

# Plasmodium Falciparum HRP2-W2 (Type B)



REFERENCE MATERIAL  
GST-Pf-HRP2-W2 (type B) 0.1mg, Lyophilised  
Instructions for use.  
(Version 1.0, Dated 01/11/2020)

## THIS MATERIAL IS NOT FOR IN VITRO DIAGNOSTIC USE.

| Cat. No.        | Protein amount                          |
|-----------------|---|
| A130112-01-W2-L | lot-specific, as indicated on the label |

### 1. INTENDED USE

Biological reference material for evaluating the performance of marketed malaria rapid diagnostic test in quality control and for calibration as well as development of HRP2-detecting assays.

### 2. Caution

This preparation is not for administration to humans.

This standard is based on the Histidine-rich protein 2(HRP2) from *Plasmodium falciparum* strain W2 (type B)<sup>1,2</sup>. The protein is fused to Glutathione-S-transferase (GST)-tag and produced recombinantly in a heterologous expression system. The protein has been purified via affinity chromatography.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such procedures should include wearing of protective gloves and avoiding the generation or aerosols.

### 3. UNITAGE

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.

### 4. CONTENTS

Country of origin of biological material: France.

Each vial contains freeze-dried residue comprising recombinant, GST-tagged *Plasmodium Falciparum* Histidine-rich Protein 2 (type B), from strain W2. The protein was purified by affinity chromatography using a Glutathione Sepharose column and dialyzed into 1x PBS buffer. The purified protein is formulated as a lyophilisate containing Hepes, D(+)-Trehalose, Sucrose, D-Mannitol and Tween 80.

#### Characteristics of protein:

| Characteristics of GST-pF-HRP2-W2  |          |
|------------------------------------|----------|
| Number of amino acids              | 502      |
| Molecular weight of GST-Pf-HRP2-W2 | 55.6 kDa |
| Molecular weight of GST            | 26.4 kDa |
| Molecular weight of Pf-HRP2-W2     | 29.3 kDa |
| Theoretical pI                     | 6.51     |

### 5. Storage

Vials should be stored at 2-8°C on receipt. It is recommended that reconstituted material is aliquoted and stored at -20°C

**For single use! Do not refreeze.**

**Please note:** because of inherent stability of lyophilized material, Span Diagnostics may ship these materials as ambient temperature.

## 6. DIRECTIONS FOR OPENING

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

## 7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the portion of the freeze-dried material prior to reconstitution.

This material should be used for evaluating the performance of marketed malaria rapid diagnostic tests in quality control, and for calibration as well as in the course of development of HRP2-detecting assays. Each vial should be reconstituted in 1 ml of sterile water and gently agitated. The resulting concentration has to be calculated on the basis of the label imprint. The vial solution should be left for 10 min prior to use. Upon reconstitution, preparation of aliquots of either the bulk material or dilutions is recommended. Aliquots can be stored at -80°C to -15°C for one year. Do not thaw and refreeze this material. For single use! Do not refreeze.

## 8. STABILITY

Reference materials are held at Span Diagnostics within assured, temperature-controlled facilities. Reference material should be stored on receipt as indicated on the label.

## 9. REFERENCES

1 Baker, J., et. al. (2005). Genetic diversity of **Plasmodium falciparum** histidine-rich protein 2 (PfHRP2) and its effect on the performance of PfHRP2-based rapid diagnostics tests. The journal of Infectious Diseases, 192(5), 870-7 doi: 10.1086/432010

2 Baker, J., et. al. (2010). Global sequence variation in the histidine-rich protein 2 and 3 of **Plasmodium falciparum**: implications for the performance of malaria rapid diagnostics tests. Malaria Journal, , 129. Doi:10.1186/1475-2875\_9\_1129

## 10. MATERIAL SAFETY SHEET

| Physical and Chemical properties                          |  |
|---|--|
| Physical appearance :<br>Lyophilised                      | Corrosive : No                                 |
| Stable : Yes  | Oxidizing : No                                 |
| Hygroscopic : Yes   | Irritant : No                                  |
| Flammable : No  | Handling : see<br>caution Section 2            |
| Other (specify): Contains material of<br>bacterial origin |  |
| Toxicological properties                                  |  |
| Effects of inhalation                                     | Not established,<br>avoid inhalation           |
| Effects of ingestion                                      | Not established,<br>avoid ingestion            |
| Effects of skin<br>absorption                             | Not established,<br>avoid contact with<br>skin |

## 11. CERTIFICATES OF ANALYSIS

Span Diagnostics provides a certificate of analysis for each lot of GST-Pf-HRP2-W2 (type B); 0,1mg, lyophilised.