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|---|--|--|---|--------|-------------|-------------|
| 1   | ईमेल आईडी   Email ID : buycon19.hmefwdj.jh@gembuyer.in<br>संपर्क   Contact : 06542-221134-<br>जीएसटीआईएन   GSTIN : -<br>पता   Address : OFFICE OF THE CIVIL SURGEON NEAR DC OFFICE CAMP II<br>BOKARO STEEL CITY,<br>BOKARO, JHARKHAND-827001, India      | PAREEKSHAK Dual Rapid<br>Test Kit for HIV and<br>Syphilis  | - | 16,500 | 13-Mar-2024 | 28-Mar-2024 |
| <b>Product Specification for PAREEKSHAK Dual Rapid Test Kit for HIV and Syphilis</b>  |  |  |   |        |             |             |
| <b>विनिर्देश   Specification</b>  | <b>उप-विनिर्देश   Sub-Spec</b>   | <b>मूल्य   Value</b>   |   |        |             |             |
| GENERAL FEATURES  | Product Description  | Dual Rapid Test Kit for HIV and Syphilis   |   |        |             |             |
|   | Clinical Purpose   | For in-vitro detection of HIV and Syphilis infection   |   |        |             |             |
| PRODUCT INFORMATION   | Assay type   | Synthetic and/or recombinant antigens coated on solid phase a) Multiple Treponema pallidum antigens, and b) Multiple Antigens of HIV1 (including gp41) and HIV2 (including gp36) |   |        |             |             |
|   | Detects  | Individually detects antibodies to all subtypes of HIV1 & HIV2 and Treponema pallidum by the rapid test, in human whole blood/ & serum/ & plasma                                 |   |        |             |             |
|   | Detection Type   | Qualitative  |   |        |             |             |
|   | Testing Principle  | Lateral Flow (Immunochromatography)  |   |        |             |             |
|   | Species Reactivity   | Human  |   |        |             |             |
|   | Type of Sample   | Whole Blood, Serum, Plasma   |   |        |             |             |
|   | Time to Result   | ≤ 30 minutes   |   |        |             |             |
|   | Ability to evaluate negative or positive test result   | Yes  |   |        |             |             |
|   | Assay Sensitivity for HIV  | ≥ 100%   |   |        |             |             |
|   | Assay Specificity for HIV  | ≥ 98%  |   |        |             |             |
|   | Assay Sensitivity for Syphilis   | ≥ 85%  |   |        |             |             |
|   | Assay Specificity for Syphilis   | ≥ 93%  |   |        |             |             |
|   | Declared sensitivity and specificity shall be claimed by the manufacturer in the kit literature  | Yes  |   |        |             |             |
|   | Contains an internal control dot/band (in-built control) for the confirmation that the test has been performed correctly   | Yes  |   |        |             |             |
| The control dot/band (in-built control) able to detect the presence of human immunoglobulin and not be just a procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology | Yes  |  |   |        |             |             |
| Maintenance of cold chain by the supplier during storage and transportation of Kits at 2°C to 8°C and placement of cumulative time temperature indicator technology on every pack of kits   | No   |  |   |        |             |             |
| KIT CONTENTS  | Kit Contents   | Test Device/Card/Cassette with Desiccant, Sample Dropper, Assay Buffer (if any)  |   |        |             |             |
|   | The kit shall be supplied with sufficient amount of capillaries to deliver the required amount of specimen specified in the kit literature   | Yes  |   |        |             |             |
|   | Positive and negative controls provided with each pack of kit  | No   |   |        |             |             |
|   | Quantity of positive and negative controls provided  | NA   |   |        |             |             |
|   | Documents detailing the principal, components, details of antigen used/coated for detection of HIV 1&2 as well as Treponema pallidum antibodies, biosafety compliance, validity criteria, interpretation of results, performance characteristic provided | Yes  |   |        |             |             |
|   | Manufacturing and expiry dates should be mentioned for each kit  | Yes  |   |        |             |             |
| PACKAGING   | Pack size of kit   | 50 Tests   |   |        |             |             |
|   | The test kit packed in such a way that there is provision to conduct single test at a time   | Yes  |   |        |             |             |
|   | Each test card/cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch  | Yes  |   |        |             |             |
| CERTIFICATIONS & REPORTS  | Compliance to Medical Device Rules (MDR) 2017 as amended till date   | Yes  |   |        |             |             |
|   | Availability of valid drug license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date   | Yes  |   |        |             |             |
|   | Valid Drug License Number  | MFG/IVD/2020/000013  |   |        |             |             |
|   | Manufacturing unit certification   | ISO:13485 (Latest)   |   |        |             |             |
|   | Additional voluntary certification available   | ISO 9001:2015  |   |        |             |             |

|                        |  |                            |
|------------------------|--|----------------------------|
|                        | Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date  | Yes                        |
|                        | Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission or along with supplies as per buyer requirement | Yes                        |
| SHELF LIFE             | Shelf life in months from the date of manufacture  | 24 month                   |
|                        | Minimum shelf life of the product at the time of delivery to the consignee   | 3/4 th of Total Shelf Life |
| ADVANCE SAMPLE         | Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding   | Yes                        |
| ADDITIONAL REQUIREMENT | Additional Requirement   | NA                         |

## ईपीबीजी विवरण | ePBG Detail

NA

## नियम और शर्तें | Terms and Conditions

### 1. Special terms and conditions- Version:2 effective from 19-05-2023

#### 1.1

- All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
- The sellers are registered on GeM based on self-declaration of valid Drug License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of drug license, product certification, manufacturer certification/licenses, test reports etc.
- In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of drug license held by them.
- The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
- Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

### 2. General Terms and Conditions-

- This contract is governed by the [General Terms and Conditions](#), conditions stipulated to this Product/Service as provided in the Marketplace.
- This Contract between the Seller and the Buyer, is for the supply of the Goods and/ or Services, detailed in the schedule above, in accordance with the General Terms and Conditions (GTC) unless otherwise superseded by Goods / Services specific Special Terms and Conditions (STC) and/ or BID/Reverse Auction Additional Terms and Conditions (ATC), as applicable

नोट: यह सिस्टम जनरेटेड फाइल है। कोई हस्ताक्षर की आवश्यकता नहीं है। इस दस्तावेज़ का प्रिंट आउट भुगतान/लेनदेन उद्देश्य के लिए मान्य नहीं है।

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