Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1088691	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Topcare Medical Group Inc	**Street Address, City, State** 701 S Stemmons Freeway Suite 260, Lewisville, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 Qualigen Fast Pack TSH controls, direct observation and staff interview, it was revealed that the laboratory failed to have documentation of the open date and the revised expiration date for the TSH Qualigen FastPack control material. Findings included: 1. The Qualigen Fast Pack TSH Control package insert (Rev 001 02/13) stated, "After opening, controls are stable for 120 days when stored and handled as directed." 2. Observed in the laboratory refrigerator on 11/27/2018/2018 at 1100 hours was one box of Qualigen Fast Pack TSH control material containing the

	following: a. One vial of Level 1 Control Lot number 1801022/Expiration Date 2019-05-17 b. One vial of Level 2 Control Lot number 1801022/Expiration Date 2019-05-17 3. The laboratory was asked to provide documentation of when the box was opened or when it would expire. The laboratory failed to provide documentation of the open date or the revised expiration date for the Qualigen Fast Pack TSH control material. 4. An interview with technical consultant #2 in the breakroom on 11/27/2018 at 1110 confirmed the above findings.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to perform annual competency assessment for 1 of 2 testing persons in 2017. Findings included: 1. A review of the laboratory's submitted CMS Form 209 revealed the following two testing persons requiring annual competency assessment in 2017: Testing person #4 Testing person #5 2. A review of the laboratory's personnel records revealed the following competency assessments were performed on testing person #5: Testing person #5 (started testing 08/2015) 6-month assessment performed 01/05/2015 Annual assessment performed 04/18/2016 3. The laboratory was asked to provide documentation of the technical consultant performing a competency assessment on testing person #5 in 2017. No documentation was provided. 4. In an interview with the technical consultants on 11/27/2018 at 1045 hours, Technical Consultant #1 stated that testing person #5 transferred to another facility location in June 2018. The technical consultants could not provide documentation of 2017 competency assessment for testing person #5. This confirmed the above findings.