Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382531	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Mary Greeley Medical Center	**Street Address, City, State** 1111 Duff Avenue, Ames, IA	
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	A routine recertification survey was completed on April 29, 2025. The laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R 493.803 Condition: Successful Participation D6076 - 42 C.F.R 493.1441 Condition: Laboratory Director, high complexity
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 College of American Pathologists (CAP) proficiency testing records and confirmed by interview with the general supervisor identifier #1 (GS #1) at 9:14 am on 4/29/2025 the laboratory failed to successfully participate in two out of three consecutive testing events for the analyte quantitative human chorionic

	gonadotropin testing. The laboratory had unsatisfactory scores for 2024 testing event 1 and 2024 testing event 3. Refer to D2097.
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 College of American Pathologists (CAP) proficiency testing records and confirmed by interview with the general supervisor identifier #1 (GS #1) at 9:14 am on 4/29/2025 the laboratory failed to successfully participate in two out of three consecutive testing events for the analyte quantitative human chorionic gonadotropin testing. The findings include: 1. For 2024 event 1, the laboratory received an unsatisfactory score of zero for the analyte, quantitative human chorionic gonadotropin testing. 2. For 2024 event 3, the laboratory receive an unsatisfactory score of 60% for the analyte, quantitative human chorionic gonadotropin testing. 3. GS #1 confirmed the above unsatisfactory proficiency testing scores.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing records (2024 event 1 and 2024 event 3) and confirmed by interview with the general supervisor identifier #1 (GS #1) at 9:14 am on 4/29/2025 the laboratory director failed to provide overall management and direction of laboratory services. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 review of College of American Pathologists (CAP) proficiency testing records and confirmed by interview with the general supervisor identifier #1 (GS #1) at 9:14 am on 4/29/2025 the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2028.