blood cell (WBC). They are best recognized by their characteristic twisting motion. Clue cells are vaginal epithelial cells with adherent coccobacilli. Yeast may be seen as budding or hyphal forms, and may be seen best with the addition of potassium hydroxide. Lastly, the presence or absence of a large number of leukocytes should be noted. A few may be normal, but more than 10 per high-power field is abnormal. An additional [drop] should be ... placed on a slide. Add a drop of 10% potassium hydroxide (KOH) and cover with a cover slip... The slide should then be examined carefully for the presence of budding yeast or hyphae. The pH of the vaginal secretions can be obtained by placing a sample from the lateral wall of the vagina on pH paper. The paper should include a range of pH from 4.0 to above 5.0. The normal pH is 4.5 or less. The whiff test is a test for the fishy odor that occurs in bacterial vaginosis (previously called Gardnerella vaginitis and nonspecific vaginitis). A drop of KOH is mixed with some vaginal discharge. A positive test is abnormal and consists of a characteristic fishy odor." B. Review of the laboratory's policy and procedure titled, Wet Prep/Mount stated, "1. During the exam, the doctor (or nurse, medical assistant, etc,) will collect a small amount of the patient's vaginal discharge using a non-sterile cotton swab. 2. Place the sab into a centrifuge tube and take it to the lab for evaluation. 3. Rub the swab on a small amount of pH paper to determine the pH level. 4. With the swab in the tube, add 3-4 drops of saline. 5. Mix the swab around in the saline to moisten the specimen. 6. Rub the swab on a slide. 7. Place a cover slip on top. 8. Evaluate the slide under the microscope for yeast, bacterial vaginosis (clue Cells), trich, and white blood cells. 9. After the microscopic evaluation, add 3-4 drops of KOH (Potassium Hydroxide) to the saline and swab. 10. Mix again and sniff the swab for the "whiff test." A strong ammonia-like odor indicates a POSITIVE result. No odor indicates a NEGATIVE result. 11. Use the 'Wet Smear' stamp to record these findings in the patient's chart, the third page of the 'History and Physical' form." The laboratory's current procedure may inhibit testing personnel from identifying microorganisms. C. Review of the test reports for Wet Prep showed results for four out of five patients had the following results for the Wet Prep: Collection date Results for: Trichomonas, clue cells, and yeast 1. 09/08/2022 uta uta uta 2. 08/04/2022 uta uta uta 3. 08/04/2022 uta uta uta 4. 3/21/2022 uta uta uta The fifth test report had the following results: 5. 08/31/2022 Neg uta uta D. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet showed an estimated 50 Wet Preps were performed annually. E. Interview with testing personnel #2 on October 21, 2022, at 1630 hours in the counseling room confirmed the laboratory director does not do wet preps, only pH and Whiff tests were done, and reported under the Wet Prep test report. KEY: ml = milliliter uta = unable to attain