

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469373	(X3) Date Survey Completed 10/29/2021
Name of Provider or Supplier Mercy Waldron	Street Address, City, State 1341 W 6th St, Waldron, 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 the 2021 CMS Casper Reports 0155D, 0153D, and the American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to have initial successful participation in proficiency testing for the analyte Total Bilirubin (TBILI). Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 2021 CMS Casper Reports 0155D and 0153D and American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to have satisfactory participation in proficiency testing for the analyte Total Bilirubin (TBILI) Survey Findings follow: A. A review of the proficiency testing results revealed the laboratory received a score of 0% for the analyte TBILI in the first proficiency testing event of 2021. B. A review of the proficiency testing results revealed the laboratory received a score of 40% for the analyte TBILI in the third proficiency testing event of 2021.
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 review of the 2021 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 the 2021 proficiency testing event, it was determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the analytes Total Bilirubin. Refer to D2096