Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0399264	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
La Clinica (Mcc) Rrl - Quest Diagnostics	153 Cesar Chavez St, Saint Paul, MN	

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	The La Clinica (MCC) RRL - Quest Diagnostics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the proficiency testing desk review survey performed on April 9, 2025. The following condition-level deficiency was cited: 493.303 Successful Participation The following standard-level deficiency was cited: 493.841 Routine Chemistry .
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 review of proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the

	laboratory failed to successfully participate in PT for multiple analytes under the subspecialty Routine Chemistry in 2024 and 2025. Finding are as follows: 1. The CMS CASPER Report 0155D and the API 2024 Chemistry Core - 3rd Event Performance Summary and Comparative Evaluation and the API 2025 Chemistry Core - 1st Event Performance Summary and Comparative Evaluation were reviewed on April 9, 2025. 2. The reports indicated the laboratory failed to achieve satisfactory performance for multiple analytes in two consecutive testing events from 2024 and 2025 resulting in unsuccessful performance of the analytes (see D2093 and D2096) and the subspecialty (see D2097). .
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to submit Routine Chemistry PT results to API prior to the submission deadline. Findings are as follows: 1. The laboratory failed to submit PT results for each of the following analytes for the 2024 Chemistry Core 3rd event. Failure to participate in the testing event resulted in a score of 0% and unsatisfactory performance for each of the analytes listed below. Chloride Creatinine Glucose Potassium Sodium Blood Urea Nitrogen .
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in 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 review of proficiency testing (PT) reports from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for multiple analytes in two consecutive testing events in 2024 and 2025, constituting unsuccessful performance. Findings are as follows: 1. The API 2024 Chemistry - Core 3rd Event Performance Summary and Comparative Evaluation and the 2025 API Chemistry - Core 1st Event Performance Summary and Comparative Evaluation were reviewed on April 9, 2025. The API reports indicated the laboratory had unsatisfactory performance for the analytes listed below: Event scores 2024-3 2025-1 Chloride 0% 60% Creatinine 0% 60% Glucose 0% 60% Potassium 0% 60% Sodium 0% 60% BUN* 0% 60% *Blood Urea Nitrogen .
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) (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 review of proficiency testing scores from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the Routine Chemistry subspecialty in two consecutive testing events, constituting unsuccessful performance for the subspecialty. Findings are as follows: 1. The API 2024 Chemistry - Core 3rd Event Performance Summary and Comparative Evaluation and the 2025 API Chemistry - Core 1st Event Performance Summary and Comparative Evaluation were reviewed on April 9, 2025. The reports from API indicated the laboratory had unsatisfactory performance for the Routine Chemistry subspecialty as listed below: Unsatisfactory Routine Chemistry PT performance was obtained in the following events. -2024 3rd event 0% -2025 1st event 60% .