



Listed in
GLOBAL FUND



WHO
Pre-Qualified

ISO 13485:2016
ISO 9001:2015

PRODUCT ORDERING INFORMATION:

| Product Name | Product Code | Specimen | Packsize | Storage Conditions | Shelf Life |
|-------------------------|-----------------------------------|-------------|------------------------|--------------------|------------|
| AdvDx™ Malaria Pf Ag | 00-DKM-RK-MAL- ADX-004-025/050 | Whole Blood | 25 T/Pack 50 T/Pack | 2° to 40°C | 24 months |

ANTIGENS | ANTIBODIES | DIAGNOSTIC KITS

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Ref. No.: ADV-MALPF-LBL-01 | Rev. No.: 01 | Date Issued : 2019-12



ADVY
Partnering with you



MALARIA
DKM

DIAGNOSTIC KITS
AdvDx™ Malaria Pf Ag



WHO PQ
APPROVED

PERFORMANCE EVALUATION STUDY

Study site: B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, Mumbai - 400008

Study period: 01-Sep-2018 to 31-Aug-2019

Test Product - Malaria Ag Pf - Rapid Detection Kit for HRP II

Reference Product - Microscopy (Venous and Finger Prick simultaneously) and Hospital Based Malaria ROT (Malaria Ag Pf/ Pv) and PCR

| DESCRIPTION | Number of Samples | Malaria Ag Pf Positive | Malaria Ag Pf Negative | Total |
|--|-------------------------|------------------------|------------------------|-------|
| Negative | 20 | 0 | 20 | 20 |
| Peripheral Smear (Thick and Thin) Negative | 20 | 0 | 20 | 20 |
| | Agreement (Specificity) | | | 100% |
| Positive | 37 | 37 | 0 | 37 |
| Positive by peripheral Smear (Thick and Thin) and PCR | 37 | 37 | 0 | 37 |
| ➤ Peripheral Smear (Thick and Thin) Positive for pf - 18 | Agreement (Sensitivity) | | | 100% |
| ➤ Peripheral Smear negative for Pf* Tested by PCR - 19 | | | | |
| *19 samples were given to Advy by BYL Nair Hospital as per Institutional Ethics Committee approval | | | | |

| DESCRIPTION | Number of Samples | Malaria Ag Pf Positive | Malaria Ag Pf Negative | Total |
|---|-------------------|------------------------|------------------------|-------|
| A) Peripheral Smear (Thick and Thin) Negative and Hospital based Malaria Ag detection test Negative | 20 | 0 | 20 | 20 |
| | Agreement | | | 100% |
| B) Peripheral Smear (Thick and Thin) Positive for Pf and Hospital based Malaria Ag detection test Positive | 18 | 18 | 0 | 18 |
| | Agreement | | | 100% |
| C) Peripheral Smear negative for Pf and Hospital based Malaria Ag detection test Positive* | 19 | 19 | 0 | 19 |
| *Agreement not calculated for these 19 samples as all samples in this category were handed over to Sponsor for Confirm of specimen status by PCR as per EC approval | | | | |
| Two samples having lab no.29 with PI< 1% and 52 with PI 2-3% were diluted in doubling dilutions from 1:2, 1:4 and so on. Lab no. 29 sample showed test band for Pf till dilution of 1:128 and thereafter negative where Lab No. 52 sample showed test band Pf till dilution of 1:512 and thereafter negative. | | | | |

CONCLUSION:

- AdvDx Malaria Pf Ag ROT is highly sensitive test to detect Malaria Pf (HRP-II) detection as it detected:
 - 18 Microscopy Pf positive specimen having parasitic index = 0 - I and more
 - 19 Microscopy negative which were PCR positive
- No discrepancy was observed in test results between specimens drawn from Venous Blood and Finger Prick for negative and positive specimens
- No invalid test result was observed during this study

DETAILS OF WHO-PQ PRODUCT:

| | |
|-----------------------|---|
| Product | AdvDx™ Malaria Pf Rapid Malaria Ag Detection Test |
| Product code | 00-DKM-RK-MAL-ADX-004-025 |
| Regulatory version | Rest-of-World |
| Manufacturer | Advy Chemical Pvt. Ltd. |
| PQDx Reference Number | 0345-101-00 |

