Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0666309	11/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Topcare Medical Group Inc	4501 Groveway Dr, Houston, 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 representative at the entrance and exit conferences. The facility representative was 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.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 and 2018, and staff interview, it was revealed the laboratory failed to attain a score of at least 80% for the analyte White Blood Cell Differential on 1 of 5 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (events 1, 2, and 3) and 2018 (events 1 and 2) revealed the laboratory failed to attain a score of at least 80% for the analyte White Blood Cell Differential for: 2018 Event 2 Score 60% 2. An interview with the technical consultant on 11/26/2018 at 0945 hours in the break room - after his review of the records- confirmed the findings.

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 manufacturer's instructions for the Sysmex XN-L Check hematology controls, surveyor observation, and staff interview, it was revealed the laboratory failed to documented opened expiration dates for control materials. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XN-L Check hematology controls (12/2015 Rev. 2) under the section titled "Storage and shelf life after first opening" revealed: "Opened vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2 - 8C after being recapped." 2. Surveyor observation of controls currently in use in the laboratory on 11 /26/2018 at 1100 hours in the laboratory identified the following vials: a) Low control Lot: 82711401 exp: 2019-01-08 b) Normal control Lot: 82711402 exp: 2019-01-08 c) High control Lot: 82711403 exp. 2019-01-08 The identified control did not have a documented opened date or a documented open expiration date. 3. The laboratory was asked to provide documentation of documenting the opened date and/or open expiration date for the controls identified. No documentation was provided. 4. An interview with the technical consultant on 11/26/2018 at 1105 hours in the laboratory - after his review of the records- confirmed the 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's verification studies performed on the Sysmex XN-330 in May 2018, review of the laboratory's policies, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges. The findings were: 1. A review of the laboratory's verification studies performed on the Sysmex XN-330 (serial number 11361) revealed the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of the laboratory's policy titled "Validation of a New Test System" revealed: "Verification of manufacturer's normal values: This will be determined by demonstrating that 5 non-patient results are within the manufacturer's normal values. 3. A review of patient test results identified a sampling of the following patient normal values in use by the laboratory: a) normal values 1 WBC 3.80 - 10.8 RBC 4.20 - 5.80 HBG 11.0 - 14.7 HCT 34.0 - 52.0 MCV 78.0 - 100.0 MCH 23.0 - 31.0 MCHC

	30.0 - 36.0 RDW 11.50 - 14.50 PLT 140.0 - 400.0 MPV 7.40 - 10.40 LYM% 25.0 - 54.0 NEU% 24.0 - 68.0 MON% 5.0 - 15.0 EOS% 0.0 - 7.0 BAS% 0.0 - 2.0 IG% 0.1 - 0.5 LYM# 0.85 - 3.90 NEU# 1.50 - 7.80 MON# 0.01 - 0.60 EOS# 0.01 - 0.50 BAS# 0.00 - 0.20 IG# 0.0 - 0.15 b) normal values 2 WBC 3.80 - 10.8 RBC 4.15 - 4.87 HBG 11.0 - 14.7 HCT 34.0 - 42.0 MCV 78.0 - 100.0 MCH 23.0 - 31.0 MCHC 30.0 - 36.0 RDW 11.50 - 14.50 PLT 140.0 - 400.0 MPV 7.40 - 10.40 LYM% 35.0 - 65.0 NEU% 24.0 - 68.0 MON% 5.0 - 15.0 EOS% 0.0 - 7.0 BAS% 0.0 - 2.0 IG% 0.1 - 0.5 LYM# 0.85 - 3.90 NEU# 1.50 - 7.80 MON# 0.01 - 0.60 EOS# 0.01 - 0.50 BAS# 0.00 - 0.20 IG# 0.0 - 0.15 c) normal values 3 WBC 5.50 - 17.0 RBC 4.15 - 4.87 HBG 11.0 - 14.7 HCT 34.0 - 42.0 MCV 78.0 - 100.0 MCH 23.0 - 31.0 MCHC 30.0 - 36.0 RDW 11.50 - 14.50 PLT 140.0 - 400.0 MPV 7.40 - 10.40 LYM% 44.0 - 74.0 NEU% 24.0 - 68.0 MON% 5.0 - 15.0 EOS% 0.0 - 7.0 BAS% 0.0 - 2.0 IG% 0.1 - 0.5 LYM# 0.85 - 3.90 NEU# 1.50 - 7.80 MON# 0.01 - 0.60 EOS# 0.01 - 0.50 BAS# 0.00 - 0.20 IG# 0.0 - 0.15 d) normal values 4 WBC 5.50 - 17.0 RBC 4.20 - 5.80 HBG 10.5 - 13.5 HCT 33.0 - 40.0 MCV 78.0 - 100.0 MCH 23.0 - 31.0 MCHC 30.0 - 36.0 RDW 11.50 - 14.50 PLT 140.0 - 400.0 MPV 7.40 - 10.40 LYM% 44.0 - 74.0 NEU% 36.0 - 65.0 MON% 5.0 - 15.0 EOS% 0.0 - 7.0 BAS% 0.0 - 2.0 IG% 0.1 - 0.5 LYM# 0.85 - 3.90 NEU# 1.50 - 7.80 MON# 0.01 - 0.60 EOS# 0.01 - 0.50 BAS# 0.00 - 0.20 IG# 0.0 - 0.15 e) normal values 5 WBC 3.80 - 10.8 RBC 4.15 - 4.87 HBG 10.5 - 13.5 HCT 33.0 - 40.0 MCV none provided MCH 23.0 - 31.0 MCHC 30.0 - 36.0 RDW 11.50 - 14.50 PLT 140.0 - 400.0 MPV 7.40 - 10.40 LYM% 44.0 - 74.0 NEU% 36.0 - 65.0 MON% 5.0 - 15.0 EOS% 0.0 - 7.0 BAS% 0.0 - 2.0 IG% 0.1 - 0.5 LYM# 0.85 - 3.90 NEU# 1.50 - 7.80 MON# 0.01 - 0.60 EOS# 0.01 - 0.50 BAS# 0.00 - 0.20 IG# 0.0 - 0.15 4. The laboratory was asked to provide documentation of verifying the identified patient normal ranges. No documentation was provided. 5. An interview with the technical consultant on 11/26/2018 at 0945 hours in the break room revealed the laboratory was using the patient normal ranges provided by the manufacturer and the laboratory did not have documentation of verifying these ranges. This confirmed the findings. Key WBC white blood cell RBC red blood cell HBG hemoglobin HCT hematocrit MCV mean corpuscular volume MCH mean corpuscular hemoglobin MCHC mean corpuscular hemoglobin concentration RDW red cell distribution width PLT platelets MPV mean platelet volume LYM% percent lymphocytes NEU% percent neutrophils MON% percent monocytes EOS% percent eosinophils BAS% percent basophils IG% percent immature granulocytes LYM# number of lymphocytes NEU# number of neutrophils MON# number of monocytes EOS# number of eosinophils BAS# number of basophils IG# number of immature granulocytes
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete (refer to D5421).

D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Sysmex XN-330 hematology analyzer, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on testing personnel prior to them performing patient testing. The finding were: 1. A review of the laboratory's verification records for the Sysmex XN-330 hematology analyzer revealed the instrument was installed and placed into service in May 2018. 2. A review of the laboratory' personnel records revealed competency assessments were performed at the following times for each of the identified testing personnel (as listed on Form CMS 209) a) Testing personnel 1 assessment performed in April 2018 b) Testing personnel 2 assessment performed in April 2018 c) Testing personnel 3 assessment performed in April 2018 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments in May 2018 on testing personnel prior to them performing patient testing. No documentation was provided. 4. An interview with the technical consultant on 11/26/2018 at 0940 hours in the break room revealed he was unaware competency assessments were required to be performed. This confirmed the findings.