

Reference material
GST-Pf-HRP2-PH1 (type C); 0.1 mg,
lyophilized

Instructions for use
(Version 1.0, Dated 01/04/2016)

This material is not for in vitro diagnostic use.

Cat. No.	Protein amount
890016	lot-specific, as indicated on the label

1. INTENDED USE

Biological reference material for evaluating the performance of marketed malaria rapid diagnostic tests 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 PH1 (type C)^{1,2}. The protein is fused to a Glutathione-S-transferase (GST)-tag and produced recombinantly in a heterologous expression system. The protein has been purified *via* affinity chromatography.

The preparation contains material of human origin, and the source materials have been tested and are non-reactive for HIV-1/ HCV/ HBV by NAT, HBsAg, HCV Ab, HIV 1&2 Ab, and RPR by currently approved FDA methods.

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 of 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: Germany.

Each vial contains freeze-dried residue comprising recombinant, GST-tagged *Plasmodium falciparum* Histidine-rich Protein 2 (type C), from strain PH1. The protein was purified *via* affinity chromatography using a Glutathione-Sepharose column and dialyzed into 1x PBS buffer. The purified protein is formulated as a lyophilisate containing human serum albumin, D(+)-Trehalose, D-Mannitol, Tween 20, HEPES, and EDTA.

Characteristics of protein:

Characteristics of GST-Pf HRP2-PH1	
Number of amino acids	439
Molecular weight of GST-Pf-HRP2-PH1	48.8 kDa
Molecular weight of GST	26.4 kDa
Molecular weight of Pf- HRP2-PH1	22.4 kDa
Theoretical pI	6.44

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, Microcoat may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have screw caps with internal stopper. The caps should be removed by turning counter-clockwise and the stopper removed. Care should be taken to prevent loss of the content.

7. USE OF MATERIAL

No attempt should be made to weigh out any 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.**

For dilution of reconstituted protein the following buffer is recommended:

Dilution buffer:

2 % (w/v) Human Serum Albumin
7.5 % (w/v) D-Trehalose
5 mM EDTA pH 8.0
0.5 % (v/v) Tween 20
optional 0.005 % (w/v) sodium azide
dissolve in 1x PBS pH 7.4
adjust pH to 7.4

8. STABILITY

Reference materials are held at Microcoat 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 diagnostic 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 proteins 2 and 3 of *Plasmodium falciparum*: implications for the performance of malaria rapid diagnostic tests. *Malaria Journal*, 9, 129. doi:10.1186/1475-2875-9-129

10. MATERIAL SAFETY 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
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin

11. CERTIFICATE OF ANALYSIS

Microcoat provides a Certificate of Analysis for each lot of GST-Pf-HRP2-PH1 (type C); 0.1 mg, lyophilized.