

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0263738	(X3) Date Survey Completed 05/23/2022
Name of Provider or Supplier Jasper Memorial Hospital	Street Address, City, State 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 proficiency testing desk review was completed on May 23, 2022. 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>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) report, the laboratory failed to maintain satisfactory performance in event 2 of 2021 and event 1</p>

of 2022 resulting in the first and second unsuccessful occurrence for Compatibility Testing analyte # 895. Findings include: Refer to D 21

D2173

COMPATIBILITY TESTING

CFR(s): 493.863(a)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory 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 proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two testing events (2nd event of 2021 and 1st event of 2022), resulting in the second unsuccessful occurrence for Compatibility testing analyte # 895. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #895 on event 2 of 2021 with a score of 80% and event 1 of 2022 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts(AAB)confirmed the laboratory failed two testing events (2nd event of 2021 and 1st event of 2022), resulting in the second unsuccessful occurrence for Compatibility testing analyte # 895.

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 a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2021 and 2022 proficiency testing (PT) evaluation reports from the American Association of Bioanalysts (AAB) , the laboratory director failed to ensure the laboratory maintained satisfactory performance in two proficiency testing events for Compatibility Testing resulting in the second unsuccessful PT occurrence for Compatibility Testing #895. The findings include: Refer to D6079 for details

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2021 and 2022 proficiency testing (PT) evaluation reports from the American Association of Bioanalysts (AAB) , the laboratory director failed to ensure the laboratory maintained satisfactory performance in two proficiency testing events for Compatibility Testing resulting in the second unsuccessful PT occurrence for Compatibility Testing #895. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory Compatibility Testing scores: 2021 event two 80%, 2022 event one 60%. 2. Review of the 2021 AAB event two evaluation report confirmed unacceptable result for sample 8. 3. Review of the AAB 2022 event one evaluation report confirmed unacceptable results for samples 1 and 3.