Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0972939	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Briarwood Health Associates	325 Briarwood Circle Building #5, Ann Arbor, MI	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to have a written or electronic request for patient testing from an authorized person for the routine chemistry testing for four (#1-#4) of 4 patient charts audited. Findings include: 1. On May 1, 2018 at approximately 12:45 PM, record review revealed for four of four patient charts audited the laboratory did not have a written or electronic request for the routine chemistry urinalysis testing by an authorized person. 2. During the interview on May 1, 2018 at approximately 12:45 PM, technical consultant #2 as listed on the CMS-209 confirmed there was no written or electronic orders for the patient testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview, the laboratory failed to ensure a policy and procedure was established and implemented for the entry and reporting of patient test results into the electronic medical records (EMR) system. Findings include: 1. On the day of the survey, the surveyor observed the laboratory was entering and resulting routine chemistry urinalysis results into the EMR system in the patient's progress notes. 2. On May 1, 2018 at approximately 12:45 PM, record review for four (#1-#4) of four patient charts audited revealed the laboratory final report was not available for review in the laboratory section of the EMR system. 3. During the interview on May 1, 2018 at approximately 12:45 PM, technical consultant #2 as listed on the CMS-209 confirmed patient laboratory test results were not entered and reported consistently in the EMR.