

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469373	(X3) Date Survey Completed 02/13/2023
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	<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 review of 2022 CMS Casper reports 0155D, 153D, and American Proficiency Institute (API) proficiency testing results, it was determined the laboratory failed to have initial successful participation in proficiency testing in the sub-specialty of Immunohematology and the test Compatibility testing as evidenced by: Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2173.</p>
D2181	COMPATIBILITY TESTING

	<p>CFR(s): 493.863(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2022 CMS CASPER Reports 155D, 153D and the American Proficiency Institute(API) proficiency testing results, the laboratory failed to achieve satisfactory performance in two consecutive proficiency testing events for the analyte compatibility testing as evidenced by: A. The Laboratory received a score of 80% for compatibility testing in the third proficiency testing event of 2022. B. The Laboratory received a score of 80% for compatibility testing in the second proficiency testing event of 2022.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2022 proficiency testing results the laboratory director failed to provide overall management and direction to the lab for successful participation in proficiency testing. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: . Based on review of the 2022 proficiency testing events, it was determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the analytes Compatibility Testing. Refer to D2173</p>