Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2220308	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Consortiums Laboratory Services Llc	31201 Chicago Rd Ste B-102, Warren, MI	

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
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: . Based on observation and interview with the Testing Personnel (TP), the laboratory failed to label the "DEPC-DW" (distilled water) bottle with the date the bottle was opened and put into use for 24 (February 15 to March 10, 2022) of 24 days of testing. Findings include: 1. During a tour of the laboratory on 3/10/2022 at 10:37 am the surveyor observed the "DEPC-DW" bottle stored in the extraction hood with no date recorded on the label when put into use. 2. When queried on 3/10/2022 at 10:37 am, TP was unable to give a date the distilled water bottle had been put into use for testing. 3. An interview on 3/10/2022 at 10:37 am, TP confirmed there was no open date recorded on the bottle of "DEPC-DW."
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 with the Laboratory Liaison (LL), the

	Laboratory Director (LD) failed to determine the procedures used in the verification process were adequate prior to testing patient samples for 24 (February 15 to March 10, 2022) of 24 days of testing. Findings include: 1. A record review revealed the LD did not review, evaluate the verification procedures, and the raw data prior to running patient samples for 24 of 24 days of testing. 2. An interview on 3/10/2022 at 1:57 pm, the LL confirmed the LD did not review, evaluate procedures, and the raw data prior to running patient samples.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the Laboratory Director failed to approve 3 of 3 procedure manuals for the laboratory's testing processes for 24 (February 15 to March 10, 2022) of 24 days of testing patient samples. Findings include: 1. A review of the laboratory's procedure manuals revealed a lack of documentation of the Laboratory Director approving the laboratory's testing procedures for the following manuals: a. Lab Procedure Manual b. ExiPrep 96 Lite SOP c. QuantStudio 5 2. An interview on 3/10/2022 at 10:51 am the LL confirmed the manuals listed above had not been approved by the Laboratory Director prior to testing and reporting patient samples.