Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1089962	05/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Topcare Medical Group Inc	9753 Webb Chapel Suite 900, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Revisit 05/20/2019 New deficiency. Based on a review of American Proficiency Institute (API) proficiency testing records and staff interview, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of bacteriology. Refer to D2028.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)

	(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: PT Desk Review conducted 08/30/2019 New deficiency. Based on review of CMS 155 report and American Proficiency Institute (API) proficiency testing records, the laboratory failed to particpate in the specialty of bacteriology (streptococcus analyte) in 2018 (2018-3) and 2019 (2019-1, 2019-2). Findings included: 1. Review of the CMS 155 report revealed the laboratory did not achieve passing scores (>/= 80%) in bacteriology: API 2018 - 3: 40% API 2019 - 1: 40% API 2019 - 2: 40% Scores from 2018 event 3 and 2019 event 1 result in initial unsuccessful performance and scores from 2019 event 1 and 2019 event 2 result in noninitial unsuccessful performance for bacteriology (streptococcus analyte). 2. The laboratory must demonstrate sustained satisfactory performance (>/= 80%) on two consecutive testing events for reinstatement.
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Revisit 05/20/2019 and PT Desk Review 08/30/19 New deficiency. Based on review of the Centers for Medicare & Medicaid Services (CMS) 155 report, American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory failed to attain an overall testing event score of at least 80% for the specialty of bacteriology resulting in unsatisfactory performance in 2018 (Event 3, E-3) and 2019 (Event 1, E-1; Event 2, E-2). Findings: 1. Review of the CMS-155 report revealed the following scores in bacteriology for 2018 E-3, 2019 E-1, and 2019 E-2: 2018 E-3: 40% 2019 E-1: 40% 2019 E-2: 40% The laboratory failed to achieve passing scores of at least 80% for the above events. 2. Review of the API PT records revealed the following scores for the streptococcus analyte tested on the Solana analyzer: 2018 E-3: 40% 2019 E-1: 40% During a telephone interview on 05/20/19 at 11:00 am, the technical consultant (TC) stated the laboratory ordered the wrong testing methodology for PT events 2018 E-3 and 2019 E-1 which resulted in the failures. This confirmed the above findings. 3. Review of API PT records obtained from the company during a PT desk review on 08/30/19 revealed the following score for streptococcus analyte tested on the Solana analyzer: 2019 E-2: 40%

D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Revisit 05/20/2019 and PT Desk Review 08/30/19 New deficiency. Based on review of the Centers for Medicare & Medicaid Services (CMS) 155 report, American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory failed to achieve satisfactory performance (80% or higher) for bacteriology in three consecutive testing events resulting in noninitial unsuccessful performance in 2018 (Event 3, E-3) and 2019 (Event 1, E-1; Event 2, E-2). Findings: 1. Review of the CMS-155 report revealed the following scores in bacteriology for 2018 E-3, 2019 E-1 and 2019 E-2: 2018 E-3: 40% 2019 E-1: 40% 2019 E-2: 40% The laboratory failed to achieve a passing testing event score of 80% or higher for three consecutive events for the bacteriology specialty. 2. Review of the API PT records revealed the following scores for the streptococcus analyte tested on the Solana analyzer: 2018 E-3: 40% 2019 E-1: 40% During a telephone interview on 05/20/19 at 11:00 am, the technical consultant (TC) stated the laboratory ordered the wrong testing methodology for PT events 2018 E-3 and 2019 E-1 which resulted in the failures. This confirmed the above findings. 3. Review of API PT records obtained from the company during a PT desk review on 08/30/19 revealed the following score for streptococcus analyte tested on the Solana analyzer: 2019 E-2: 40% Scores from 2018 event 3 and 2019 event 1 result in initial unsuccessful performance and scores from 2019 event 1 and 2019 event 2 result in noninitial unsuccessful performance for bacteriology (streptococcus analyte).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Revisit 05/20/2019 New deficiency. Based on review of proficiency testing records, it was revealed that the Laboratory Director failed to ensure the overall quality of the laboratory services provided. The Laboratory Director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2028.