

Celllabs Product Profile

Quantimal pLDH MALARIA CELISA









INTENDED USE AND PRINCIPLE OF THE TEST

Malaria can be diagnosed by many methods. It is well established that the presence of pLDH in clinical blood samples is indicative of active infection and its absence reflects the cure or the lack of malaria infection. Unlike histidine rich proteins like HRP-2, the pLDH enzyme is secreted only by live parasites and survives only briefly in the patient blood. The Quantimal™ pLDH Malaria CELISA test can therefore be used to detect current and active infection as well as assist in monitoring anti-malarial chemotherapy.

The Quantimal™ pLDH CELISA kit detects the enzyme lactic dehydrogenase (pLDH) common to all *Plasmodium spp.* This is a confirmatory test for active and current human malaria. Quantimal™ pLDH Malaria CELISA can also be used to monitor anti-malarial chemotherapy, to monitor resistance of *Plasmodium* parasites to chemotherapy and for in-vitro evaluation of anti-malarial drugs. It is not intended to replace the conventional blood film diagnosis. The sandwich ELISA principle is employed.

Quantimal™ pLDH Malaria CELISA can be used with a variety of clinical samples such as whole blood, patient blood culture (drug resistance studies), plasma or serum.

CONTENTS OF THE KIT

		Standard	Bulk
	Celisa Plate – 1x96 wells - (single use only)	2 plates	10 plates
	Positive Control	1 x 0.5mL	1 x 1.0mL
	Negative Control	1 x 2.5mL	1 x 5.0mL
	Enzyme Conjugate (x200)	1 x 0.12mL	1 x 1.2mL
	PBS/Tween (x20)	1 x 125mL	1 x 650mL
	Substrate Chromogen (TMB) (20x)	1 x 1.2mL	1 x 7.5mL
	Substrate Buffer	1 x 24mL	1 x 125mL
	Stopping Solution	1 x 12mL	2 x 30mL

All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

MATERIALS REQUIRED BUT NOT PROVIDED

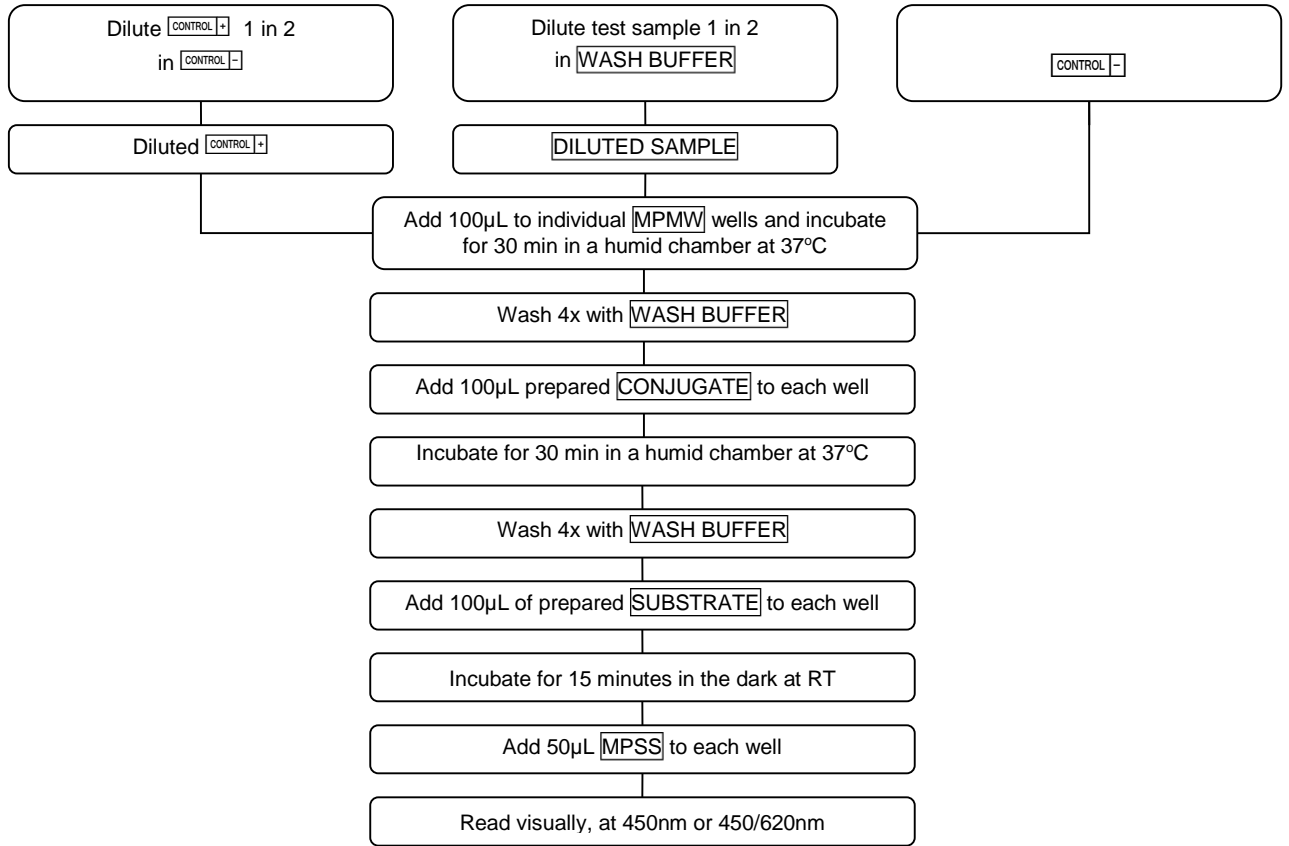
- Malaria positive blood samples
- Micropipettes and tips
- Clean glassware or plastic containers for solutions.
- Humid chamber
- ELISA washer
- Spectrophotometer to read absorbances at 450nm or 450/620nm

DIAGRAM FOR USE

Use Celllabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.



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READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

Samples may be read visually or photometrically. Visually, samples giving the same or less colour than the negative control are considered negative. Samples giving colour greater than the negative control, similar to the positive control, are considered positive. Using a spectrophotometer, negative samples should give an optical density below a certain level and positive samples should give an optical density above a certain level. Please refer to the kit insert for detailed information.

Methods of quantifying pLDH in samples are being verified at the time of writing this Product Profile. Please contact Celllabs for a recommended method.

PERFORMANCE DATA FOR MALARIA ANTIGEN CELISA

Sensitivity/Specificity

A	n=14 true positive samples determined in microscopy; 20 true negative samples	Sensitivity: 86% Specificity: 100%
B		

Repeatability & Reproducibility

For Ordering Assistance:

See Your Local Distributor:

OR

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