अनुबंध|Contract



अनुबंध क्रमांक|Contract No: GEMC-511687792172199 अनुबंध तिथि|Generated Date: 08-Mar-2024

संगठन विवरण|Organisation Details

प्ररूप|Type : State Government

मंत्रालय|Ministry:

विभाग|Department : NA संगठन का नाम|Organisation Name : N/A

कार्यालय क्षेत्र|Office Zone: Basti

खरीदार विवरण|Buyer Details

पद|Designation : buyer संपर्क नंबर|Contact No. : 05542-247169-

ईमेल आईडी|Email ID : pharma.dwh.bs-up@gov.in

जीएसटीआईएन|GSTIN: -

V.R.T.K District Women Hospital, Near Kateshwar Park,

पता|Address : Gandhi Nagar Basti,

BASTI, UTTAR PRADESH-272001, India

वित्तीय स्वीकृति विवरण|Financial Approval Detail

आईएफडी सहमित|IFD Concurrence : No प्रशासनिक अनुमोदन का पदनाम| CMS

Designation of Administrative Approval: वित्तीय अनुमोदन का पदनाम|

Designation of Financial Approval :

भुगतान प्राधिकरण विवरण|Paying Authority Details

Role: BUYER भुगतान का तरीका| Payment Mode: पद|Designation : buyer

ईमेल आईडी|Email ID : pharma.dwh.bs-up@gov.in

जीएसटीआईएन|GSTIN : -

V.R.T.K District Women Hospital, Near Kateshwar Park,

पता|Address: Gandhi Nagar Basti,

Basti, UTTAR PRADESH-272001, India

विक्रैता विवरण|Seller Details

जेम विक्रैता आईडी|GeM Seller ID : 4A85200001292327 कंपनी का नाम|Company Name : VRINDAVAN TRADERS संपर्क नंबर|Contact No. : 09140900158

ईमेल आईडी|Email ID : vrindavantraders2020@gmail.com

पता| Address : 80/2,SADAR CANTT,SAUDAGAR MOHAL,SADAR CANTT,

Lucknow, UTTAR PRADESH-226018, -

एमएसएमई पंजीकरण संख्या|MSME Registration number :

जीएसटीआईएन|GSTIN: 09AKDPA5886H2ZY

*जिसके नाम के पक्ष में GST/TAX इनवॉइस पेश किया जाएगा|GST / Tax invoice to be raised in the name of - Buyer

CMS

वितरण निर्देश | Delivery Instructions : NA

उत्पाद विवरण|Product Details

| # | आइटम विवेरण Item Description | आइटम विवरण Ordered Quantity | इकाई Unit | इकाई मूल्य (INR) Unit Price (INR) | कर विभाजन (INR) Tax Bifurcation (INR) | मूल्य (INR में सभी शुल्क और कर सहित) Price (Inclusive of all Duties and Taxes in INR) |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------|---------------------------------------------|----------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| 1 | ज्याद का नाम Product Name : BIOGENIX (BSURE)BIOGENIX INC. PRIVATE LIMITED Syphilis Antibody Rapid Test Kit ब्रांड Brand : BIOGENIX (BSURE)BIOGENIX INC. PRIVATE LIMITED ब्रांड प्रकार Brand Type : Unregistered Brand कैटलॉग की स्थिति Catalogue Status: OEM verified catalogue कैसे बेचा जा रहा है Selling As : OEM verified Reseller श्रेणी का नाम और चतुर्घाश Category Name & Quadrant : Syphilis Rapid Test Kits (Q2) मॉडल Model: BIOGENIX BSURE एचएसएन कोड HSN Code: HSN not specified by seller | 17,820 | Test | 28 | NA | 498,960 |
| कु | ल ऑर्डर मूल्य Total Order Value (in INR) | | | | | 498,960 |

परेषिती विवरण|Consignee Detail

| क्र.सं. S.No | परेषिती Consignee | वस्तु Item | लॉट नंबर Lot No. | मात्रा Quantity | दिनांक के बाद डिलीवरी शुरू करना है Delivery Start After | वितरण पूरा कब तक करना है Delivery To Be Completed By |
|--------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------|-----------------|----------------------------------------------------------------------|----------------------------------------------------------------------|
| 1 | पद Designation : consinee1 ईमेल आईडी Email ID : modwh.bs-up@gov.in संपर्क Contact : 05542-247169- जीएसटीआईएन GSTIN : - | BIOGENIX (BSURE) BIOGENIX INC. PRIVATE | - | 17,820 | 08-Mar-2024 | 23-Mar-2024 |

| Product Specification for BIOGENIX (BSURE)—BIOGENIX INC. PRIVATE LIMITED Syphilis Antibody Rapid Test Kit (BRAZI Specification अनिसंध Sub-Spec Syphilis Rapid Test Kit Product Description Syphilis Rapid Test Kit CENERAL FEATURES Clinical Purpose To provide a quick and accurate diagnosi infection in all stages of infection by detection by detectio | ecting | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--|
| Product Description Syphilis Rapid Test Kit Clinical Purpose Clinical Purpose Type of Kit Detects Detects Detection Type The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum Antibody IgA) Detection Type The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum Antibody IgA) Testing Principle Species Reactivity Type of Sample Time to Result Ability to evaluate negative or positive test result Sensitivity Specificity Dedared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Rit Contents Kit Contents | ecting | |
| Product Description Syphilis Rapid Test Kit To provide a quick and accurate diagnosi infection in all stages of infection by dete infibodoles to Treponema Pallidum Propose Type of Kit Syphilis Antibody Rapid Test Kit Detects Detects Detector Type The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum Antibody Iqal Testing Principle Species Reactivity Type of Sample Time to Result Ability to evaluate negative or positive test result Sensitivity Specificity Detared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Kit Contents Syphilis Activated and accurate diagnosi infection in alteral flow decinology Assay Buffer (if any) | ecting | |
| Clinical Purpose Type of Kit Syphilis Antibody Rapid Test Kit Detects Detects Detection Type Qualitative The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens Testing Principle Lateral Flow Immunochromatographic Assay Species Reactivity Human Type of Sample Species Reactivity Ability to evaluate negative or positive test result Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | ecting | |
| Detects Detection Type Qualitative The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens Testing Principle Species Reactivity Human Type of Sample Time to Result Ability to evaluate negative or positive test result Sensitivity Sensitivity Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sampless and the contents of the conte | y (IgG,IgM & | |
| Detection Type Detection Type Qualitative The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens Testing Principle Species Reactivity Type of Sample Time to Result Ability to evaluate negative or positive test result Sensitivity Sensitivity Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sampl Assay Buffer (if any) | y (IgG,IgM & | |
| The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens Testing Principle Species Reactivity Human Type of Sample Time to Result Ability to evaluate negative or positive test result Yes Sensitivity Sensitivity Sensitivity Sepcificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature Yes The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Pallidum antigens Testing Principle Lateral Flow Immunochromatographic Asterior Species Reactivity Human Type of Sample Time to Result Ability to evaluate negative or positive test result Sensitivity Sensitivity Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Species Reactivity Type of Sample Serum,Plasma Time to Result Ability to evaluate negative or positive test result Yes Sensitivity Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Human Serum,Plasma 4 30 minutes 299% 299% 299% 298% Yes Yes Yes Yes Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Type of Sample Time to Result Ability to evaluate negative or positive test result Yes Sensitivity Sensitivity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | ∖ssay | |
| Time to Result Ability to evaluate negative or positive test result Yes Sensitivity Sensitivity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Ability to evaluate negative or positive test result Sensitivity Sensitivity Sensitivity Sepsificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Ability to evaluate negative or positive test result Yes Yes No Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Sensitivity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Sensitivity Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Kit Contents Kit Contents Test Card/Cassette with Desiccant, Sampin Assay Buffer (if any) | | |
| Specificity Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Declared sensitivity and specificy shall be claimed by the manufacturer in the kit literature The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sampl Assay Buffer (if any) | | |
| The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer Contains an internal control dot/band for the confirmation that the test has been performed correctly The control dot/band 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 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 Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| The control dot/band 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 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 Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| procedural control or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology 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 Kit Contents Test Card/Cassette with Desiccant, Sampl Assay Buffer (if any) | | |
| and placement of cumulative time temperature indicator technology on every pack of kits Kit Contents Test Card/Cassette with Desiccant, Sample Assay Buffer (if any) | | |
| Kit Contents Assay Buffer (if any) | | |
| All the components shall be in the quantity as per pack size Yes | ole Dropper, | |
| | | |
| Adequate document detailing principle, components, methodologies, validity criteria, interpretation of results, performance characteristics, bio-safety, limitations of assay, storage condition, mfg & exp date and method of disposal provided with kit | | |
| Positive and negative controls provided with each pack of kit No | | |
| Quantity of positive and negative controls provided NA | | |
| Each test card/strip supplied with sterile auto retractable disposable lancet and disposable alcoholic swabs | | |
| Pack size of kit 50 Tests | | |
| The test kit packed in such a way that there is proivision 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 | | |
| Compliance with Medical Device Rule (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 there under as amended till date Yes | | |
| Valid Drug License Number MFG/IVD/2020/000068 | | |
| CERTIFICATIONS & Manufacturing unit certification ISO:13485 (Latest) | | |
| REPORTS Additional voluntary certification available ISO:9001 , QMS | | |
| 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 |
|---------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------|
| - | 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

- 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.
- 2. 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.
- 3. 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.
- 4. 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.
- 5. 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-
- 2.1 This contract is governed by the General Terms and Conditions, conditions stipulated to this Product/Service as provided in the Marketplace.
- 2.2 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 प्रिटे आउट भुगतान/लेनदेन उद्देश्य के लिए मान्य नहीं है।

Note: This is system generated file. No signature is required. Print out of this document is not valid for payment/ transaction purpose.