Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0666309	09/17/2020
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 proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attain a score of at least 80% for one analyte in the 2019- 3rd testing event, hematocrit (HCT). Findings include: 1. Proficiency Testing (PT) records revealed the laboratory was enrolled in API (American Proficiency Institute) program for hematology for 2019 2. The 2019 -3rd PT event showed the hematology analyte HCT received a score of 60%. 3. An interview with the technical consultant on September 17, 2020 at 1135 hours in the office confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's proficiency testing report, and confirmed in interview with the Technical Consultant, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems identified in general laboratory system requirements at 493.1231 through 493.1236 for 2018 to 2020. The findings were: 1. Review of the laboratory's policies and procedures, revealed the laboratory failed to have a written quality assurance plan to monitor, assess and correct problems with proficiency testing. (refer to D2121) 2 On interview with the technical consultant 09 /17/2020 1215 hours in the conference room, he confirmed the laboratory failed to develop a quality assurance plan to monitor and assess proficiency testing.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, review of patient test records, and confirmed in interview of the technical consultant, laboratory's quality assessment plan failed to identify and correct problems in preanalytic systems. The findings were: 1. The laboratory's quality assurance program failed to detect the laboratory didn't follow the manufacturer's instructions for entering controls in the hematology analyzer (refer to 5403) .
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: I. Based on review of laboratory's procedure manual, review of manufacturer's instructions for the hematology analyzer, interview with Sysmex technical service, review of the quality control (QC) analysis data, and confirmed in interview with facility personnel, the laboratory failed to implement a written policy for entering QC values for new lot changes. Findings included: 1. Review of the laboratory's procedure manual, failed to include procedures for implementing QC values for for new lot changes and signed and dated by the laboratory director. Testing person #1 (as listed on form CMS-209) revealed she used a hand written sheet that was taped on the wall on 09/17/2020 at 1140 hours. 2. Review of the manufacturer's instructions for the Sysmex hematology analyzer (document number 62-1563; 11/2019) under "Issue" states "Good laboratory practice .... Note: For Quality Monitor for Hematology users, the limits have automatically updated and no action are required. Accrediting organizations recommend that laboratories employ statistical quality control and verify control policies to meet clinical requirements. Sysmex has completed the statistical analysis and recommend the following actions: a. Enter model specific controls limits from the table attached. b. Auto-set the control target value and limit for each parameter using a minimum of 10 analyses. c. Verify target values are within published assayed ranges. d. Document corrective action when daily controls exceed limits. e. Review control recovery for shift and trends according to your laboratory's established protocols." 3. Interview with the Sysmex technical service on 09/17/2020 at 1303 hours states the laboratory failed to enter the QC values correctly. She stated "The range would be so wide you could drive a truck through the target limit. If the target limit is at 100%, then all QC is acceptable." The target limit was at 100%. 4. Review of the QC data analysis on the Sysmex instrument indicated the target limit was set at 100%. The laboratory failed to see any shifts and trends with their QC. 4. During an interview on 09/17/2020 at 1330 hours with the technical consultant in the laboratory confirmed they did not have a policy for implementing QC values for new lots. Key CMS- Centers for Medicare and Medicaid Services
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, observation and confirmed in interview of technical consultant, it was revealed the laboratory failed to provide documentation of a written procedure manual for the tests it documented in the procedure manual. The findings were: 1. Review of the laboratory procedure "Panic values", revealed the following tests were listed for panic values: Glucose BUN Creatinine Total Protein Calcium Sodium Potassium Chloride CO2 Digoxin Phenytoin Theophylline WBC HGB HCT Platelets Prothrombin Time 2. At the time of the survey, only 4 of 17 procedures listed in the laboratory procedure manual are being performed. 3. The laboratory procedure manuel failed to have a written policy and procedure manual for all the tests the laboratory performs. The laboratory failed to removed 13 procedures that are not performed from their panic values. 4 An

	interview with the technical consultant on September 17, 2020 at 1215 hours in the office confirmed the laboratory policy included tests in the manual that were not performed in the laboratory. Key: BUN- Blood Urea Nitrogen CO2- Carbon Dioxide WBC- White blood cell HGB- Hemoglobin HCT- Hematocrit
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 the manufacturer's instructions for the hematology analyzer, review of the laboratory's policies, review of patient test results from September 14 to September 16, 2020, and staff interview, it was revealed the laboratory failed verify patient CBC (complete blood count) results as required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-330 hematology analyzer (Document number 1051-CFL , Revision 2 June 2014) titled "Results Interpretations" under "Notation for Abnormal Data" revealed the manufacturer identified notations, meanings and descriptions. Data Masks Notations Meaning Description [- - - -] Analysis impossible Indicates that an analysis error or parsing error has occurred; no value displayed [++++] Out of range Indicates that the data cannot be displayed; the values exceeds the display limit [ ] No order Indicates that the analysis order does not exist [*] Low reliability Indicates the reliability of the data is low [@] Out of Range Indicates that the data is outside the linearity limits [!] Exceeds upper panic limit Indicates that the value is higher than or less than the clinical panic value or below lower panic limit [+] Exceeds upper limit Indicates the value is higher than the reference interval [-] Exceeds lower limit Indicates the value is less than the reference interval 2. A review of the laboratory's policy titled "Troubleshooting Histogram Hematology Flags)" (approved and signed by the laboratory director on 02/27/2017) revealed: "To ensure accuracy of CBC results, the testing personnel will repeat any CBC that yields WBC, RBC and/or PLT Histogram flags (See Guidesheet). If the flag goes away, the CBC results may be released to the physician for patient treatment and/or diagnosis. If the flag(s) persist, the testing personnel will send the sample to a reference laboratory for testing. Pending installation of a middleware, the testing personnel will keep a running log of all patients' samples referred out due to instrument flags." 3. A review of patient test records from 09/14/2020 to 09/172020 identified 4 of 12 patient results with flags on the differential portion of the results: Date Sequence Flag Message 09/14 2009141106 * WBC- Blasts/Abn Lympho? 09/15 2009151109 * WBC- Blasts/Abn Lympho? 09 /15 2009151115 * PLT - Abn distribution 09/17 2009171129 * WBC - Blasts/Abn Lympho? 4. The laboratory was asked to provide documentation of performing additional testing to verify the results. Testing person #1 (as listed on form CMS 209) stated on 09/17/2020 at 1100 hours in the laboratory, " We don't look at the stars. We leave it up to the doctor to look in the LIS and decide." The flags do not cross from the instrument to the LIS. And the LIS is where the physician reviews the patient results. 5. An interview with the technical consultant on 09/17/2020 at 1105 hours in the laboratory- after his review of the patient records from the analyzer and the LIS

	printout confirmed the findings. Key WBC- White blood cell RBC- Red blood cell PLT- Platelet Abn- Abnormal Lympho-Lymphocytes CMS- Centers for Medicare and Medicaid Services
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and a random review of the laboratory quality control records from December 2018 to August 2020, and staff interview, revealed the laboratory failed to have documentation of reviewing temperatures. The findings were: 1. A review of the laboratory's policy titled "Instrument Operation and Maintenance" (signed by the laboratory director) revealed: "All calibration documentation sheets, Instrument Maintenance Sheets, Work Space Maintenance Sheets, Temperature Log Sheets and Calibration Documentation sheets will be reviewed, signed/initialed and dated monthly by the Laboratory Technical Consultant." 2. A random review of laboratory quality control from December 2108 to August 2020, revealed the laboratory technical consultant failed to review, sign, initial and date temperature log sheets. 3. An interview with the technical consultant on 09/17 /2020 at 1235 hours in office- after his review of the records- confirmed he failed to sign and date the monthly temperature logs.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's QC (quality control) records, manufacturer's instructions, patient reports, and staff interview, the laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems identified in the analytic systems as evidenced by: 1. The laboratory failed to have a policy for entering Quality control values in the Sysmex hematology analyzer when entering a new lot. (refer to D5403) 2. The laboratory failed to follow manufacturer's instructions for addressing flags generated by the Sysmex Hematology analyzer on patient's CBC results. (refer to D5411) Key: CBC - Complete Blood Count
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of patient CBC (complete blood count) instrument printouts from September 14 to September 17, 2020, review of patient CBC results provided to providers, and staff interview, it was revealed the laboratory failed to ensure flags on CBC (complete blood count) results were transmitted into the laboratory's information system (LIS) The findings were: 1. A review of Sysmex XP-330 analyzer instrument printouts from September 14, 2020 to September 17, 2020 identified the following CBC results with flags: Date ID Flag 09/14 2009141106 * Blasts/Abn Lympho? 09 /15/ 2009151109 * Blasts/Abn Lympho? 09/15 2009151115 * PLT abn distribution 09 /17 2009171129 * Blasts/Abn Lympho? The results were interfaced into the laboratory's information system. 2. A review of 12 patient results as reported to the provider for the identified patients revealed 4 of 4 results with flags did not have documentation of the flags in the LIS system. 3. An interview with the technical consultant at 1105 hours in the laboratory, revealed the flags did not transfer into the LIS and were not part of the report to the providers. This confirmed the findings. Key Abn- Abnormal Lympho-Lymphocytes LIS- Laboratory Information System
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, patient results, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of establishing a quality assurance plan to identify and correct problems in the post-analytic systems. The findings were: 1. A review of the laboratory policy "Control Policy" stated " Every month the Technical Consultant will report to the Laboratory Director and the Testing Personnel his findings about the laboratory's performance of quality control, quality assurance and proficiency testing." 2. A review of the CBC patient printout from the hematology analyzer and compared with the LIS results viewed by the provider, the laboratory failed to ensure the hematology flags transmitted to the LIS system. 3. An interview with the technical consultant on 09/17 /2020 at 1354 hours in the office stated "No, we have no QA policy. I just do the QA report." He confirmed the laboratory failed to ensure the address flags were available on final patient results for the provider to review. (refer to D5801). Key QA- Quality Assurance LIS- Laboratory Information System
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 review of policies and procedures and interview facility personnel found that the laboratory director failed to ensure that a quality assessment program had been established and maintained. (refer to D5291, D5391 D5791, D5891 Findings were as follows: 1. The laboratory director failed to have a quality assessment program that monitored, identified and corrected problems in the preanalytic, analytic and post analytic areas for the general laboratory services provided. 2. Interview with the technical consultant on 9/17/2020 at 1354 hours in the office, stated "No, We have no QA policy. I just do the QA report".