Recombinant *Plasmodium falciparum* Lactate dehydrogenase (Pf-LDH) Lyophilised

Cat N° : A130112- 02 – L

1. INTENDED USE

Biological reference material for evaluating the performance of malaria rapid diagnostic tests in Quality control, batch release and for calibration as well as development of pLDH -detecting assays.

2. CAUTION

This material is not for In vitro diagnostic or therapeutic use.
It is not for administration to humans.

Being a material of biological origin, this preparation should be considered as potentially hazardous to health. It should be handled and discarded according to standard safety procedures applicable to Laboratories, viz.use of protective gloves and prevention of generation of aerosols.

3. CONTENTS

The material is provided on a weight basis (mg). Actual protein amount is stated on the vial. Resulting concentration after reconstitution has to be calculated accordingly.

Each vial contains freeze-dried residue comprising recombinant, full length, His tagged *Plasmodium falciparum* parasitic Lactate dehydrogenase (pF -LDH) expressed in *E.coli*. The protein was purified via IMAC and dIalysed against 10 mM PBS buffer. The purified protein is formulated as a lyophilisate containing HEPES, trehalose, sucrose and Mannitol as stabilisers. The preparation does not contain any material of human origin.

Characteristics of protein :
Number of amino acids : 351
Molecular weight as per SDS-PAGE : 36 kDa
pI as per Isoelectric focusing : 6,6

4. STORAGE

Vials should be stored at 2-8°C upon receipt.
It is recommended that reconstituted material is aliquoted and stored at -20°C.
Aliquots are for single use ! Do not refreeze.
Please note that because of inhérent stability of lyophilized material, Span Diagnostics may ship this material at ambient temperature.

5. DIRECTIONS FOR OPENING OF VIAL

Vials have metal caps with internal rubber stoppers. The caps should be removed by using forceps and the stopper removed thereafter. Care should be taken to prevent any inadvertent loss of the contents.

6. DIRECTIONS FOR USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution. Entire contents should be reconstituted in one step.

Contents of each vial should be reconstitued in 1ml of ultrapure water and gently agitated. The resulting concentration has to be calculated on the basis of the weight printed on the label. The solution in the vial should be left for 10 minutes prior to use. Upon reconstitution, preparation of aliquotes of either the bulk material or dilutions is recommended. Aliquots can be stored at -80°C for 2 years. Do not thaw and refreeze these aliquots.

For single use ! Do not refreeze !

For the dilution of the protein the following buffer is recommended :

10mM PBS, pH 7,4

7. STABILITY

Samples from each batch of Reference material are held at Span Diagnostics in assured, temperature-controlled facilities. Reference material should be stored on receipt as indicated on the label.

8. MATERIAL SAFETY DATA SHEET

Physical and Chemical properties	
Physical appearance : Lyophilized	Corrosive : NO
Stable : YES	Oxidizing : NO
Hygroscopic : YES	Irritant : NO
Flammable : NO	Handling : see caution, Section 2
Other (specify) : Contains material of bacterial origin	
Toxicological properties	
Effects of inhalation :	Not established, avoid inhalation
Effect of ingestion :	Not established, avoid ingestion
Effect of skin absorption :	Not established, avoid contact with skin

9. CERTIFICATE OF ANALYSIS

Span Diagnostics provides a Certificate of Analysis for each batch of Pf-pLDH, 0,1 mg, (lyophilized)

(Instructions for use 1.0, Dated 30/03/2020)