| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D0464490 | 11/17/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Madison Parish Hospital | 900 Johnson Street, Tallulah, LA | |

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 |
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| **D0000** | A Recertification survey was performed on November 14, 2022 through November 17, 2022 at Madison Parish Hospital, CLIA # 19D0464490. Madison Parish Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1441 CONDITION: Laboratory Director, High Complexity |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory's American Proficiency Institute proficiency testing records, CASPER 155D report and interview with personnel, the laboratory failed to successfully perform in Compatilbilty Testing proficency testing events in 2021. |

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| | Findings: 1. The laboratory failed to achieve a satisfactory score of 100% for two (2) of five (5) proficiency testing events in 2021 and 2022 resulting in an initial unsuccessful performance for Compatibility Testing. Refer to D2181. |
| **D2181** | COMPATIBILITY TESTING<br>CFR(s): 493.863(e)<br><br>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing records from American Proficiency Institute (API), the CASPER 155D report, and interview with personnel, the laboratory failed to achieve a satisfactory score of 100% for two (2) of five (5) proficiency testing events in 2021 and 2022 resulting in an initial unsuccessful performance for Compatibility Testing. Findings: 1. Review of the CASPER 155D report revealed the laboratory received the following scores of less than 100% for Compatibility Testing for the following two (2) of five (5) consecutive testing events: a) 2021 event 2 for Compatibility Testing: score of 80% b) 2021 event 3 for Compatibility Testing: score of 80% 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory received the following scores for Compatibility Testing in 2021: a) API 2021 Immunology/Immunohematology 2nd event: score of 80% for sample SER-10 (unacceptable) b) API 2021 Immunology/Immunohematology 3rd event: score of 80% for sample SER-12 (unacceptable) 3. In interview on November 15, 2022 at 1115 am, Technical Consultant 2 confirmed the laboratory proficiency testing events were unsuccessful and that remedial actions for the two (2) events in 2021 were already performed. |
| **D5559** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(e)(f)<br><br>(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies, quality control records, patient transfusion logs and interview with personnel, the laboratory failed to document quality control for blood bank testing prior to patient testing. Findings: 1. Review of the laboratory's Blood Bank quality control (QC) policy revealed the laboratory performs QC each day of blood bank testing which covers a twenty-four (24) hour period. 2. Review of the laboratory's blood bank QC records and patient transfusion logs from July 2021 |

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| | through October 2022 revealed the laboratory did not perform QC for the following: a) American Proficiency Testing (API) proficiency testing event performed on August 6, 2022 at 20:00 pm - Last documented QC performed August 5, 2022 18:30 pm 3. In interview on November 15, 2022 at 11:50 am, General Supervisor 1 stated that the quality assurance (QA) checks performed for the month of August 2022 obviously missed that QC was not documented. General Supervisor 1 confirmed the laboratory did not have documentation of QC for the sample identified. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory proficiency testing records and interview with personnel, the laboratory failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D6092. |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing records and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Findings: 1. The laboratory failed to achieve a satisfactory score of 100% for two (2) of five (5) proficiency testing events in 2021 and 2022 resulting in an initial unsuccessful performance for Compatibility Testing. Refer to D2181. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control records, patient test logs and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5559. |