Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2217768	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quantum Laboratory Services Llc	824 North Creek Drive, Conway, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Through a review of the instructions for use of the Atila Biosystems iAMP Covid-19 Detection Kit, laboratory policies and procedures "COVID-19 Patient Sample Collection, Shipping and Reporting" and interviews with laboratory staff, it was determined the laboratory did not ensure specimen preservation until the time of testing which has the potential to affect all patient specimens shipped to the laboratory for testing by FedEx overnight delivery.. Survey findings follow: A) The instructions for use of the Atila Biosystems iAMP Covid-19 Detection Kit state under "specimen handling and storage" the "specimens can be stored at room temperature for up to 12 hours or - 20 degrees C. for up to 2 days after collection before spcimen processing". B) The Quantum Laboratory policies and procedures "COVID-19 Patient Sample Collection, Shipping and Reporting" states "specimens can be stored at room temperature for up to 12 hours, or -20 degrees C. for up to 2 days after collection and before specimen processing". C) At 09:10 a.m. on 11/29/22, the laboratory testing personnel (# 3 on the CMS 209 form) said the laboratory performs testing for clinics located in Arkansas and clinics located in Louisiana and Texas. That specimens from Arkansas are picked up by courier by appointment and specimens from out of state are delivered by FedEx overnight delivery in an unfrozen state and without any temperature regulation device. D) In an intrerview at 09:30 a.m. the laboratory consultant , identified as number 2 on the Entrance and Exit Conference Attendance

	form confirmed that it was unlikely that specimens sent overnight by FedEx were frozen or delivered within 12 hours of collection and "we will have to do a specimen stability study".
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of the CMS 209 form, personnel files for the two testing personnel listed on the CMS-209 form, lack of documentation and interviews with staff, it was determined the laboratory director failed to specify, in writing, the procedures each testing person can perform and whether supervision is required for two of the two testing personnel. Survey findings follow: A) Review of the CMS 209 form revealed that two testing personnel (# 3 and #4 on the CMS 209 form) were identified. B) In an interview on 11/29/22 at 09:20 a.m. the testing personnel (#3 on the CMS 209 form) stated that both testing personnel identified on the CMS 209 form performed tests and reported test results. C) Through a review of testing personnel employment files it was revealed that testing personnel (numbers three and four on the CMS 209 form) lacked documented authorization to perform testing. D) Upon request the laboratory was unable to produce written authorization by the laboratory director allowing testing personnel (# 3 and #4 on the CMS 209 form) to perform testing E) In an interview on 11/29/22 at 09:25 a.m. the laboratory consultant, identified as # 2 on Entrance and Exit Conference Attendance form, confirmed the laboratory director failed to document authorization to perform testing for the teesting personnel identified above.