Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316753	09/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Delta Health System - The Medical Center	1400 East Union St - Laboratory, Greenville, MS	

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	The following condition level deficiencies were cited: D2016 - 42 C.F.R. 493.803 Condition: Successful participation, proficiency testing D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
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 surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the American Proficiency Institute and the CASPER report 0153D /0155D from the Centers for Medicare and Medicaid Services data system) on 9/23

	/2022, the laboratory has not successfully performed proficiency testing for Prothrombin Time on three of three events (3rd event of 2021, 1st and 2nd events of 2022). Refer to D2130.
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 surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the American Proficiency Institute and CASPER reports 0153D /0155D from the Centers for Medicare and Medicaid Services data system) on 9/23 /2022, the laboratory has not successfully performed proficiency testing for Prothrombin Time in three of three events. Findings include: A review of the laboratory records from the American Proficiency Institute (API) and the CMS CASPER reports 0153D/0155D revealed the laboratory scored the following for Prothrombin Time: Year 2021-3rd Event: 0% Year 2022-1st Event: 20% Year 2022-2nd Event: 60%
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 surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the American Proficiency Institute and CASPER reports 0153D /0155D from the Centers for Medicare and Medicaid Services data system) on 9/23 /2022, the laboratory director failed to provide overall management and direction for ensuring Hematology proficiency testing was tested for three out of three events as required under Subpart H. 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 surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the American Proficiency Institute and CASPER report 0153D /0155D from the Centers for Medicare and Medicaid Services data system) on 9/23

	/2022, the laboratory director failed to ensure Hematology proficiency testing was tested as required under Subpart H. The laboratory failed to maintain satisfactory performance in three consecutive events (3rd event of 2021, 1st and 2nd events of 2022) resulting in the subsequent unsuccessful performance for Prothrombin Time. Refer to D2130.