Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1074665	02/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
La Familia Primary Care	168 Hospital Dr, Raton, NM	

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	During a proficiency desk review on 01/16/2020, the laboratory was found out of compliance with the following condition: 42 CFR Part 493.803 Proficiency Testing, Successful Participation
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: Based on the review of 2019 proficiency scores from the CMS (Centers for Medicare & Medicaid) database and reports from MLE (Medical Laboratory Evaluation), the laboratory failed 2 consecutive(2019-2 and 2019-3) test events resulting in Unsuccessful Participation for the analyte Sodium. Findings are: A. Review of CASPER Reports 153 & 155 from the CMS Proficiency database indicated the

	laboratory received failing scores for 2 consecutive test events in 2019. 2019-2 Sodium = 60% 2019-3 Sodium = 0% See D2087
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 the review of 2019 proficiency scores from the CMS (Centers for Medicare & Medicaid) database and reports from MLE (Medical Laboratory Evaluation), the laboratory failed 2 of 3(2019-2 and 2019-3) test events for the analyte Sodium. Findings are: A. Review of CASPER Reports 153 & 155 from the CMS Proficiency database indicated the laboratory received failing scores for 2 consecutive test events in 2019. 2019-2 Sodium = 60% 2019-3 Sodium = 0% B. Review of the MLE scores confirmed these scores.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the review of 2019 proficiency scores from the CMS (Centers for Medicare & Medicaid) database and reports from MLE (Medical Laboratory Evaluation) and API (American Proficiency Institute), the laboratory failed 2 of 3(2019-2 and 2019-3) test events for the analyte Sodium and must undergo training and technical assistance. Findings are: A. Review of CASPER Reports 153 & 155 from the CMS Proficiency database indicated the laboratory received failing scores for 2 consecutive test events in 2019. 2019-2 Sodium = 60% 2019-3 Sodium = 0% B. Review of the MLE results for 2019-3 showed a high bias (5 of 5 samples) when compared to other laboratories in the method group. As indicated in the 08/28/2019 survey, there were less than 10 laboratories enrolled with MLE that used the Envoy 500 Chemistry Analyzer and the laboratory's results were compared to results using other chemistry analyzers. C. Review of the laboratory's plan of correction from the survey dated 08/28/2019 indicated the laboratory enrolled in proficiency testing with a second agency, API, for the 3rd event of 2019 because of the larger number of participating laboratories using the Envoy 500. The laboratory scored 100% for this event and showed no bias when compared to other laboratories.