

Malaria Antibodies

Improved Assay for the
determination of total antibodies
to Plasmodium species

known worldwide



GENTAUR

Introduction



More than 40% of world's population lives in areas where malaria is endemic and therefore are exposed to infection.

Upon infection antibodies are raised against the major immunodominant antigens of the infecting Plasmodium species.

The presence of antibodies to P. species is considered an evidence of an happened infection but is not a marker of infectivity for which the P. species antigen test remains the method of excellence.

Main Features



- CE marked product
- No sample predilution
- Automatable for routine Ab testing
- Total process time of 2.30 hours
- Biotine-Avidin amplification system
- Total antibodies detected
- Designed for shipping to hot climate countries

Sensitivity 1



- The **Analytical Sensitivity** was defined on the sample coded # 71281 (version 3 15 September 2005) of the panel of positive Ab samples to Plasmodium species produced by NIBSC, UK.
- Results of limiting dilution of the positive sample into a negative specimen (Dil.) are reported in the table below with reference to a CE marked kit (Diamed/Biorad):

Dil.	Dia.Pro S/Co	Diamed S/Co
1x	2.1	0.4
2x	1.1	0.4
4x	0.5	0.3
Dil.	0.1	0.4

Sensitivity 2



- In addition the sensitivity of the system was also assessed on the panel supplied by NIBSC, UK, for antibodies to Plasmodium species.
- Results (S/Co values) for three lots of product are reported in the table below with reference to a CE marked kit (Diamed/Biorad):

Member	Dia.Pro S/Co	Diamed S/Co
72/345	2.6	1.6
71/281	2.8	0.4
71/326	1.6	0.9
72/341	4.1	1.6
72/348	2.7	1.6
72/138	0.5	0.8

Specificity



It was evaluated on samples from blood donors and non-selected patients from hospital laboratories. Results are reported in the table below:

	Blood donors	Non selected	Total
N° samples	500	300	800
N° false positive	5	6	11
% Specificity	99	98	99