Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465641	03/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Magnolia Regional Health System Inc	101 Hospital Drive, Magnolia, AR	

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
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 2019 and 2020 CMS Casper Reports 0155D, 0153D, and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to have non-initial unsuccessful participation in proficiency testing for the test of Blood Cell Identification (Cell I.D.). Survey findings follow: Failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2130.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)

	(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: . Based on review of 2019 and 2020 CMS Casper Reports 155D, 153D and American Proficiency Institute (API) testing results, it was determined the laboratory had a subsequent unsuccessful performance for the test of Blood Cell Identification (Cell I. D.). Failure to achieve satisfactory performance for the test Blood Cell ID in three of four proficiency testing events. A. A review of the proficiency testing results revealed the laboratory received a score of 0% for the test of Cell ID in the first proficiency testing event of 2019. B. A review of the proficiency testing results revealed the laboratory recieved a score of 60% for the test of Cell ID in the third proficiency testing event of 2019. C. A review of the proficiency testing results revealed the laboratory recieved a score of 0% for the test of Cell ID in the first proficiency testing event of 2020.
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 review of the 2019 and 2020 CMS Casper Reports 155D, 153D and American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed three of four proficiency testing events which constitutes non-initial unsuccessful performance for the test of Blood Cell Identification (Cell ID). Survey findings follow: A. A review of the proficiency testing results revealed the laboratory received a score of 0% for the test of Cell ID in the first proficiency testing event of 2019. B. A review of the proficiency testing results revealed the laboratory recieved a score of 60% for the test of Cell ID in the third proficiency testing event of 2019. C. A review of the proficiency testing results revealed the laboratory recieved a score of 0% for the test of Cell ID in the first proficiency testing event of 2020.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on a review of the 2019 and 2020 proficiency testing results, it was determined the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that 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 2019 and 2020 proficiency testing event results, it was determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the analyte Blood Cell Identification. Refer to D2130