ANNEX-1

BID NO. : DHS/L/WW/23/24
DATE OF ISSUE : 23RD MAY 2023
CLOSING DATE & TIME : 06TH JULY 2023 at 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka

2. Offered item should bear both our SR number and the Item number.

3. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.

4. **Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.**

5. **Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Bids" of the bid document in this regard.**

6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

7. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C&F price

8. The volume of the total quantity of each item should be given in cubic meters (m^3)

9. Representative samples in respect of items offered should be submitted to reach SPC on or before the closing time on the closing date of bid and acknowledgement receipt to be obtained from Administration Department of SPC.

10. The original payment receipt should be annexed to the offer. Offers without same are liable rejected.

11. We reserve the right to reject offers which do not comply above.

CONDITIONS FOR SUPPLY OF LABORATORY ITEMS

(a) Part A-General Order Conditions (GOC) of Supply

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of Registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharma & relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier.
A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.

5. If MSD decides to accept consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% administrative charge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply surcharge (as clause No. 37).

6. The specifications of the product offered by the suppliers in the tender, shall match with the tender specifications for the item and **any form of alternate offers for the same, will not be entertained,** when there are products offered in compliance with the tender specification.

Shelf life & Warrantees

7. In respect of Non consumables; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and /or it's sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repair and spares, when necessary (**This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory items)**

8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA)

(a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items. (Shelf life of not applicable for surgical non-consumables) and 24 months for Pharma/Laboratory items. The Difference of the residual and requested product shelf life shall not exceed $1/6^{th}$ (one sixth) of the original product shelf life.
(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 37 and footnote 01)

Standards & Quality

9. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia Standards accepted in the product registration by the National Medicines Regulatory Authority.

10. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceuticals items and the user manual/instruction pamphlet for surgical items. With information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub-components/accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set) shall be rejected.

11. Withdrawal from use of items due to quality failure found as manufacturer's fault:
(a). In case of batch withdrawal, **value of entire batch quantity supplied** shall be recovered from the supplier.
(b). In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
(c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative surcharge of the same**.**

12. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.24)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

13. Immediately after delivery at MRI, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology and facilities)

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling and testing charges, etc, will be recovered from the supplier.

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

15. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

16. In respect of bulk packs (not applicable for blister/strip packs), "DHS" mark shall be ;
(a). embossed or printed in case of tablets
(b). printed in case of capsules
Above condition can be waved off, if the purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **or** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and "STATE LOGO" of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

19. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

21. In case of receiving goods under inappropriate packaging conditions(not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

Storage Conditions & Temperature

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a) In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.

b) Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized **USB**

Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers **&/ software (reading apps compatible with Windows-07/latest)** to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

c) If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d) The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e) The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 2-25^0c, 15-20^0c/30^0c, 2-8^0c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30^0c +/- 2^0c & 75% +/- 5% RH for **AC stored** items and at 25^0c +/- 2^0c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

Delivery Requirements

25. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

26. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments **to reach Sri Lanka from 15th December to 10th January** shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

27. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.

(b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

32. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

33. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO. (applicable for all surgical items and laboratory regular items except when stated otherwise in the relevant order lists).

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No's, as necessary for the surgical items (**not relevant to pharmaceutical & Laboratory items)** shall be provided with the bid document, for reference in the; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions shall be provided before signing the contract with the performance bond.

34 The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (**follow instructions in website www.msd.gov.lk**), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)
If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the condition No. 27 will not be applicable.

Common conditions

36. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

37. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. **(eg. As in conditions No. 08,05,10,13)**

Abbreviations :*NMRA ; National Medicines Regulatory Authority/Sri Lanka,* SPC ; State *Pharmaceuticals Corporation, MSD; Medical Supplies Division,/Ministry of Health-Sri Lanka*

(b) Part B-Special Order Conditions (SOC) of Supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the each item exceeds LKR 1 million. Bid Bond should be submitted with valid up to 01.02.2024 together with the tender

Sufficient quantity of samples should be forwarded for evaluation.

BID NO: DHS/L/WW/23/24 CLOSING ON : 06.07.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/D/00002

Item No.	SR No.	Item Specification	Quantity	Delivery	Bid Bond Value (LKR)
1	43502101	Anti C Sera 5ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard	216 vials	108 – Jan/2024 108 – Jul/2024	132,088.32

		quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination (=2+ reaction) with 3-5% red Cell suspension which is heterozygously positive for C antigen following centrifugation. 13. Should be equal or exceed the potency of reference preparation (reference ? QC lab NBC) 14. Should not produce a positive reaction when tested with red cells lacking C antigens. 15. The final container label shall preferably be colour coded according to standard guidelines.			
2	43502201	Anti c Sera 5ml/vial **Specification :** Anti c Sera 5ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents.	330 vials	165 – Jan/2024 165 – Jul/2024	233,738.27

		D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells which are heterozygously positive for c antigen in 1:4 dilution of the reagent. 14. Should not produce a positive reaction when tested with red cells lacking c antigens. 15. The final container label shall preferably be colour coded according to standard guidelines.			
3	43502301	Anti E Sera 5ml/vial **Specification :** Anti E Sera 5ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel.	300 vials	150 – Jan/2024 150 – Jul/2024	183,862.20

		2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination (=2+ reaction) with 3-5% red cellsuspension which isheterozygously positive for E antigen following centrifugation			

		13. Should be equal or exceed the potency of reference preparation(QC NBC) 14. Should not produce a positive reaction when tested with red cells lacking E antigens. 15. The final container label shall preferably be colour coded according to standard guidelines.			
4	43502401	Anti e Sera 5ml/vial **Specification :** Anti e Sera 5ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold	221 vials	111 – Jan/2024 110 – SEP/2024	137,290.19

		chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells which are heterozygously positive for e antigen in 1:4 dilution of the reagent. 14. Should not produce a positive reaction when tested with red cells lacking e antigens. 15. The final container label shall preferably be colour coded according to standard guidelines			
5	43502501	Anti-Fya Sera 2ml/vial **Specification :** Anti-Fya Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate	106 Vials	53 – Jan/2024 53 – Jul/2024	66,395.88

		container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be Monoclonal/polyclonal 12. Should give direct agglutination or agglutination at IAT (as per manufacturers? instructions) with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells heterozygously positive for Fya antigen in 1:8 dilution of the monoclonal reagent. 14. Should not produce a positive reaction when tested with red cells Lacking Fya antigens			

6	43502601	Anti-Fyb Sera 2ml/vial **Specification :** Anti-Fyb Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters(batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard	55 vials	28 – Jan/2024 27 – Jul/2024	31,743.40

		quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be Monoclonal/polyclonal 12. Should give direct agglutination or agglutination at IAT with 3-5% red Cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 2+ reaction with undiluted reagent with red cells heterozygously positive for Fyb antigen. 14. Should not produce a positive reaction when tested with red cells Lacking Fyb antigens			
7	43502701	Anti-Jka Sera 2ml/vial **Specification :** Anti-Jka Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group	20 vials	10 – Jan/2024 10 – Jul/2024	N/A

		serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells which are heterozygously positive for Jka antigen in 1:8 dilution of the reagent. 14. Should not produce a positive reaction when tested with red cells Lacking Jka antigens			
8	43502801	Anti-Jkb Sera 2ml/vial **Specification :** Anti-Jkb Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters	48 vials	24 – Jan/2024 24 – Jul/2024	41,912.83

		(batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 2+ reaction with undiluted reagent when tested with cells which are heterozygously positive for Jkb antigen.			

		14. Should not produce a positive reaction when tested with red cells Lacking Jkb antigens.			
9	43502901	Anti-k Sera 2ml/vial **Specification :** Anti-k Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin	20 vials	10 – Jan/2024 10 – Jul/2024	N/A

		certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be polyclonal /monoclonal 12. Should give direct agglutination or agglutination at IAT with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells heterozygously positive for k antigen in 1:8 dilution of the reagent. 14. Should not produce a positive reaction when tested with red cells lacking k antigens			
10	43503001	Anti-K Sera 5ml/vial **Specification :** Anti-K Sera 5ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave	320 vials	160 – Jan/2024 160 – Jul/2024	203,314.18

		uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA,UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with red cells which are heterozygously positive for K antigen in 1:8 dilution of the reagent. 14. Should not produce a positive reaction when tested with red cells lacking K antigens.			
11	43503101	Anti-Lea Sera 2ml/vial **Specification :** Anti-Lea Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel.	104 vials	52 – Jan/2024 52 – Jul/2024	88,406.26

		2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at			

		least 2+ reaction with red cells which are heterozygously positive for Lea antigenin undiluted reagent. 14. Should not produce a positive reaction when tested with red cells Lacking Lea antigens			
12	43503201	Anti-Leb Sera 2ml/vial **Specification :** Anti-Leb Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a istinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these	104 vials	52 – Jan/2024 52 – Jul/2024	89,414.48

		reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 2+ reaction with red cells which are heterozygously positive for Leb antigen in undiluted reagent. 14. Should not produce a positive reaction when tested with red cells acking Leb antigens.			
13	43503301	Anti-M Sera 2ml/ vial **Specification :** Anti-M Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave	67 vials	34 – Jan/2024 33 – Jul/2024	66,335.36

		uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM/IgG Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with 1:4 dilution of the reagent when tested with cells which are heterozygously positive for M antigen. 14. Should not produce a positive reaction when tested with red cells lacking M antigens.			
14	43503401	Anti-N Sera 2ml/vial **Specification :** Anti-N Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel.	33 vials	17 – Jan/2024 16 – Jul/2024	29,401.77

		2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM/IgG Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at			

		least 2+ reaction in undiluted reagent sera when tested with cells which are heterozygously positive for N antigen. 14. Should not produce a positive reaction when tested with red cells lacking N antigens.			
15	43503502	Anti-P1 Sera 2ml/vial **Specification :** Anti-P1 Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these	12 vials	6 – Jan/2024 6 – Jul/2024	N/A

		reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with 1:4 dilution of the reagent when tested with cells positive for P1 antigen. 14. Should not produce a positive reaction when tested with red cells Lacking P1 antigens.			
16	43503601	Anti-S Sera 2ml/vial **Specification :** Anti-S Sera 2ml/vial 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave	78 vials	39 – Jan/2024 39 – Jul/2024	70,359.07

		uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension 13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with 1:4 dilution of the reagent when tested with the cells which are heterozygously positive for S antigen. 14. Should not produce a positive reaction when tested with red cells lacking S antigens.			
17	43503702	Anti-s sera (monoclonal)2ml **Specification :** Anti-s sera (monoclonal)2ml 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended	65 vials	33 – Jan/2024 32 – Jul/2024	98,913.27

		shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal 12. Should give direct visual agglutination with 3-5% red cell suspension			

		13. Should equal or exceed potency of reference preparation. Should give at least 1+ reaction with 1:4 dilution of the reagent when tested with the cells which are heterozygously positive for s antigen. 14. Should not produce a positive reaction when tested with red cells lacking s antigens.			
18	43538401	Anti-Cw sera 2ml 1. The method of manufacture should result in a product within an immediate container that is homogeneous and free of properties which adversely affect its intended use throughout its recommended shelf life. The reagent should have no precipitate, particles or fibrin gel. 2. Each batch or sub-batch should be specifically identified by a Distinctive combination of numbers and/or letters (batch reference) which permits its history to be traced. 3. Reagents should be produced by a validated process that is shown to be suitable for the intended purpose. 4. Volume should be mentioned in milliliters (ml) on immediate container 5. Absence of rouleaux formation, prozone and haemolysis. 6. Labelling requirements; A. Should have a label on the immediate container B. Printing on all final container labels shall be in solid black. C. The label fixed to the immediate container of a reagent should leave uncovered sufficient area of the full length or circumference of the container to allow ready visual inspection of the contents. D. The specificity of the reagent for blood group serology should be of a Print size which is clearly legible. The print size of other information on the label should not exceed that used for the specificity of the reagent. E. Should include Lot number and sub lot designations, if available F. Expiry date should be mentioned. G. Should mention the recommended storage temperature (2-6 ?C) 7. Precautions must be taken to maintain the cold chain while transportation until it reaches the blood bank, as these reagents	02 vials	2 – Jan/2024	N/A

		are kept at 2-6 ?C. 8. Reagent shall contain FDA and/or WHO certification/ country of origin certificate and certificate of use in the country of origin/end user evaluation certificate/free sales certificate in USA, UK, France, Germany, Canada, New Zealand or Australia with standard quality certificates. 9. Reagent brochure, labels and any other information provided, should be in English language. 10. Minimum expiry of 18 months should be present on delivery. 11. Should be IgM Monoclonal. 12. Should give direct visual agglutination (= 2+ reaction) with 3-5% red Cell suspension which is positive for Cw antigen following centrifugation. 13. Should equal or exceed potency of reference preparation. (reference QC Lab ? NBC) 14. Should not produce a positive reaction when tested with red cells Lacking Cw antigens. 15. The final container label shall preferably be colour coded according to standard guidelines.			

Packing : 01 vials

The offer should be valid till 180 days from closing of bid. (02.01.2024)

Amendment to the Bid Document
Page 9 condition No 19.b

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

The registrar of public contracts should be amended as awards over Sri Lanka Rupees (LKR) Five Million instead of LKR Ten Million should be registered with the registrar of public contracts by the successful tenderer or his local agent.

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.
A non refundable fee of Rs. 20,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

(a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.

(b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

BID NO/ BID REFERENCE :
(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :
(SRI LANKAN TIME)

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR …….. or USD …….. to be submitted along with the Bid Bond valid till …… (date)

Bid validity period : Bid should be valid till …….. (date)

Bid Document Fee : ……
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.
2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of *1957)*
ñMehewara Piyasaò 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka.
Telephone (00)94-1-2335008 Fax: (00)94-11-2582495
E-mail: dgmsurgical@spc.lk or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA

AGREEMENT

SPC Ref. No Date :

Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at ñMehewara Piyasaò 16th Floor, No. 41, Kirula Road, Colombo 05, Sri Lanka (hereinafter called the ñSPCò which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the **FIRST PART**

AND

M/s é ..

…business under the time, style and firm of a company duly registered and carrying business (hereinafter called ñthe supplierò and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **SECOND PART.**

AND

M/s é ..

…business under the time, style and firm of a company duly registered and carrying business (hereinafter called ñthe Local Agentò and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s é for the supply and delivery ofé é é é é é é é é é é é é é é é é é é as per the attached indent for é é é é é é marked SPC é é é é é é é é é é é é . Dated é é é é é é é é é é é é and M/s é will act as local agent of the supplier for all matters arising out of supplies here of.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The following documents:

   (a) Conditions of Contract marked ï Annex 1
   (b) Bid Documents marked ï Annex 2
   (c) Copy of Indent marked ï Annex 3

(hereinafter called ñthe Contract Documentsò) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial of this agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC, the supplier and the local agent may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and é é é é é é é é é and é é é é é é é é é é . of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this é é é é é .20é

The Common Seal of M/s (supplier)é é é é é é é é é é é é é é é é é é ... herein.

1. é é é é é é é é é é é é é ..

President/Managing Director/C.E.O.

2. é é é é é é é é é é é é é ..

Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é é .	é é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é é .	é é é é é é é é é é é é é é é é é

The Common Seal of M/s. é é é é é é é é é é é é é é é (Local Agent) herein.

é é é é é é é é é é é é é é é .

President/Managing Director/C.E.O.

é é é é é é é é é é é é é é é .

Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

3.1.1 Short packing
3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
3.1.3 Packs which cannot be identified due to labels falling off.
3.1.4 Goods supplied fails to perform or meet requirements of the specification/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or itôs fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 **Withdrawal from use of Item due to quality failure.**

a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

heretoé)

é .)

é .)

é .)

Authorized signatory

Authorized signatory

Witnesses

Signature Name, Address and ID No

1…….. ……

2…… ……