Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D1067492	**(X3) Date Survey Completed** 02/17/2022
Name of Provider or Supplier Center For Health Education Medicine	**Street Address, City, State** 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**
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: An onsite survey conducted on February 17, 2022 found the laboratory of CHEMED in compliance with CLIA regulations for waived laboratories.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the

	manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Nurse Manager (NM), the laboratory failed to check each batch of Selective Strep Agar (SSA) used for Throat Culture (TC) tests for sterility and document the physical characteristics of the media from 3/16/21 to the date of the survey. The findings include: 1. QC sterility and the physical characteristics of the media were last documented on 3/16/21. 2. The laboratory performed approximately 15-20 TC per month. 3. The NM confirmed on 2/17/22 at 1:50 pm that the laboratory did not perform QC as stated above.