# **BIOANALYTICAL ASSAY FEATURE:**





In the battle against COVID-19, Frontage, a contract research organization ("CRO") providing integrated, science-driven, product development services, is first to develop a cocktail Bioanalytical PK assay for hydroxychloroquine, chloroquine and azithromycin in human plasma.

While separate PK assays for each individual drug are available, our novel 3 in 1 multiplex assay provides higher efficiency for faster data delivery and lower cost to support clinical trials with combination of the drug treatments. In addition, the multiplexed assay requires minimal sample volume to be collected from patients.

CHLOROQUINE	HYDROXYCHLOROQUINE	AZITHROMYCIN
HN N	HN N OH	H <sub>3</sub> C N CH <sub>3</sub> H <sub>3</sub> C N CH <sub>3</sub> H <sub>3</sub> C N CH <sub>3</sub> H <sub>3</sub> C CH <sub>3</sub>

In addition, the multiplexed assay requires minimal sample volume to be collected from patients and therefore minimal exposure to biohazardous samples for Bioanalytical scientists.

Analytes	Chloroquine/Hydroxychloroquine/Azithromycin	
Matrix	Human K2EDTA Plasma	
Assay Range	2-1000 ng/mL for all	
Plasma volume/extraction	50 uL	
Instrument	AB Sciex API5000	
Validation Parameters meeting FDA Guidance	Intra-run and Inter-run Accuracy & Precision, Sensitivity, Matrix Selectivity, Linearity, Carryover, Batch size, Stability (benchtop, freeze-thaw, re-injection, long term frozen stability), reproducibility, analyte to IS, hemolysis, whole blood stability, lipemic	

**FOR MORE INFORMATION, CONTACT US AT:** sales@frontagelab.com **OR VISIT US AT:** frontagelab.com



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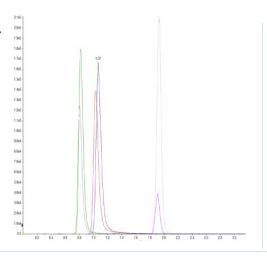
Covid-19 Cocktail PK Assay Hydroxy-Chloroquine Chloroquine and Azithromycin



A representative chromatogram at the LLQ (Lower Limit of Quantitation, 2 ng/mL for all three analytes in human plasma) shows excellent sensitivity, separation and peak shape for three analytes along with their SIL-IS, respectively (6 MRM transitions).

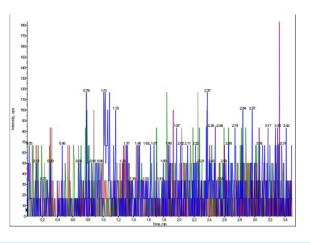
### FIGURE 1.

IS (6 MRM channels for 3 analytes and 3 IS's)



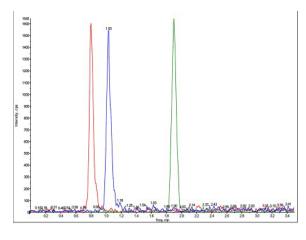
#### FIGURE 2.

Control Blank Human plasma (6 MRM channels for 3 analytes and 3 IS's)



#### FIGURE 3.

LLOQ (3 MRM channels for analytes, IS not shown)



Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, scientifically-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their drug development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Rigorous scientific expertise, high quality standards and regulatory compliance is committed to every program. Frontage has enabled many innovator, generic and consumer health companies of all sizes to advance hundreds of molecules through development and file regulatory submissions in global markets allowing for successful development of important therapies and products for patients worldwide. Frontage Laboratories, Inc. is a CRO providing integrated, scientifically-driven research, analytical and development services throughout the drug discovery and development process to enable biopharmaceutical companies to achieve their drug development goals. We offer our clients comprehensive services in analytical testing and formulation development, drug metabolism and pharmacokinetics (DMPK), bioanalysis, preclinical safety and toxicology and early phase clinical studies. We have enabled many innovator, generic and consumer health companies of all sizes to file IND, NDA, ANDA, BLA and 505(b)(2) submissions in global markets allowing for successful development of important therapies and products for patients. We have successfully assisted clients to advance hundreds of molecules through development to commercial launch in global markets. We are committed to providing rigorous scientific expertise to ensure the highest quality and compliance.

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