Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1100037	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Topcare Medical Group Inc	2207 Gus Thomasson Road, Dallas, 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	An entrance conference was held 08/28/2018 with the laboratory staff. The survey process was discussed. An opportunity for questions and comments was given. Based on the onsite survey conducted on 08/28/2018, this facility was found NOT to be in compliance with the CLIA regulations found at: 42 CFR 493.1250 Analytic Systems 42 CFR 493.1403 Laboratory Director, (moderate complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. 23-day termination process recommended. The laboratory voluntarily suspended all Thyroid Stimulating Hormone testing as of 08/28/2018. An exit conference was held 08/28/2018 with the laboratory staff. The process for submitting the corrections was explained. An opportunity for questions and comments was provided. The laboratory has voluntarily ceased Thyroid Stimulating Hormone (TSH) testing.
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 review of the submitted CMS-209, the laboratory's procedure manual, review of the laboratory's personnel files and staff interview, it was revealed that the laboratory failed to ensure policies and procedures were established and followed to access the competency of 2 of 2 Technical Consultants. Findings included: 1. A review of the submitted CMS-209 revealed the laboratory identified two Technical Consultants. 2. A review of the laboratory's personnel files for 2017 and 2018 competency assessments for Technical Consultant #1 and Technical Consultant #2 revealed the following: a. The competency assessment for Technical Consultant #1 was assessed by Technical Consultant #2. b. The competency assessment for

	Technical Consultant #2 was assessed by Technical Consultant #1. 3. A review of the laboratory's procedures revealed the facility do not have a procedure for assessing the competency of the Technical Consultants. 4. During an interview on 08/28/2018 at 11: 10 AM, Technical Consultant #1 confirmed the laboratory did not establish written policies and procedures for competency assessment of Technical Consultants.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016, review of laboratory procedures and staff interview, it was revealed that the laboratory failed to have documentation of grading proficiency testing results returned by the proficiency testing agency as "not graded." Finding included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (Event 3) revealed the following results returned to the facility as "not graded" by the proficiency testing agency: TSH CH-13 2. The laboratory procedure titled "Proficiency Testing (PT) Assessment Policy stated, "Any 100% score that is notated with a code should be self-graded and investigated for corrective action, if needed." 3. During an interview with Technical Consultant #2 on 08/28/2018 at 09:40 AM in the breakroom, the laboratory was asked to provide documentation of self-grading. No documentation was provided. This confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions for the Qualigen Fast Pack analyzer, review of the laboratory's verification records, review of the laboratory's control records, review of the laboratory's patient test records, direct observation, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements. The findings included: 1. The laboratory failed to follow manufacturer's instructions for ensuring the correct storage conditions of patient samples prior to testing. (Refer to D5411) 2. The laboratory failed to have documentation of the open date and the revised expiration date for the TSH control reagent. (Refer to D5415) 3. The laboratory failed to have documentation of verifying normal patient ranges as part of the verification studies. (Refer to D5421)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, review of patient test records and confirmed in an interview, the laboratory failed to follow manufacturer's instructions for ensuring the correct storage conditions of patient samples prior to testing. Findings included: 1. The manufacturer's instructions for Qualigen Fast Pack TSH Immunoassay (Rev.010 10/17) stated in "Specimen Collection/Preparation", "If not tested within 24 hours, the sample should be frozen at -20C or colder." 2. Review of a random sampling of patient test records from October 2017, January 2018, and July 2018 revealed the following: Patient Number 230033 Date Drawn 09/29/2017 Frozen No Date Tested 10/03/2017 Specimen not frozen for 96 hours Patient Number 863857 Date Drawn 10/16/2017 Frozen No Date Tested 10/19/2017 Specimen not frozen for 72 hours Patient Number 806879 Date Drawn 10/16/2017 Frozen No Date Tested 10 /19/2017 Specimen not frozen for 72 hours Patient Number 306209 Date Drawn 10/17 /2017 Frozen No Date Tested 10/19/2017 Specimen not frozen for 48 hours Patient Number 1022704 Date Drawn 10/17/2017 Frozen No Date Tested 10/19/2017 Specimen not frozen for 48 hours Patient Number 356881 Date Drawn 10/20/2017 Frozen No Date Tested 10/24/2017 Specimen not frozen for 96 hours Patient Number 1054133 Date Drawn 01/16/2018 Frozen No Date Tested 01/18/2018 Specimen not frozen for 48 hours Patient Number 1032424 Date Drawn 01/26/2018 Frozen No Date Tested 01/30/2018 Specimen not frozen for 96 hours Patient Number 1046214 Date Drawn 01/26/2018 Frozen No Date Tested 01/30/2018 Specimen not frozen for 96 hours Patient Number 539274 Date Drawn 06/25/2018 Frozen No Date Tested 07/03 /2018 Specimen not frozen for 192 hours Patient Number 1119033 Date Drawn 06/25 /2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 192 hours Patient Number 812973 Date Drawn 06/26/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 168 hours Patient Number 805027 Date Draw 06/26/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 168 hours Patient Number 676864 Date Drawn 06/26/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 168 hours Patient Number 1117699 Date Drawn 06/26/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 168 hours Patient Number 1120858 Date Drawn 06/27/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 144 hours Patient Number 706030 Date Drawn 06/27/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 144 hours Patient Number 810346 Date Drawn 06/27/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 144 hours Patient Number 557999 Date Drawn 06/27/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 144 hours Patient Number 111121 Date Drawn 06/28/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 120 hours Patient Number 826900 Date Drawn 06/28/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 120 hours Patient Number 183700 Date Drawn 06/28/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 120 hours Patient Number 680623 Date Drawn 06/28/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 120 hours Patient Number 1081165 Date Drawn 06/29/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 96 hours Patient Number 1125602 Date Drawn 06/29/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 96 hours Patient Number

	214155 Date Drawn 06/29/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 96 hours Patient Number 606963 Date Drawn 06/29/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 96 hours Patient Number 457160 Date Drawn 06/29/2018 Frozen No Date Tested 07/03/2018 Specimen not frozen for 96 hours Patient Number 268586 Date Drawn 06/29/2018 Frozen No Date Tested 07/03 /2018 Specimen not frozen for 96 hours Patient Number 915386 Date Drawn 07/26 /2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 168 hours Patient Number 74722 Date Drawn 07/26/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 168 hours Patient Number 1147284 Date Drawn 07/26/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 168 hours Patient Number 391984 Date Drawn 07/26/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 168 hours Patient Number 636694 Date Drawn 07/26/2018 Frozen No Date Tested 08 /02/2018 Specimen not frozen for 168 hours Patient Number 175522 Date Drawn 07 /27/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 144 hours Patient Number 1146726 Date Drawn 07/27/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 144 hours Patient Number 408105 Date Drawn 07/27/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 144 hours Patient Number 873917 Date Drawn 07/27/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 144 hours Patient Number 689542 Date Drawn 07/30/2018 Frozen No Date Tested 08/02/2018 Specimen not frozen for 72 hours The laboratory failed to follow manufacturer's instructions for ensuring the correct storage conditions of patient samples prior to testing. 3. The above findings were confirmed during staff interview on 08/28/2018 at 11:30AM in the laboratory. Word Key: TSH=Thyroid Stimulating Hormone
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 control reagent. 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 08/28/2018 at 11:10 AM was one box of Qualigen Fast Pack TSH control material containing the following: a. One vial of Level 1 Control Lot number 1712022/Expiration Date 2019-05-17 b. One vial of Level 2 Control Lot number 1712022/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 testing person #2 in the laboratory on 08/28/2018 at 1130 revealed the controls observed in the refrigerator were in use and that he was unaware of when the control material was opened or that the manufacturer stated it should be used within 120 days. This confirmed the above findings.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory verification studies for the Qualigen Fast Pack IP TSH analyzer, review of laboratory records and staff interview, it was revealed that the laboratory failed to have documentation of verifying normal patient ranges as part of the verification studies. Findings included: 1. Review of the laboratory verification studies for the Qualigen Fast Pack IP TSH analyzer revealed the laboratory failed to have documentation of verifying its patient normal ranges as part of the verification studies. 2. Review of the laboratory form titled "TSH Patient Results" revealed the laboratory's patient normal range was 0.4 -5.45 uIU/mL. 3. The laboratory was asked to provide documentation of verifying patient normal ranges on the analyzer. No documentation was provided. 4. In an interview on 08/28/2018 at 10:50 AM in the breakroom, Technical Consultant #2 was asked, "How did the laboratory establish normal patient ranges?". Technical Consultant #2 stated, "We took normal ranges from another clinic." This confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's verification records, review of the laboratory's procedures, review of the proficiency testing records, review of the manufacturer's instructions for the Qualigen Fast Pack TSH analyzer, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory director failed to provide overall management and direction for the laboratory. The findings were: 1. The laboratory director failed to ensure test systems provided quality test results. (Refer to D6007) 2. The laboratory director failed to ensure verification studies of the Qualigen Fast Pack TSH analyzer were complete prior to testing patient samples. (Refer to D6013) 3. The laboratory director failed to investigate proficiency testing results returned by the proficiency testing agency as "not graded." (Refer to D6018)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of patient test records, review of the manufacturer's instructions for the Qualigen Fast Pack TSH analyzer, review of the laboratory's quality assessment records, and staff interview, it was revealed the laboratory director failed to ensure test systems provided quality test results. (Refer to D5400).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification records and staff interview, it was revealed the laboratory director failed to ensure verification studies of the Qualigen Fast Pack TSH analyzer were complete prior to testing patient samples. (Refer to D5421).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 Event 3, review of laboratory procedures and staff interview, it was revealed the laboratory director failed to investigate proficiency testing results returned by the proficiency testing agency as "not graded". (Refer to D5213)