EUROPEAN COMMISSION

Expert panels on medical devices and *in vitro* diagnostic medical devices (Expamed)

Ongoing performance evaluation under the IVD

Administrative information

Internal PECP dossier #	IVD-2023-000019

Ongoing performance evaluation consultation procedure

Tick to confirm ☒	There are currently no relevant CS available for the class D device under assessment

Intended purpose (P)		
P1	what is detected and/or measured *please specify the analyte(s) or marker(s), e.g. SARS-CoV-2 spike protein, Kel1 (K)*	Plasmodium (P. *falciparum*, P. *malariae*, P. *vivax*, P. *ovale* and P. *knowlesi*) DNA and RNA
P2	function of the device *e.g. diagnosis, aid to diagnosis, monitoring, determining the infectious load, tissue typing etc*	This test is intended for the screening of donor samples for the direct detection of Plasmodium DNA and RNA in whole blood samples. It is also intended for use in testing whole blood samples to screen organ and tissue donors when samples are obtained while the donor's heart is still beating.
P3	the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate *e.g. hepatitis C infection, exposure to SARS-CoV-2, risk of HIV transmission in blood transfusion etc.*	Malaria infection
P4	whether it is automated or not	Automated
P5	whether it is qualitative, semi-quantitative or quantitative	Qualitative
P6	type of specimen(s) *e.g. whole blood, serum, saliva etc*	Whole blood
P7	where applicable, the testing population *e.g. persons with specific health conditions, persons with specific symptoms, children in a certain age range*	Living donors of whole blood and blood components.
P8	intended user	Trained laboratory professionals proficient in using automated platform
Technology (T)		
T1	principle of the assay method or principles of operation of the instrument *e.g. real-time PCR, qualitative PCR, digital PCR, sandwich immunoassay, competitive immunoassay, immunoturbidimetric assay etc.*	Real-time PCR