Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1067492	04/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Center For Health Education Medicine	1771 Madison Avenue, Lakewood, NJ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on survey review of the Competency Assessment (CA) records and interview with the Nurse Manager (NM), the laboratory failed to follow its Competency Assessment (CA) procedures for 30 out of 30 Testing Personnel (TP) from 5/9/17 to the date of the survey. The findings include: 1. CA were not performed from May 2017 to the date of the survey. 2. The laboratory failed to include how CA was performed and what records were reviewed. 3. Four CA records were signed by the employer four to five days before the reviewer signed the CA. 4. The NM confirmed on 4/16/19 at 11:30 am the laboratory did not follow the CA procedure.
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 surveyor review of the Procedure Manual (PM) and interview with the Nurse Manager (NM) the laboratory failed to have all applicable procedures for Throat Culture (TC) Tests from 5/9/17 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for: a. Quality Control of Bacitracin Discs (BD) b. Quality Assurance c. Step-by-step performance of TC tests d. The laboratory's system for entering results in the patient record and reporting patient results e. The course of action if the test becomes inoperable. 2. The NM confirmed on 4/16/19 at 11: 50 am that the PM did not have all applicable procedures.
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 surveyor review of the Final Reports (FR) and interview with the Nurse Manager (NM), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 5/9/17 to the date of survey. The NM confirmed on 4/16/19 at 1:00 pm that the TRD was not on the FR.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Individual Quality Control Program (IQCP) Quality Assessment (QA) procedure and interview with the Nurse Manager (NM), the Laboratory Director failed to maintain the IQCP QA program for laboratory testing

	from 1/26/17 to the date of the survey. The finding includes: 1. The QA program was not reviewed annually as required by an IQCP. 2. The NM confirmed on 4/16/19 at 11: 00 am the IQCP QA was not maintained.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Nurse Manager (NM), the Laboratory Director failed to have appropriate education records for 14 out of 30 Testing Personnel on file from 5/9/17 to the date of the survey. The NM confirmed on 4/16/19 at 10:30 am all education records were not in the PF.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Nurse Manager (NM), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for thirty of thirty Testing Personnel (TP) engaged in the performance of preanalytical, analytic and post analytic phases for Throat Culture tests from 5/9/17 to the date of survey. The NM confirmed on 4/16/19 at 10:15 am that the LD did not specify the duties and responsibilities of TP.