



QuantuMDx

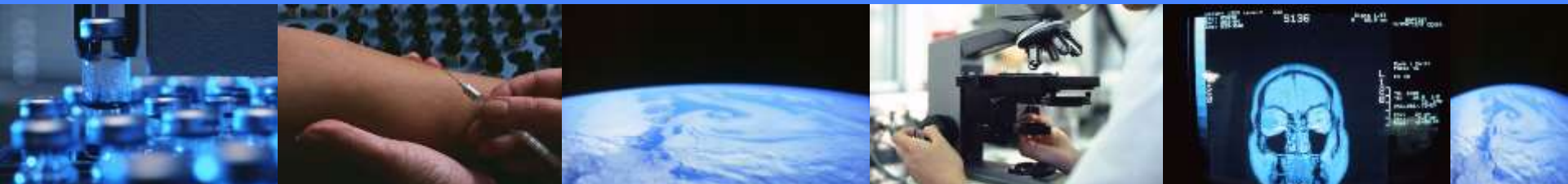
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Development of a *Leishmania* identification PCR assay for use with next generation PoC diagnostic devices

Dr Evangelia Piperaki & Dr Henry M. Staines

DoI : SK is on the Scientific Board of QuantuMDx and both HMS and SK are shareholders



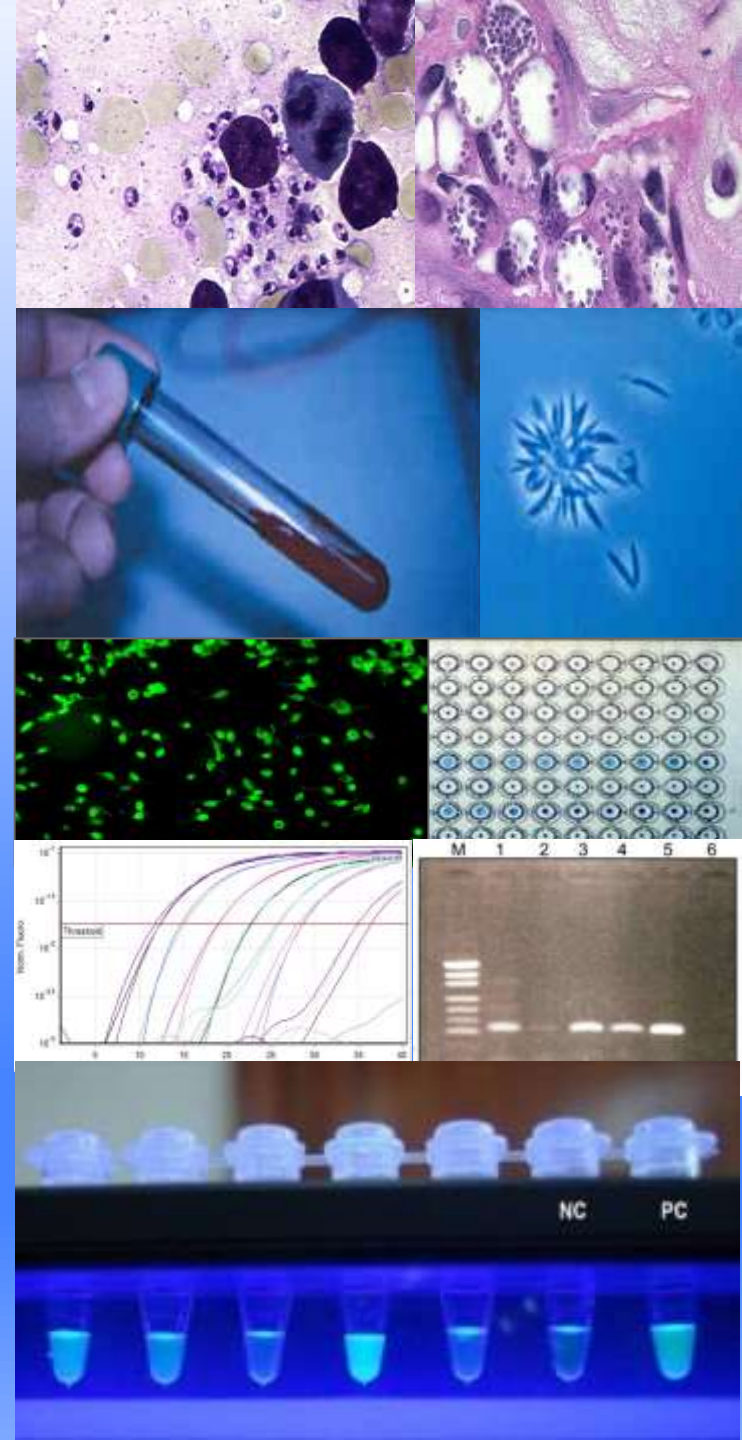
Leishmaniasis

- ~20 species of *Leishmania* infect humans
- 98 countries
- 9th largest disease burden among infectious diseases
- VL Incidence 0.2 - 0.4 mil
~50,000 deaths
- CL Incidence 0.7 to 1.2 mil



Diagnosis

- Microscopy – Culture
 - Invasive/dangerous sampling
 - Expertise/equipment
- Serology
 - Sensitivity, cross-reactivity, differentiation of past/current infection
- Molecular methods
 - Infrastructure, expertise



Need for improved diagnosis

- Post Kala-azar Dermal Leishmaniasis (PKDL) diagnosis & determination of parasitic load
- Detection of asymptomatic infections
- Test of cure
 - Follow up
 - relapses (HIV+)



The Partners

- LSHTM – Prof Simon Croft (PI), Dr Vanessa Yardley, Dr Evangelia Piperaki
- QuantuMDx – industrial partner (SME based in Newcastle)
- SGUL – Prof Sanjeev Krishna, Dr Henry Staines, Ms Rebekah Burrow



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NanoMal

- £4 million, FP7 European Union funded
- Develop a diagnostic device for malaria for:
 - All spp.
Pf, Pv, Pm, Po, Pk
- which must be:
 - Simple
 - Handheld, Point-of-Care (PoC)
 - Accurate
 - Rapid (< 20 mins)
 - Uploadable data
 - Cheap
- In addition.....

Resistance mutations

Antimalarial Drug	Resistance Mutation
Artemisinin	A623E and S769N in PfATP6
Amodiaquine	K76T mutation in PfCRT and N86Y mutation in PfMDR1
Atovaquone	Y268S/C/N mutation in cytochrome <i>b</i>
Azithromycin	G76V mutation in the ribosomal protein L4
Chloroquine	K76T mutation in PfCRT
Clindamycin	A1875C mutation in apicoplast 23S rRNA
Cycloguanil	Mutations in DHFR: A16V and S108T
Fosmidomycin	<i>pfdxr</i> amplification
Lumefantrine	<i>pfmdr1</i> amplification and N86Y
Mefloquine	<i>pfmdr1</i> amplification
Pyrimethamine	Mutations in DHFR: S108N, N51I, C59R and I164L
Sulfadoxine	Mutations in DHPS: S436A/F, A437G, K540E, A581G and A613S/T

A. Ecker, A.M. Lehane & D. Fidock
in Staines & Krishna (Eds) Treatment and Prevention of Malaria

Malaria v1

Test Results

Patient ID

46MM768/LS

DOB

03.17.1978

Result

Positive

Species

Plasmodium falciparum, P. vivax,
P. ovale, P. malariae, P. knowlesi

Chloroquine

K76T

Atovaquone

Anti-Folates

Output

The Project

- Use the platform PoC technologies that QuantuMDx have developed for diagnosis of *Leishmaniasis*
- Develop a sensitive PCR assay for diagnosis of *Leishmaniasis* that is compatible
 - Small sample volume
 - *Leishmania donovani*, multicopy target (kDNA)
- Demonstrate the assay with QuantuMDx's PoC device



Thank you to the
Tropical Infectious
Disease Consortium
for this opportunity



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