Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2129713	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Indigobridge Laboratories, Llc	3000 Kent Ave Ste 2962, West Lafayette, IN	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a policy /procedure or perform twice annual accuracy verification for one of one assay not included in subpart I (EGCg-Epigallocatechin gallate) in 2019. Findings include: 1) Review of "Enclosure I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," signed and dated by the laboratory director on 2/18/20, indicated UHPLC (Ultra-High-Performance Liquid Chromatography) testing was being performed to detect EGCg levels in plasma. 2) Upon request for a policy/procedure for twice annual verification of EGCg testing on 3/11/20 at 1:25 pm, SP-2 indicated none was available. 3) Medical record review indicated the following patients had UHPLC testing performed: PT=patient uM=micro Molar PT Date Result a) PT#1 1-28-20 . 205uM b) PT#2 1-19-20 .874uM c) PT#3 1-15-20 .543uM d) PT#4 2-21-20 .457uM e) PT#5 2-26-20 .273uM 4) In interview on 3/11/20 at 1:26 pm, SP-2 confirmed the laboratory failed to establish a policy/procedure for twice annual verification of EGCg testing (not included in Subpart I). SP-2 further indicated testing occurred beginning 3 /28/19. No policy/procedure was in place for twice annual verification in 2019 or 2020, and no twice annual verification occured in 2019. 5) Approximate annual test volume for EGCg is, 300.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to

	determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure verification procedures were accurate for UHPLC (Ultra-High-Performance Liquid Chromatography) testing prior to patient testing for one of one procedure, EGCg (Epigallocatechin gallate). Findings include: 1) Review of "Enclosure I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," signed and dated by the laboratory director on 2/18/20, indicated UHPLC testing was being performed to detect EGCg levels in plasma. 2) Personnel file review indicated a hire date for the laboratory director on 1/6/20. 3) Review of test verification data indicated the laboratory director signed approval on 2/18/20 for EGCg testing. 4) Medical record review indicated the following patients had UHPLC testing performed prior to the laboratory director's signed approval for EGCg testing accuracy on 2/18/20: PT=patient uM=micro Molar PT Date Result a) PT#1 1-28-20 .205uM b) PT#2 1-19-20 .874uM c) PT#3 1-15-20 .543uM 5) In interview on 3/11/20 at 10:54 am, SP-2 confirmed the laboratory director's signed the test verification documentation on 2/18 /20, a date after patient testing had begun. 5) Approximate annual test volume for EGCg is, 300.