Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0263738	02/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jasper Memorial Hospital	898 College Street, Monticello, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 26, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 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 Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of 3 events (Events 1

	and 3 of 2019), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT). 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 Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of 3 events (Events 1 and 3 of 2019), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT). Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte PTT #0835 on Event 1 of 2019 with a score of 60% and Event 3 of 2019 with a score of 20%. 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 Association of Bioanalysts (AAB) confirmed the laboratory failed PT on Events 1 and 3 of 2019 resulting in the first unsuccessful performance.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on testing personnel document review and staff interview, the laboratory failed to perform competencies for 3 out of 14 testing personnel as required. Findings include: 1. Personnel record review revealed there were no annual competencies performed for the following TP (CMS 209) for 2018: TP #2, TP #3, and TP #6. 2. An interview with the general supervisor, in a front office on February 26, 2020 at approximately 1:45 p.m. confirmed there were no competency documents available at the time of survey for 3 out of 14 staff for 2018.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on the review of the Implementation Documents for the Beckman Coulter Unicell DxH 600 (DxH) Hematology Analyzer, and staff interview, there was no documentation that the Laboratory Director(LD) had reviewed and approved for the use of the DxH before patient testing was performed. Findings: 1. Review of the Implementation Documents for the DxH there was no documentation that the LD had reviewed and approved the use of the DxH before patient testing was performed. 2. Interview with the Technical Supervisor, on February 26, 2020, at approximately 1 pm in the front office, confirmed that there was no documentation that the LD had reviewed and approved the use of the DxH, Hematology Analyzer before patient testing was performed.
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of 3 events (Event 1 and 3 of 2019), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT). The findings include: Refer to D6089
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 Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of 3 events (Events 1 and 3 of 2019), resulting in the first unsuccessful occurrence for Activated Partial Thromboplastin Time (PTT). Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte PTT #0835 on Event 1 of 2019 with a score of 60% and Event 3 of 2019 with a score of 20%. 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 Association of Bioanalysts (AAB) confirmed the laboratory failed PT on Events 1 and 3 of 2019 resulting in the first unsuccessful performance.