

## QUALIFICATION DECISION LETTER

DDTBMQ000044

October 12, 2018

Sean C. Murphy, MD/PhD  
University of Washington  
Department of Laboratory Medicine  
750 Republican Street, E633  
Seattle, WA 98109

Re: Biomarker Qualification Determination

Dear Dr. Murphy:

Please refer to your Full Qualification Package for biomarker qualification DDTBMQ000044 dated and fully completed March 10, 2017, and reviewed under the legacy qualification process prior to establishment of the section 507 process of the Federal Food, Drug, and Cosmetic Act (FD&C).

The Biomarker Qualification Program (BQP) has completed its review of your submission and is qualifying the following biomarker for the listed context of use (COU):

**Biomarker:** *Plasmodium falciparum* 18S rRNA/rDNA (copies/ml) measured in blood samples by a nucleic acid amplification test

**Context of Use:** A monitoring biomarker, that when positive, informs initiation of rescue treatment with an anti-malarial drug  $\geq 6$  days following controlled human malaria infection (CHMI) with *P. falciparum* sporozoites in healthy subjects (18-50 years old) from non-endemic areas enrolled in clinical studies for vaccine and/or drug development

For full details regarding this qualification determination, including specific information about how this qualified biomarker can be used in drug development programs and clinical trials, please refer to the following information on our [List of Qualified Biomarker website](#)<sup>1</sup>.

If you have any questions, please contact the Biomarker Qualification Program at [CDER-BiomarkerQualificationProgram@fda.hhs.gov](mailto:CDER-BiomarkerQualificationProgram@fda.hhs.gov).

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<sup>1</sup><https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram>



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

Sincerely,

Christopher Leptak, MD/PhD  
Director, CDER Biomarker Qualification Program  
Office of New Drugs/CDER

Marion Gruber, PhD  
Director, Office of Vaccines Research and Review  
CBER

Sumathi Nambiar, MD  
Director, Division of Anti-Infective Drug Products  
Office of Antimicrobial Products  
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