Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0696913	(X3) Date Survey Completed 01/16/2026
Name of Provider or Supplier Ccm Health - Clara City	**Street Address, City, State** 140 Nw 1st Ave, Clara City, 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 CCM Health - Clara City 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 January 16, 2026. The following condition-level deficiencies were cited: 493.803 Successful Participation The following standard-level deficiencies were cited: 493.851 Hematology . .
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 a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and 2025

	American Proficiency Institute (API) records, 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 failed to successfully participate in the specialty of Hematology and for the analytes Eosinophils, Monocytes, Neutrophils, and White Blood Cell (WBC) Differential. Refer to D2130. .
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 proficiency testing desk review of CASPER 0155D report and American Proficiency Institute (API) 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three consecutive testing events in the specialty of Hematology and for the analytes Eosinophils, Monocytes, Neutrophils, and White Blood Cell (WBC) Differential. Findings are as follows: 1. Review of the CASPER 0155D report revealed the following results: Hematology/Coagulation 2025 1st Event laboratory received an unsatisfactory score of 60% for Eosinophils. Hematology/Coagulation 2025 2nd Event laboratory received an unsatisfactory score of 20% for Monocytes. Hematology /Coagulation 2025 2nd Event laboratory received an unsatisfactory score of 60% for Neutrophils. Hematology/Coagulation 2025 2nd Event laboratory received an unsatisfactory score of 64% for WBC Differential. Hematology/Coagulation 2025 3rd Event laboratory received an unsatisfactory score of 60% for Eosinophils. Hematology /Coagulation 2025 3rd Event laboratory received an unsatisfactory score of 0% for Monocytes. Hematology/Coagulation 2025 3rd Event laboratory received an unsatisfactory score of 60% for Neutrophils. Hematology/Coagulation 2025 3rd Event laboratory received an unsatisfactory score of 64% for WBC Differential. 2. A review of the American Proficiency Institute (API) 2025 proficiency testing records (Hematology/Coagulation 2025 1st, 2nd, and 3rd Events) confirmed the laboratory received the above results. .
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: . Based on a proficiency testing desk review of CASPER 0155D report and 2025 American Proficiency Institute (API) records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016. .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	(e)(4)(i) 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 proficiency testing desk review of CASPER 0155D report and 2025 American Proficiency Institute (API) records, the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130. .