Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0021848	(X3) Date Survey Completed 11/12/2020
Name of Provider or Supplier Dodge County Hospital Laboratory	**Street Address, City, State** 901 Griffin Avenue, Eastman, GA	
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 proficiency testing desk review was completed on November 12, 2020. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (Event 1 and 2

	of 2020), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT) #0835. The findings include: Refer to D2130
D2130	HEMATOLOGY CFR(s): 493.851(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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (Event 1 and 2 of 2020), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT) #0835. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte PTT #0835 on Event 1 of 2020 with a score of 20% and Event 3 of 2020 with a score of 60% 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 3. Desk review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed two consecutive events (Events 1 and 2 of 2020) for PTT, resulting in the first unsuccessful performance.
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 an in-office desk review of proficiency testing (PT) records, the Laboratory Director failed to ensure the laboratory successfully participated in two consecutive proficiency testing events (Events 1 and 2 for 2020) for analyte # 0835, Activated Partial Thromboplastin Time (PTT) in the specialty of Hematology Findings include: Refer to: (D2016 and D2130)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (Event 1 and 2 of 2020), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT) #0835. Findings include: 1. Desk review of Casper

	Reports 153 and 155 disclosed the laboratory failed analyte PTT #0835 on Event 1 of 2020 with a score of 20% and Event 3 of 2020 with 60% 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 3. Desk review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed two consecutive events (Events 1 and 2 of 2020) for PTT, resulting in the first unsuccessful performance.