Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0674058	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
William Brent Young Md Pa	1550 Pinehurst Dr, Spring Hill, FL	

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	An announced CLIA validation survey was conducted at William Brent Young MD PA on 07/08/2024 - 07/16/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: 493. 803 Condition: Successful participation
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 laboratory's proficiency testing records for 2022-2023, the laboratory failed to successfully participate in subspecialty of Routine Chemistry for the analyte glucose for two of two events (2nd Event 2022 - 60% and 1st Event 2023 - 0%). Refer to 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 American Proficiency Institute (API) proficiency testing and interview with Testing Person #C, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of two proficiency testing event (2022 2nd Event and 2023 1st Event) in the Subspecialty of Routine Chemistry for the analyte glucose. Findings Included: Review of API proficiency testing revealed unsuccessful performance for the following analyte: Event #2 2022 Glucose (non - waived) 60% Event #1 2023 Glucose (non-waived) 0% On 07/08/2024 at 11:15 AM, the Testing Person #C stated the 2nd Event 2022 the unacceptable proficiency testing specimens were reran after receiving the proficiency results and the results were acceptable. Testing Person #C stated the laboratory did not investigate why the laboratory did not get acceptable results when the specimens were tested the first time. The laboratory did not address the 0% for glucose(non - waived) for the 1st Event 2023. The 1st Event 2023 proficiency testing specimens were put in the freezer which was unacceptable and the testing persons did not know they were there until it was too late to submit the proficiency results.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: 0Based on observation, record review, and interview with the Testing Person #C, the laboratory failed to ensure three out of three tubes labeled with a L and three out of three tubes labeled H in the laboratory freezer were labeled with the name of the reagent, lot number, and expiration date. Total annual volume for total bilirubin was 344 and the total annual volume for direct bilirubin was 176. Findings included:. On 07/08/2024 at 10:00 am, observations revealed three out of three tubes labeled with a L and three out of three tubes labeled H in the laboratory freezer were labeled with the name of the reagent, lot number, and expiration date. Record review of the "Serum Control Kit" package insert for lot number 1449 revealed that the freezer storage temperature of "-15 C - -25 C was acceptable for four weeks but the package insert stated "Excepttion for Total and Direct Bilirubin" was six days. Record review of the total bilirubin and direct bilirubin Low and High serum control records from 07/13 /2023 to 07/14/23 revealed all quality controls were within range. On 07/08/2024 at 11:15 am, Testing Person #C stated after she reconstitutes the low and high chemistry controls, makes five aliquots of each and puts four of each of the aliquots in the freezer. Photographic evidence was obtained.