Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0897266	05/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Caballero Family Healthcare Group, Pllc	1920 Kirby Pkwy Suite 202, Germantown, TN	

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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the red blood cell, hematocrit, hemoglobin, and white blood cell analytes and the hematology specialty in resulting in non-initial unsuccessful PT occurrence. (Refer to D2130 and D2131)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Center for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2021 and 2022 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance in three out of four PT events for the red blood cell, hematocrit, hemoglobin and white blood cell analytes, resulting in non-initial unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores: Red Blood Cell: 2021 Event 1=0%, 2021 Event 2=40%, 2022 Event 1=60% Hematocrit: 2021 Event 1=0%, 2021 Event 2=40%. 2022 Event 1=40% Hemoglobin: 2021 Event 1=0%, 2021 Event 2=40%. 2022 Event 1=60% White Blood Cell: 2021 Event 1=0%, 2021 Event 2=40%. 2022 Event 1=60% 2. Review of the laboratory's American Association of Bioanalysts (AAB) PT performance evaluation records revealed the following: 2021 Event 1: Scored as 0% for red blood cell, hematocrit, hemoglobin and white blood cell for non-reporting. 2021 Event 2: Red blood cell: Sample numbers six, nine and ten scored as unacceptable resulting in an overall score of 40%. Hematocrit: Sample numbers six, nine and ten scored as unacceptable resulting in an overall score of 40%. Hemoglobin: Sample numbers six, nine and ten scored as unacceptable resulting in an overall score of 40%. White Blood Cell: Sample numbers six, nine and ten scored as unacceptable resulting in an overall score of 40%. 2022 Event 1: Red blood cell: Sample numbers four and five scored as unacceptable resulting in an overall score of 60%. Hematocrit: Sample numbers two, four and five scored as unacceptable resulting in an overall score of 40%. Hemoglobin: Sample numbers four and five scored as unacceptable resulting in an overall score of 60%. White Blood Cell: Sample numbers four and five scored as unacceptable resulting in an overall score of 60% and non-initial unsuccessful PT performance.
D2131	HEMATOLOGY CFR(s): 493.851(g) 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: Based on a desk review of the Center for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2021 and 2022 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance in three out of four PT events for the hematology specialty, resulting in non-initial unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the hematology specialty: 2021 Event 1=0%, 2021 Event 2=60%, 2022 Event 1= 57% 2. Review of the laboratory's American Association of Bioanalysts (AAB) PT evaluation records revealed the following for the hematology specialty: 2021 Event 1: Scored as 0% for non-reporting. 2021 Event 2: Scored of 60% for the hematology specialty. 2022 Event 1: Score of 57.8% for the hematology specialty and non-initial unsuccessful PT occurrence.
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: The laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance with successful proficiency testing (PT) for the red blood cell, hematocrit, hemoglobin, and white blood cell analytes and the hematology specialty, resulting in non-initial unsuccessful PT occurrence. (Refer to D6016)
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: Based on a desk review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's 2021 and 2022 proficiency testing (PT) evaluation reports, and laboratory communication, the laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance, resulting in unsatisfactory performance for three out of four consecutive proficiency testing events for the red blood cell, hematocrit, hemoglobin and white blood analytes and the hematology specialty, resulting in non-initial unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 and the laboratory's American Association of Bioanalysts (AAB) PT evaluation reports revealed the following unsatisfactory scores: Red Blood Cell: 2021 Event 1=0%, 2021 Event 2=40%, 2022 Event 1=60% Hematocrit: 2021 Event 1=0%, 2021 Event 2=40%, 2022 Event 1=40% Hemoglobin: 2021 Event 1=0%, 2021 Event 2= 40%, 2022 Event 1=60% White Blood Cell: 2021 Event 1=0%, 2021 Event 2=40%, 2022 Event 1=60% Hematology Specialty: 2021 Event 1=0%, 2021 Event 2=60%, 2022 Event 1=57% 2. Review of a letter received April 4, 2022 revealed the following statement: "This letter is to notify the CLIA office that due to another PT failure we have voluntarily stopped testing for CBC's as of March 30th. We have currently ordered a new Hematology Analyzer and contacted a Technical Consultant [technical consultant name] to come work with us." The letter was signed by the laboratory director.