Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0913493	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Madera Family Medical Group	1111 W 4th St, Madera, CA	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on reviews of 2019 - 2021 proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records, personnel reports, and patients test records; observation of the Horiba Micros 60 hematology analyzer, and interview with the Technical Consultant, it was determined the laboratory failed to test proficiency samples by personnel routinely testing patients specimen. Findings included: 1. Proficiency testing reports documented the laboratory participated in API's program and received hematology samples according to schedule for testing in March, July, and November. 2. For 7 out of 7 events in 2019 - 2021, the laboratory proficiency testing Attestation statements documented that the proficiency samples were tested by the Technical Consultant. 3. Laboratory personnel report (form LAB-116, 8/19/21) documented 9 persons assisted with hematology testing by operating the moderate-complexity Micros 60. 4. The Technical Consultant (TC) affirmed (8/19/21 @ Noon) that he/TC didn't test patients specimen, but did test proficiency samples; and that of 9 persons routinely testing patients specimen, only 2 (HH, VM) had tested proficiency samples. 5. And thus, the reliability and quality of hematology results could not be assured when the laboratory failed to test proficiency samples by persons routinely testing patients specimen. Based on the stated test volume (CMS116, CLIA Application, 8/17 /21), personnel routinely tested 1,340 patients specimens to obtain 6,700 results annually. A few examples from 2019 -2021 are as follows: Date Testing Person Specimen ID ---------- 3/12/19 MM DS 3 /13/19 MM OB 3/16/19 AR BV 4/23/19 JS JA 7/24/19 NT AR 7/24/19 JS MR 7/25

	/19 NT JS 11/12/19 MS DE 3/19/20 GR FR 3/19/20 AR MR 7/22/20 GR RG 9/21/20 MD DG 11/16/20 YA JR 3/22/21 YA JS 3/23/21 BE AP 7/26/21 YA SF 7/26/21 YA GK 7/26/21 YA EG 7/26/21 MD NAG 7/26/21 JR AM 7/26/21 GR SB .
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 findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure that proficiency samples are tested as required. Findings included: 1. Under the Laboratory Director's administration the laboratory failed to test proficiency samples by persons routinely testing patients specimen. 2. When signing the Attestation Statements, the Laboratory Director was deficient in ensuring the proficiency samples were tested by persons routinely testing patients specimen. . .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in responsibility to ensure that policies and procedures are established and maintained for monitoring staff performing preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: 1. Under the Laboratory Director's overall administration, the laboratory failed to at least annually evaluate and document competencies of persons performing hematology testing. 2. The Laboratory Director was deficient in ensuring that policies/procedures for assessing competencies in test performance were maintained in 2019. 3. The

	Laboratory Director was deficient in ensuring that competencies of test performance included proficiency testing samples, previously tested patients specimen, or internal blind testing samples. .
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on reviews of competency records for laboratory testing personnel and laboratory proficiency testing records, the lack of laboratory records, and interview with the Technical Consultant, it was determined that competency evaluations failed to include assessment of performance on proficiency testing samples, internal blind testing samples, or previously analyzed patients specimen. Findings included: 1. The form for documenting individual staff competency in operating the Horiba Micros 60 for hematology testing included evaluation by direct observation of test performance, review of QC and instrument maintenance records, and problem solving skills, but failed to include performance on testing proficiency samples. 2. The laboratory proficiency testing records failed to include participation by 7 of 9 persons routinely performing hematology testing. The laboratory failed to have other records assessing test performance on previously analyzed patients specimen or internal blind testing samples. 3. The Technical Consultant affirmed (8/19/21 @ Noon) that competency assessment of individuals didn't include evaluation by testing proficiency samples, previously tested patients specimen, or internal blind testing samples. 4. The reliability and quality of hematology results could not be assured when competency assessments were incomplete due to the failure to include evaluations of performance in proficiency testing, or testing previously analyzed patients specimen or internal blind samples. Laboratory personnel reported approximately 6,700 hematology results annually in 2019 - 2021. .
D6054	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 at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing records, laboratory documents for individual competency assessments, the lack of documents, and interview with the Technical Consultant, it was determined that the Technical Consultant was deficient in responsibility for evaluating and documenting personnel competencies in performing hematology testing at least annually in 2019. Findings included: 1. The laboratory had individual competency assessments for the years 2018, 2020, and 2021, but not for 2019. 2. The Technical Consultant affirmed (8/19/21 @ Noon) that competency assessment records for 2019 were missing. 3. And thus, the reliability and quality of approximately 6,700 hematology results reported in 2019 could not be assured. Test records included, but were not limited to, the following testing persons: AR, JS, NT, MM, MS.