Bihar Medical Services & Infrastructure Corporation Limited
4th floor State Building Construction Corporation Limited. Hospital Road, Shastri Nagar, Patna 800023
Phone/Fax: +917008050665,+ 919471009193

CORRIGENDUM-III

Tender for rate contract and supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets for the State of Bihar for the Year 2019-2021

Notice Inviting Tender Ref No.: - BMSIC/MEDICAL DEVICE/CONSUMABLE/19-05 Dated: -10-12-2019

(Only through E- Tender on website: -www.eproc.bihar.gov.in)

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) invites E-Bids from the interested parties for "**Tender for rate contract and supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets for the State of Bihar for the Year 2019-2021.", vide Notice Inviting Tender No.- BMSIC/ MEDICAL DEVICE/CONSUMALE/19-05"**,. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website **www.eproc.bihar.gov.in**.

All the suggestions /queries received from the prospective bidders during and after Pre-Bid meeting and the technical aspects were reviewed by the Technical Specification Committee (TSC) in its meeting dated 05-11-2019. The Minutes of the TSC meeting is attached here with along with this Corrigendum-III. The floated bid document is amended hereby in accordance with the attached minutes of the TSC meeting.

The Financial bid sheet has also been amended accordingly. Those Bidders who have already submitted their bids should also have to Re-submit their bids accordingly.

In order to give sufficient time and to ensure wider participation of the bidders the Tender Schedule is being revised as follows:-

Revised Tender Schedule

Tender Reference No.	**BMSIC/ MEDICAL DEVICE/CONSUMALE/19-05**
Date and time for downloading of bid document	**Upto 26th December 2019 till 1500 Hrs.**
Last date and time of submission of online bids	**Upto 27th December 2019 by 18:00 Hrs.**
Last date and time for submission of original bid documents with EMD and Tender Fees	**Upto 30th December 2019 till 14:00 Hrs.**
Date, Time and Place of opening of Technical Bid	**Upto 30th December 2019 (at 15:00 Hrs.) on the website of www.eproc.bihar.gov.in in the office of BMSICL**
Date and time of opening of Financial Bids	**To be announced later on www.bmsicl.gov.in and www.eproc.bihar.gov.in**
Validity of Tender	**180 Days**
Cost of the tender document	**Rs. 10,000/- (Ten Thousand only) Non-refundable.**
Bid Processing Fee	**Rs 1180/-(One thousand one hundred eighty only) Non-refundable.**

Sd/-
GM (Procurement)
BMSICL

Minutes of the Technical Specification Committee Meeting for Finalization of Technical Specification of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets floated vide tender no.- BMSIC/MEDICAL DEVICES/CONSUMABLE/19-05 (Tender for rate contract & supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable for state of Bihar for the year 2019-21).

Date: 05th November 2019 **Venue: BMSICL Conference Hall.**

The Technical Specification Committee Meeting for finalization of the specification of **Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets floated vide tender no.- BMSIC/MEDICAL DEVICES/CONSUMABLE/19-05** was held on 05th November 2019 under the Chairmanship of Dr. Ashok Kumar, Director in Chief, Department of Health, GoB. The other committee members present in the meeting were:

1. Sh. Khalid Arshad, Administrative Officer, SHS Bihar.
2. Sh. Rajani Kant, CGM (Supply Chain), BMSICL.
3. Dr. Vijay Prakash Rai, State Programme Officer (Child Health), SHS Bihar.
4. Dr. MD. Sajjad Ahmed, State Programme Officer (Family Welfare Health),SHS Bihar.
5. Dr. Bal Krishna Mishra, State Programme Officer, Anemia Mukt Bharat, SHS Bihar.
6. Sh. Sunil Kumar Singh, GM (Procurement), BMSICL.
7. Dr. Biswaprakash Pradhan, DGM (Drugs), BMSICL.
8. Dr. Rashmi, Deputy Director (Maternal Health), SHS Bihar.
9. Sh. Ravi Kiran Rakesh, Manager (Drugs), BMSICL.

During and after pre-bid meeting held on 05-11-2019, various suggestion from prospective Bidders were received. All the received suggestion and technical aspects were discussed in today's meeting. After due deliberations on all the aspects, it was unanimously decided to recommend to make certain amendments and clarifications as given in Annexure-A (Clarification/ Amendment), Annexure- B (Revised tendered product list), Annexure- C (Amended Technical Specification) of this minute of the meeting. The bidder has to submit Performance Statement (Annexure- D) & Production/ Import Capacity Statement (Annexure-E) in the prescribed format.

Along with the Manufacturers or Direct Importers the distributors are also allowed to participate in this tender. In case of Distributor, they will have to furnish all the requisite documents of the manufacturers/ importers as required under various clauses of the bid document. In case of Importer/ Distributor, the bidder (importer/ distributor) must have authorization certificate from Original Equipment Manufacturer (OEM) for participating in this tender i.e., tender no. BMSIC/MEDICAL DEVICES/CONSUMABLE/19-05 in the prescribed format (Annexure- F).

The meeting was thus concluded with a vote of thanks.

Sd/-
(Ravi Kiran Rakesh)
Manager (Drugs), BMSICL, Patna.

Sd/-
(Dr. Rashmi)
Deputy Director (Maternal Health), SHS Bihar.

Sd/-
(Dr. Biswaprakash Pradhan)
DGM (Drugs), BMSICL, Patna.

Sd/-
(Sunil Kumar Singh)
GM (Procurement), BMSICL, Patna

Sd/-
(Dr.MD. Sajjad Ahmed)
State Programme Officer (Family Welfare Health), SHS Bihar.

Sd/-
(Dr Vijay Prakash Rai)
State Programme Officer (Child Health), SHS Bihar.

Sd/-
(Rajani Kant)
CGM (Supply Chain), BMSICL, Patna.

Sd/-
(Khalid Arshad)
Administrative Officer, SHS Bihar.

Sd/-
(Dr. Ashok Kumar)
Director in Chief, Department of Health, GoB.

Sd/-
(Dr.Bal Krishna Mishra)
State Programme Officer
Anemia Mukt Bharat
SHS Bihar

ANNEXURE-A				
BMSIC/MEDICAL DEVICES/CONSUMABLE/19-05, Clarification in the light of queries/suggestions received from various firms during and after Pre-Bid Meeting held on 05/11/2019				
S. N.	**Name of the Firm**	**Bidders Queries**	**Present Clause**	**Clarification/Amendment**
1	**M/s Deep Meditech Pvt. Ltd.**	**<u>Change request: Range of HB estimation 5- 20gm/dl</u>** **1)** As per WHO studies conducted on Indian Population & guidelines from Ministry of Health & Family Welfare under National Iron + Initiative (Towards infinite potential in an anaemia free India), any value below 7 g/dl to be considered under severe anemia and anemia screening below 3 g/dl is not clinically viable. **2)** Any value below 7 g/dl has serious intervention like blood transfusion & further needs Iron injection for which patient will undergo detailed blood analysis hence our proposed measuring range 5g/dl-25 should be considered clinically sufficient range for anemia screening at primary health care centers. **3)** We are already supplying our devices to NHM funded project for anemia screening in various states with similar range. Hence making it to 5g/dl to 25 g/dl will extend more options for your organization.	**<u>Annexure- VII</u>** **Technical Characteristics** Point (3)- Range of HB estimation 0-20gm/dl	No Change
		Change request: Measuring time: <15 Seconds	**Annexure- VII** **Technical Characteristics** **Point (7)-** Measuring Time-Less than one Minute	No Change
		It is recommended to incorporate Findings/ Evaluation from NABL Labs.	**Annexure- VII** **Technical Characteristics** **Point (9)-** Sensitivity- more than 80%	1) Sensitivity, Specificity & Bias (limit of agreement) certificate of in house quality control laboratory of the OEM has to be

			Annexure- VII Technical Characteristics Point (10)- Specificity more than 80%	submitted. 2) During Demonstration the specificity & sensitivity will be evaluated by the team of experts nominated by BMSICL
			Annexure- VII Technical Characteristics Point (11)- 11. Bias (limit of agreement)- 0.5gm/dl(+_1gm/dl)	
		Distributor can also quote tender but valid import license of importer or manufacturing license of manufacturer should be there.	5. **GENERAL CONDITIONS**a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS**a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.**
2	**M/s Zeal India Chemicals**	**<u>Change request:</u>** Scope of bidder should include Authorized Distributor for Indian Manufacturer. The tender is for the Medical device and if the foreign manufacturer allow to bid via importer the facility shall be granted on equal platform for support the Indian manufacturer for support the Indian manufacturer for ground lever service, training and logistics support. You may further ask Genuine price confirmation from OEM for their quoted product through distributor for price justification. In NIT the requirement of local service station mentioned, meaning the rate of local service station/ Authorized distributor is important.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.** **• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**
		<u>Change request:</u> Working Temps 5 to 50 Deg for Haemoglobinometer and Test Strip both. As per the environmental condition of Bihar witnessed	**<u>Annexure- VII</u> Environmental consideration Point 1-** Should be able to perform in the temperature range of	No Change

		High, temp upto 46-47 deg this amendments request made for unrestricted usage of equipment for patient benefit.	10-40 deg centigrade.	
		Change request: Open vial stability minimum 6 months Once the sealed strip/ cuvette vial is open for test, the stability of the test strip/ cuvette in opened vial should be maintained for minimum 6 month for use for hemoglobin test. This will save the scope of unused strip.	Annexure- VII Accessories Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-95%. Shelf life for storage should be at least one year.	**Annexure- VII Accessories Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-90%. Shelf life for storage shall be at least 24 months for unopened vials/ packs from the date of manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.**
		Change request: The scope of market standing should be extended in ration of required quantity with supplied quantity. As discussed in the pre-bid this will ensure the acceptance of product in wider aspect as well as capability of the product in terms of service & logistic.	Clause 3(f) Bidders must have: - •Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.•Must have three years of experience in manufacturing / Importing of the quoted item.•Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.• Bidder who are manufactures for all the floated items or bidder who are direct importers for all the floated items or bidder who are manufacturer for some of the floated items as well as importer for the remaining floated items are allowed to participate in the bidding process.Bidders shall submit self-attested copies of their manufacturing license	No Change in Clause 3(f)• **In case of Distributor**, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under clause 3(f).

			(for manufacturer)/ import License (for direct importer)/ manufacturing & import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions.• In case of Importer, they will have to furnish the manufacturer's authorization form from the original equipment manufacturer (OEM) as per Annexure IX.	
		Change request: Memory to store Data- At least 500 tests As ANM is performing the tests on field, there is a chance of data loss in case of missed entry by ANM due to which an internal memory storage is required.	**Annexure- VII** **User Interface** **Point 1** Memory to store Data- desirable-up to 500 tests with data and time.	**Annexure- VII** **User Interface** **Point 1** Memory to store Data- desirable-up to 500 tests with **date** and time.
		Change request: As discussed in pre-bid meeting, This should be as replacement warranty for device and/ or their accessories	**Annexure I** **Note 1**- The device and test strips (per batch/packet) shall be quoted with 2 years of replacement warranty deliverable at the user site.	**Annexure I** **Note 1**- The device and test strips/ cuvette (per batch/packet) shall be quoted with 2 years of replacement warranty deliverable at the user site. **The successful bidder has to replace the defective device, test strips/ cuvette (per batch/packet) & Auto Disable Lancet with new device test strips/ cuvette (per batch/packet) & Auto Disable Lancet within a week of reporting.**
		Change request: As discussed in pre-bid meeting, NIB not certifying HB strip	**Clause 3 (i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.	Clause 3 (i) The Test strips/ Cuvettes should be certified **by any independent NABL Accredited Testing Laboratory.**

		Change request: The machine should be able to perform upto 200 or more test when full charge Different manufacturer uses different capacity of battery and device when on battery may have difference test capacity as per the power consumed by the battery in device they use. The test capacity when full charge depends on 3rd party accessories (battery) and may vary OEM to OEM. For ensuring wider participation the limit should be 200 or more should be define.	**<u>Annexure- VII</u>** **Energy Source** **Point 2-** Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.	No Change
		Change request: This will be cover by replacement warranty clause because field calibration is difficult and time consuming Requirement of A state level service/ logistic depot may be asked from bidder with maintenance of minimum 5% stock for timely replacement.	**<u>Annexure- VII</u>** **Quality control** **Point 2-** Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: The supply kit (Haemoglobinometer, strip/ cuvette vial of 50's, Lancet - 50's Data Cable etc) should be asked to supply in a well stitched pouch, item wise foam compartment, zipped open & close, with sticker/ embossment in the outer side. As the device is expected to use in ground level and in regular movement for usage. This will ensure safety of the product, easy handling and prevention of loss of government property.	**Clause 23- LOGOGRAMS** a) Logogram and "BIHAR GOVERNMENT SUPPLY – NOT FOR SALE" shall appear in primary, secondary and tertiary packing of all products which will be bolder than those already printed on the label. b) All the products have to be supplied in standard pack size with printed logogram of proportionate size and shall also conform to the relevant provisions of **Medical Device Rules 2017** & **Drugs & Cosmetics Act 1940**. Affixing of stickers and rubber stamps shall be accepted only if permitted by the concerned licensing	No Change

			authority. Affixing of stickers will be permitted on request only in case of imported products on merits. c) Supply of items without the logogram and/or "BIHAR GOVERNMENT SUPPLY – NOT FOR SALE" shall not be accepted.	
		Change request: Transportation of control solution is temperature sensitive. This facility should be readily available at service center during the contract period.	**<u>Annexure-VII</u>Quality controlPoint 2-** Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: With reference to the working temperature. Cuvette/ Strip (storage environment) should be stable at temperature of 5 to 50 deg, Humidity 5-95 deg, Shelf life of storage should be at least one year.	Annexure- VII Accessories Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-95%. Shelf life for storage should be at least one year.	**Annexure- VII** **Accessories** **Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-90%. Shelf life for storage shall be at least 24 months for unopened vials/ packs from the date of manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.**
		Change request: Weight should not be more than 300 gm after installation of battery The transportation of 500 gm device is not user friendly	**Annexure- VII** **Physical Characteristics** Weight-should not be more than 500 gm.	No Change
		Change request: Please add scope of intended user should be Doctors, ANM, field Medical Staff etc.	NA	The tender has been floated for rate contract & supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets for state of Bihar for

				the year 2019-2021. The said device shall be utilized as and when required.
		Change request: To reduce the burden on the bidder Kindly make it to 5% of order value before GST	**Clause 19. SECURITY DEPOSIT / PERFORMANCE GUARANTEE** a) There will be a Security Deposit amounting to 10 % of the total value of the awarded items as per letter of Intent which shall be furnished by the successful bidder to the Tender Inviting Authority within the stipulated time period as per the LOI.	No Change
3	**M/s Wrig Nano system Pvt. Ltd**	**Change request:** Should be able to perform in the temperature range of **5-50** deg CentigradeCuvette/Strip working environment - Disposable and stable specified Environmental (working temperature **5-50 deg C** working humidity - 5-95%) conditionTo ensure the device chosen can give accurate results in field settings in Bihar where temperatures rise upto 48°C during summermonths, it is critical that the meter as well as the test strips (that contain the dry reagent) are capable of operating at temperatures ranging from 5-50°C. As the meter and strips work in combination, both these components separately need to be capable of operating at 5-50 deg Celsius so that the entire system works at 5-50 deg Celsius	Annexure-VIIEnvironmental considerationPoint1- Should be able to perform in the temperature range of 10-40 deg centigrade.Point 2- Working humidity- 5-95%AccessoriesPoint 1- Cuvette/strip (working environment)- Disposable and stable specifiedEnvironmental (working temperature 40 deg C working humidity- 5-95%) condition	Annexure-VIIEnvironmental considerationPoint1- Should be able to perform in the temperature range of 10-40 deg centigrade.Point 2- Working humidity- 5-90%AccessoriesPoint1- Cuvette/strip (working environment)- Disposable and stable specifiedEnvironmental (working temperature 40 deg C working humidity- 5-90%) condition
		Change request: Shelf life of storage should be at least one year and open vial stability should be at least 6 months. In order to ensure that the opened packs are not wasted and perform optimally at places where the demand is not high, it is required that procured strips/Cuvettes have	Annexure- VII Accessories Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-95%. Shelf life for	**Annexure- VII Accessories** **Point 2- Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 deg C humidity- 5-90%. Shelf life for storage shall be at least 24 months for**

		an open vial stability of 6 months.	storage should be at least one year.	**unopened vials/ packs from the date of manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.**
		Change request: Tender bid is invited directly from manufacturers or Distributors (authorized by manufacturer) or Direct importers or Manufactures as well as direct importers only Servicing the order requires a lot of working capital in activities like raw material procurement, production, warehousing, logistics and support which puts an additional burden on the manufacturer and impairs his ability to service the order.Also, a local distributor shall ensure better local support and service which shall help in addressing issues on ground and ensure success of the programme.As the same is being allowed for foreign manufacturers by allowing importers, we request to allow Indian manufacturers to bid via authorized distributors so that **Indian manufacturers are given equal opportunity and allow for greater tender participation.**	5. **GENERAL CONDITIONS**a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS**a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**
		Change request: As this is a huge tender in terms of the quantity as well the value of items, we request you to consider 5% as security deposit as this will help companies with the working capital issues as well as allow for greater participation. There will be a security deposit amounting to 5% of the total value of the awarded items as per letter of intent which shall be furnished by the successful bidder to the Tender Inviting authority within the stipulated time period as per the LOI.	**Clause 19. SECURITY DEPOSIT / PERFORMANCE GUARANTEE** a) There will be a Security Deposit amounting to 10 % of the total value of the awarded items as per letter of Intent which shall be furnished by the successful bidder to the Tender Inviting Authority within the stipulated time period as per the LOI.	No Change

		Change request: Memory to store Data- At least 500 tests As ANM is performing the tests on field, there is a chance of data loss in case of missed entry by ANM due to which an internal memory storage is required.	**Annexure- VII** **User Interface** **Point 1** Memory to store Data- desirable-up to 500 tests with data and time.	**Annexure- VII** **User Interface** **Point 1** Memory to store Data- desirable-up to 500 tests with **date** and time.
		Change request: Weight-should not be more than 100 gmAs the ANM will carry several products on field along with the Haemoglobinometer being procured, it is essential that the products are light and portable to ensure wider acceptance and portability.	**Annexure- VII** **Physical Characteristics**Weight-should not be more than 500 gm.	No Change
		Change request: Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform more than 200 tests when full charge. This will allow for greater number of participants and it is also suitable taking into consideration the number of tests an ANM performs in a month.	**Annexure- VII** **Energy Source** **Point 2-** Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.	No Change
		Change request: Intended Users: ANMs, technicians etc Intended users are not mentioned in the tender document but they are important from regulatory point of view as some devices are regulated to be only used by health professionals such as doctors, clinicians, etc and not by ANMs due to which not all intended users may be able to use the device which can result in **regulatory, legal and operational issues.**	N/A	The tender has been floated for rate contract & supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets for state of Bihar for the year 2019-2021. The said device shall be utilized as and when required.
		Change request: Auto Disable lancets: pack of 50 nos. As the standard SKU available in the market is a pack of 50 lancets, so we request to incorporate pack of 50 lancets to avoid practical challenges.	**Annexure 1: TENDERED PRODUCT LIST** **Sl no.3 & Note point 2-** Each pack of Auto Disable lancets consisting of 55 numbers of Auto Disable lancets	**Annexure 1: TENDERED PRODUCT LIST** **Sl no.3 & Note point 2-** Each pack of Auto Disable lancets consisting of **50 numbers** of Auto Disable lancets

		Change request: Must have supplied at least 50% of the quoted items in the last 2 years to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.As this tender involves huge quantities of the quoted items, it is imperative to ensure that the supplier has successfully supplied substantial quantity of products in the past two years to mitigate any risk of non-execution from the supplier.	**Clause 3 (f)**Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.	**Clause 3 (f)**Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers/distributors own experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.
		Change request: As the Haemoglobinometer are factory calibrated and the same activity cannot be performed on site, so it is requested that any faulty device shall be covered under replacement warranty rather than on site.	**Clause 21 (m)** The bidder shall undertake on-site calibration of the Haemoglobinometer machine every 6 (six) month as part of the after sales service during the period of comprehensive warranty and submit a "calibration certificate" to the head of the User Institution with a copy to the Tender Inviting Authority afterwards.	No Change
		Change request: All the batches of the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets supplied shall be supported by in house Quality Control report of the manufacturer as applicable. The TIA has the right to get the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets tested at the laboratories of his choice for further verifications. The process of getting all the batches tested by a third party independent laboratory is a highly expensive and time taking process. As this tender involves	**Clause 25 (d)** All the batches of the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets supplied shall be supported by test/analysis reports furnished by independent NABL Accredited Testing Laboratory/Central Medical device testing laboratory as applicable along with In House Quality Control report of the	No Change

		huge quantities of products, this shall result in great impact on the cost and lead to logistical challenges as well. A certificate of analysis provided by the Manufacturer should be used to ascertain quality along with independent testing that can be carried out by the Buyer from the accredited laboratories as required.	manufacturers applicable. The TIA has the right to get the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets tested at the laboratories of his choice for further verifications.	
		Change request: National Institutes of Biologicals (NIB) does not have hemoglobin meter and hemoglobin test strips testing under their scope and hence, the same shall not be possible.	**Clause 3 (i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.**
		Change request: The Haemoglobinometer should have the facility of real time data management of anaemia across the state, enabled through an android app. The data to be transferred via USB cable. The collection of real time data of Hb levels will enable you to accumulate the district/block wise data throughout the state and track the prevalence of anemia, on the basis of which new policies and programs can be initiated to help eradicate anemia completely.	**<u>Annexure- VII</u>** **User Interface** 1. Memory to store Data- desirable-up to 500 tests with data and time. 2. Bluetooth connectivity- desirable. 3. Data transfer- desirable-provision for data transfer to printer and PC.	No Change
4	**M/s Sensa Core Medical Instrumentation Pvt. Ltd.**	**Change request:** Please allow to submit experience proof of being supplied to private hospitals/ dealer/ distributor etc**.** Govt. supplies are limited so far and the same is picking up now only.	**Clause 3 (f)** Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.	No Change
		Change request: NIB certification is not available for Haemoglobino Test Strips. Please advise to delete.	**Clause 3 (i)** The Test strips/ Cuvettes should be certified by the National Institutes	Clause 3 (i) The Test strips/ Cuvettes should be certified by the **NABL Accredited Testing Laboratory**

			of Biological (NIB), Govt. of India.	
		Change request: Please add the clause to get the production capacity of Tenderers. This will help in undisputed supplies to BMSICL.	NA	**The bidder has to submit production/ import capacity statement as per Annexure-E**
5	**M/s HemoCue India**	**Change request: Absorbance photometry with isobestic point working on dual wavelength technology.** Micro Cuvette based absorbance photometry has been used across the world since several years and finds acceptance with renowned global bodies like WHO, UNICEF, MSF etc. due to its accuracy (documents attached). Dual wavelength technology ensure lab quality results - 1 wavelength for Hb estimation and other for turbidity compensation.	**Annexure- VII Technical Characteristics Point 2-** Working Principal-reflectance photometry/ absorbance photometry.	No Change
		Change request: Measuring Time- Within 5 seconds Given the scope of a mass project a shorter TAT is desirable. It allows more subjects to be screened in a given limited time compared to TAT of 60 seconds	**Annexure- VIITechnical CharacteristicsPoint 2-** Measuring Time- Less than one Minute	No Change
		Change request: **Sensitivity >90%** Ideally, both sensitivity and specificity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Notably, low sensitivity and specificity to identify anemia may result in erroneous population-based prevalence estimates of anemia, which army have significant consequences for state's policies	**Annexure- VII Technical Characteristics Point 9-** Sensitivity- more than 80%	1) Sensitivity, Specificity & Bias (limit of agreement) certificate of in house quality control laboratory of the OEM has to be submitted. 2) During Demonstration the specificity & sensitivity will be evaluated by the team of experts nominated by BMSICL
		Change request: Specificity >90% Ideally, both sensitivity and specificity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Notably, low sensitivity and specificity to identify anemia may result in erroneous population-based prevalence estimates of anemia, which any have	**Annexure- VII Technical Characteristics Point 10-** Specificity more than 80%	

		significant consequences for state's policies		
		Change request: 1.5 volt 4AA Batteries should be able to perform up to 500 tests. Only 1.5 Volts 4 AA batteries. Lithium- polymer rechargeable batteries may not be easily available leading to down time of instrument. Moreover, if there is no electricity, it may not be possible to charge the instruments and tests can not be performed.	**<u>Annexure- VII</u>** **Energy Source** **Point 2-** Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.	No Change
		Change request: Should be stable at 10-40 deg C, working humidity 5- 90%. Shelf life of 24 months both opened/ unopened from date of manufacture. This Should be added considering the scale of the project the shelf life and temperature range will play an important role in maintaining the quality of cuvette across a wide range of temperatures for a longer duration and hence avoid expiry due to shorter shelf life.	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-95%	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-90% Shelf life for storage shall be at least 24 months for unopened vials/ packs from the date of manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.
		Change request: Third party blood based liquid controls to be available for low, normal & high hemoglobin values. Instrument should be factory calibrated against ICSH method. Third party blood based liquid controls are more authentic. ICSH is the international reference method for calibration of hemoglobin measuring devices.	**<u>Annexure- VII</u>Quality controlPoint 2-** Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: Service center in India should be of the original OEM and not of the distributor. Ensures timely and genuine support to the user.	NA	NA

6	**M/s Aroma Health Care**	**Change request: "Bidder should be having a valid manufacturing/ import license"** There is no relevance regarding how old the manufacturing/ import license exists with the bidder. The only point of importance is regarding its validity that whether a bidder holds a valid license or not. Hence, the point should be amended accordingly.	**Clause 3 (f)** Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.	No Change
		Change request: "Must have three years experience in manufacturing/ importing of the quoted or equivalent item." Bidders who are not manufacturers in general are channel partners of more than one principal manufacturing company for similar equipment to be able to quote the relevant product according to the requirement of a tender. Hence, having three years of experience in the quoted item is not justified. So, it should be amended as per our suggestion.	**Clause 3 (f)** Must have three years of experience in manufacturing / Importing of the quoted item.	No Change
		Change request: Haemoglobinometer is not critical equipment and doesn't determine results of utmost importance. Hence, this requirement should be deleted to enable wider participation in the tender.	**Clause 3(i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.**
		Change request: Since, it is already required that Haemoglobinometer should be USDFA/CE, hence, there is no requirement for the auto disable lancets to be USFDA/CE/BIS certified because they are used as accessories with the equipment.	**Clause 3(j)** The Auto disable lancets should be CE or USFDA certified or BIS Certified.	No Change
		Change request: Bluetooth mode of data transfer is one of the slowest modes for transferring data. It also requires the other device to be compatible and having Bluetooth facility in order to transfer data. Therefore, it should be deleted.	**Annexure- VIIUser Interface**1. Memory to store Data-desirable-up to 500 tests with data and time.2. Bluetooth connectivity-desirable.3. Data transfer- desirable-provision for data transfer to printer and PC.	No Change

		Change request: Equipment to work on direct connection with electricity source (AC) should be removed. Ideally, Haemoglobinometer do not work on direct power (AC supply) because they are handled devices that are meant to be used on the go i.e on fields where there is no power. Hence, the clause should be removed.	**Annexure- VII** **Energy Source** **Point 1.** Power requirement – preferably battery operated. Should also be able to work on direct connection with electricity source (AC). The manufacturer must provide the charger and cable for electricity power connection, wherever required by the equipment.	No Change
7	**M/s Shree Balaji Biomedicals**	**Change request: Absorbance photometry with isobestic point working on dual wavelength technology. ICSH method calibrated.** Micro Cuvette based absorbance photometry has been used across the world since several years. It is used by global organizations. Dual wavelength technology ensure higher.	**Annexure- VII** **Technical Characteristics** **Point 2-** Working Principal-reflectance photometry/ absorbance photometry.	No Change
		Change request: Measuring Time- Within 10 seconds Given the scope of a mass project a shorter TAT is desirable. It allows more subjects to be screened in a given limited time compared to TAT of 60 seconds	**Annexure- VII** **Technical Characteristics** **Point 2-** Measuring Time-Less than one Minute	No Change
		Change request: Sensitivity >95% Sensitivity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Low to identify anemia may result in wrong population-based prevalence estimates of anemia, which may have significant consequences for national policies for anemia.	**Annexure- VII** Sensitivity- more than 80%	1) Sensitivity, Specificity & Bias (limit of agreement) certificate of in house quality control laboratory of the OEM has to be submitted. 2) During Demonstration the specificity & sensitivity will be evaluated by the team of experts nominated by BMSICL
		Change request: Specificity >95% Specificity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Low specificity to wrong population-based anemia, which may have significant consequences for national	**Annexure- VII**Specificity more than 80%	

		policies		
		Change request: 1.5 volt 4AA Batteries Lithium- polymer rechargeable batteries are not be easily available leading to down time of instrument.	**<u>Annexure- VII</u>** **Energy Source** **Point 2-** Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.	No Change
		Change request: Should be stable at 10-40 deg C, working humidity 5- 90%. Shelf life of 2 years both opened/ unopened from date of manufacture. Since project is big it is important to have long shelf life.	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-95%	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-90% Shelf life for storage should be at least 24 months for both open and unopened vials- packs.
		Change request: Third party blood based liquid controls to be available. Third party blood based liquid controls are better for quality check.	**<u>Annexure- VII</u>Quality controlPoint 2-** Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: Service center in India should be of the original OEM and not of the distributor. Ensure prompt, and genuine support to the user.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.** **• In case of Distributor,**

			in the tender.	**they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**
		Change request: i. Original Manufacturers can apply ii. Authorized Distributors Direct Importers with Authorization Letter from Original Manufacturer can apply To ensure wider participation from reputed manufacturer will help in sourcing quality product at competitive rates	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization form OEM for participating in this tender.** **• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**
		Change request: Bidder who are Manufacturers:i. The manufacturers have to provide documentary evidence certifying that he is manufacturing the item under consideration for the past five years. (Not necessarily of the same specification).Ii. Manufacturing Experience certified by CA along with supporting documents to be submitted.Bidder who are not Manufacturers:i. If the Bidder is not a Manufacturer then the Bidder then the Bidder should be duly authorized by the Manufacturer who meets the above Criteria (b.1).Bidder should have experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Government or State Government PSU. To ensure wider participation from	Clause 3(f) Bidders must have: - •Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.•Must have three years of experience in manufacturing / Importing of the quoted item.•Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.• Bidder who are manufactures for all the floated items or bidder who are direct importers for all the floated items or bidder	No Change in Clause 3(f)• **In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under clause 3(f).**

		reputed manufacturer will help in sourcing quality product at competitive rates.	who are manufacturer for some of the floated items as well as importer for the remaining floated items are allowed to participate in the bidding process.Bidders shall submit self-attested copies of their manufacturing license (for manufacturer)/ import License (for direct importer)/ manufacturing & import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions.• In case of Importer, they will have to furnish the manufacturer's authorization form from the original equipment manufacturer (OEM) as per Annexure IX.	
		Change request: Understand NIB is not conducting Hb testTo be deleted.b) Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets should be supplied along with COA and should be CE marked. The TIA has the right to get the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets tested at the laboratories of his choice for further verifications.	**Clause 3(i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.Clause 25(d) All the batches of the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets supplied shall be supported by test/analysis reports furnished by independent NABL Accredited Testing Laboratory/Central Medical device testing laboratory as applicable along with In House Quality Control report of the manufacturer as applicable. The TIA has the right to get the	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.**

			Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets tested at the laboratories of his choice for further verifications.	
8	**M/s Biosense Technologies Pvt. Ltd.**	**Change request:** **Each pack having 50 nos of test strip/Cuvette 3)Each pack having 50 nos of auto disable lancets(Equal no. of Strip/Cuvette) in the respective rows of financial bid.** There is no packsize available for 55 nos. Making it to equal no of Strip/Cuvette or 50 nos will further ease the supply process followed by tracking of used consumables in right manner.	**Annexure 1: TENDERED PRODUCT LIST** Sl no.3 & Note point 2- Each pack of Auto Disable lancets consisting of 55 numbers of Auto Disable lancets	**Annexure 1: TENDERED PRODUCT LIST** Sl no.3 & Note point 2- Each pack of Auto Disable lancets consisting of 50 numbers of Auto Disable lancets
		Change request: **Minimum three years old valid manufacturing/import license renewal certificate/Minimum 8 months for Make in India Company with valid documents.Must have three years of experience in manufacturing /factory/ importing of the quoted item/Minimum 8 month for Make in India.Company with valid documents. Must have three years of experience in supplying the quoted items to central Government/Any State government / Government corporation /any central Government corporation/ any central Government or State Govt PSU or Must have minimum & month of experience(For Make in India Company) in supplying the quoted items to central Government /Any State government /Government Corporation/ any central Government or State Govt PSU/Private Hospital /Private Practitioner.**Government of India is promoting "make in India " program vigorously and due to serious effort from Indian Government in recent times, it has become possible to start manufacturing some of the Portable Healthcare devices in India, without compromising on quality at reasonable rates. Clause of three year manufacturing / factory license will restrict manufacture like us and thus home grown business will abide playing in foreign manufacturer's hand .We should adopt a	Clause 3(f) Bidders must have: - •Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.•Must have three years of experience in manufacturing / Importing of the quoted item.•Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.• Bidder who are manufactures for all the floated items or bidder who are direct importers for all the floated items or bidder who are manufacturer for some of the floated	No Change in Clause 3(f)• **In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under clause 3(f).**

		procedure where genuine importers as well as domestic manufacturer get equal chance to participate. Excellent quality should get a chance to bid, over performance tenure or supply history. Theme of "Make in India " should be protected followed by providing equal chance to every potential bidder. **Please refer enclosed document from Govt. of India which clearly states that relaxation should be given to MSME/ Start ups company, (Content has been highlighted in Blue.** We should also include Private Hospital/ Private Practitioner as they are also genuine and regular user unlike govt. and its aided institute.	items as well as importer for the remaining floated items are allowed to participate in the bidding process.Bidders shall submit self-attested copies of their manufacturing license (for manufacturer)/ import License (for direct importer)/ manufacturing & import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions.• In case of Importer, they will have to furnish the manufacturer's authorization form from the original equipment manufacturer (OEM) as per Annexure IX.	
		Change request: Quality Evaluation report from Any NABL Accredited Laboratory. This clause should be removed as Hemoglobin Meter comes under Non Notified category and NIB has no protocol to do so yet.	**Clause 3(i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.**
		Change request: There will be a security deposit amounting to 2% of the total value of the awarded items as per letter of intent which shall be furnished by the successful bidder to the Tender inviting Authority within the stipulated time period as per the LOI. 1)Considering the quantity and business value, 10% would block major portion of funds which will further create trouble in internal operational activities including production expenditure. 2) In the last health conclave held in Hotel Maurya, this issue being addressed by all concern authority of Bihar and it is being announced that matter will be taken care of so we further expect	**Clause 19. SECURITY DEPOSIT / PERFORMANCE GUARANTEE**a) There will be a Security Deposit amounting to 10 % of the total value of the awarded items as per letter of Intent which shall be furnished by the successful bidder to the Tender Inviting Authority within the stipulated time period as per the LOI.	No Change

		to reduce it by 2% from 10%.		
		Change request: A flat 1% of the total bill amount(without tax) shall be deducted from the bills of the supplies of Haemoglobinometer machine. The Strips/ Cuvettes and auto disable lancets towards testing & handling charges of Haemoglobinometer machine test strips / Cuvettes and auto disable lancets from the supplier. 1) Amount deduction with tax will create mismatch in the accounting. Kindly be requested to look in to it. 2) There is no storage of extra effort involve which demands for handling. So it is be requested to reduce it from 2% to 1%.	**Clause25 (g)** A flat 2% of total bill amount shall be deducted from the bills of the supplies of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets, towards testing & handling charges of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets from the supplier.	No Change
		Change request: Power requirement preferably battery operated and should also be able to run minimum 500 Test when it is fully charged or with new battery Desirable -Should be also be able to work on direct connection with electricity source(AC). 1) For fair competition and without compromising on quality, battery should be used as a power source. Carrying adapter or charger would be difficult for ANMs of field workers.	**Annexure- VII Energy Source Point 1.** Power requirement – preferably battery operated. Should also be able to work on direct connection with electricity source (AC). The manufacturer must provide the charger and cable for electricity power connection, wherever required by the equipment.	No Change

		Change request: Certification US FDA/ European or CE and should have in vitro diagnostic 98/79/EC. European CE or USA FDA restricts Indian manufacturer/ Startups to participate. CE issued in India has similar guidelines which European does. So humble request to mention "CE" in place of "European CE"	**Clause (h)** The Haemoglobinometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate.	No Change
9	**M/s Microgene Diagnostics Systems Pvt. Ltd.**	**Change request: CE compliance with FSC issued by European country for sale. This confirms the acceptance of the quality of the product as per European standards. Hence kindly modify as "Certification USA FDA/ European CE/CE compliance with FSC issued by European Country."** Certification USA FDA/ European CE.	**Clause (h)** The Haemoglobinometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate.	No Change
		Change request: **All these devices are factory calibrated and in practice run QC to check reliability of result .Hence kindly modify this" All devices should be Factory Calibrated and facility to run Quality Control be available. Also please do not change any condition of QC solutions as each company prepares QC as per the test methodology, test system, matrix effect etc. While providing COA these effects are considered and hence it can give reliable result on samples.** Calibration facility should be available. Control Solution Check quality - should be available for low, normal and high hemoglobin values.	**Annexure- VII Quality control** Point 2- Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: Kindly modify this for more participation of companies "Must have three	**Clause 3 (f)** Must have three years of experience in	No Change in Clause 3(f) • **In case of Distributor, they will have to furnish**

		years of experience in supplying the quoted items to Central Government/any state government/Government corporation/ any Central Government or State Government PSU/Private Hospitals/Laboratories. Must have three years of experience in supplying the quoted items to Central Government /any state government /Government corporation /any Central Government or State Government PSU.	supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.	**all the requisite documents of the manufacturer's/ importers as required under clause 3(f).**
		Change request: Import license along with FSC issued by European country confirms this requirement. Hence that also to be accepted. Hence kindly Modify this as "The Haemoglobinometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD)/ US FDA certificate or CE compliance with FSC issued by European Country. The Haemoglobinometer machine must have valid CE certificate as per Invitro Diagnostic Devices(IVD) or US FDA certificate.	**Clause 3 (h)** The Haemoglobinometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate.	No Change
		Change request: **NIB does not do the testing of Hb strips. Hence NABL accredited laboratory testing can be made acceptable. Hence kindly modify that "The Test strips/ Cuvettes should be tested by NABL Accredited Laboratory and report provided.** The Test strips/Cuvettes should be certified by the national Institutes of Biological(NIB), Govt. of India.	**Clause 3(i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India.	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.**
		Change request: **As discussed in the pre bid meeting kindly modify this as "Import license copy of Hemoglobin test/Strips as per the Medical Device Rules 2017 issued by CDSCO" to be provided.** All certificates/documents as	**Clause 3 (s)** All certificates/documents as required to comply with the Medical device rules 2017 for supply of invitro diagnostic devices should be	No Change

		required to comply with the Medical device rules 2017 for supply of in vitro diagnostic devices should be provided.	provided.	
		Change request: **Kindly amend the same to "There will be a Security Deposit amounting to 5% of the total value of the awarded items as per letter of Intent" as all the other state tenders authorities call for this only.** a) There will be a Security Deposit amounting to 10% of the total value of the awarded items as per letter of Intent.	**Clause 19. SECURITY DEPOSIT / PERFORMANCE GUARANTEE**a) There will be a Security Deposit amounting to 10 % of the total value of the awarded items as per letter of Intent which shall be furnished by the successful bidder to the Tender Inviting Authority within the stipulated time period as per the LOI.	No Change
		Change request: **As the equipment's are factory calibrated this can be modified as The bidder shall undertake on site QC of the Haemoglobinometer machine every 6(six)month as part of the after sales service during the period of comprehensive warranty and submit a "QC certificate" to the head of the User Institution with a copy to the Tender Inviting Authority afterwards."** The bidder shall undertake on-site calibration of the Haemoglobinometer machine every 6(six)month as part of the after sale service during the period of comprehensive warranty and submit a "calibration certificate "to the head of the User Institution with a copy to the Tender Inviting Authority afterwards.	**Clause 21 (m)** The bidder shall undertake on-site calibration of the Haemoglobinometer machine every 6 (six) month as part of the after sales service during the period of comprehensive warranty and submit a “calibration certificate‟ to the head of the User Institution with a copy to the Tender Inviting Authority afterwards.	No Change

		Change request: **As the quantity is high need more time and hence need to be amended to 120 days from the receipt of order.** Scheduled of purchase order and Supply of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets with in 90days 100% of the quantity.	**Clause 22** Supply Condition	No Change
		Change request: **Kindly amend the same as "Payments for supply will be considered only after supply of at least 10% of the quantity ordered is completed."**Payment for supply will be considered only after supply of at least 75% of the quantity ordered is completed.	**Clause 23** Payment Provisionb) Payments for supply will be considered only after supply of at least 75% of the quantity ordered is completed, provided reports of Standard Quality of the batch tested at a NABL Accredited Testing Laboratory/Central Medical device testing laboratory along with the In house quality control Laboratory of the manufacturer is furnished along with the invoice in respect of each batch supplied. Where it is observed that for any batch of the supplies the report as above is not furnished, payment of the entire consignment would be withheld pending verifications and the entire consignment would be liable to be rejected.	No Change

		Change request: **Supply of the products is done by the company only after the receipt of order of BMSICL. It is understood that BMSICL while preparing the order has taken due consideration of the quantity required and utilization plan. Hence kindly remove this clause as this is waste of money even for the company as expired stocks are not saleable. Further this is already taken care on the sufficient expiry clause of 66%.** In the event of Haemoglobinometer machine, Test strips/Cuvettes and Auto disable lancets not being utilized within their shelf life period, the firm shall replace unspent /unused/expired stock by fresh stock with shelf life as per the Clause 21(f) without any extra cost unconditionally.	**Clause 21(l)** In the event of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets not being utilized within their shelf life period, the firm shall replace unspent/unused/expired stock by fresh stock with shelf life as per the Clause 21(f) without any extra cost unconditionally.	No Change
		Change request: **Currently battery operated instruments are become more energy complaint. Earlier many battery operated systems use to work only for 100 tests and currently it can work up to 1000 tests. As the current requirement is for more of field testing kindly modify as "Power requirement -Must be battery operated. Should also be able to work on direct connection with electricity source (AC) if the number of tests it can do is less than 500 tests on a single set of battery of charge. (As mentioned in the next clause point no 2 of power requirement.)The manufacturer must provide the charger and cable for electricity power connection, wherever required by the equipment.**Power requirement-preferably battery operated. Should also be able to work on direct connection with electricity source(AC). The manufacturer must provide the charger and cable for electricity power	**Annexure-VIIEnergy SourcePoint 1.** Power requirement – preferably battery operated.Should also be able to work on direct connection with electricity source (AC). The manufacturer must provide the charger and cable for electricity power connection, wherever required by the equipment.	No Change

		connection, wherever required by the equipment.		
		Change request: **There are 2 ways: This amount can be deducted from the principal amount and not from the amount including taxes. Second way is while placing order you may add 2% value to the principal order value and place to us as handling charges and then deduct the same while payment released.** A flat 2% of total bill amount shall be deducted from the bills of the supplies of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets, towards testing & handling charges of Haemoglobinometer machine, Test strips/Cuvettes and Auto disable lancets from the supplier.	**Clause25 (g)** A flat 2% of total bill amount shall be deducted from the bills of the supplies of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets, towards testing & handling charges of Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets from the supplier.	No Change
10	**M/s Sysmed Exim Pvt. Ltd.**	Change request: **Absorbance photometry with isobestic point working on dual wavelength technology.** Micro Cuvette based absorbance photometry has been used across the world since several years and finds acceptance with renowned global bodies like WHO, UNICEF, MSF etc. due to its accuracy. Dual wavelength technology ensure higher accuracy - 1 wavelength for Hb estimation and other for	**Annexure- VII Technical CharacteristicsPoint 2-** Working Principal- reflectance photometry/ absorbance photometry.	No Change

		turbidity compensation.		
		Change request: Measuring Time- Within 10 seconds Given the scope of a mass project a shorter TAT is desirable. It allows more subjects to be screened in a given limited time compared to TAT of 60 seconds	**Annexure-VIITechnical CharacteristicsPoint 2-** Measuring Time- Less than one Minute	No Change
		Change request: **Sensitivity >90%** Ideally, both sensitivity and specificity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Notably, low sensitivity and specificity to identify anemia may result in erroneous population - based prevalence estimates of anemia, which may have significant consequences for national policies.	**Annexure- VII Technical Characteristics Point 9-** Sensitivity- more than 80%	1) Sensitivity, Specificity & Bias (limit of agreement) certificate of in house quality control laboratory of the OEM has to be submitted. 2) During Demonstration the specificity & sensitivity will be evaluated by the team of experts nominated by BMSICL
		Change request: **Specificity >90%** Ideally, both sensitivity and specificity should be high in order to avoid misdiagnosis of anemia and unnecessary treatment. Notably, low sensitivity and specificity to identify anemia may result in erroneous population - based prevalence estimates of anemia, which may have significant consequences for national policies.	**Annexure- VII Technical Characteristics Point 10-** Specificity more than 80%	
		Change request: **1.5 volt 4AA Batteries should be able to perform up to 500 tests.** Only 1.5 Volts 4 AA batteries. Lithium - polymer rechargeable batteries may not be easily available leading to down time of instrument	**<u>Annexure- VII</u> Energy Source Point 2-** Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.	No Change

		Change request: **Should be stable at 10-40ºC, working humidity 5-90%. Shelf life of 24 months both opened / unopened from date of manufacture.** This should be added considering the scale of the project the self life and temperature range will play an important role in maintaining the quality of Cuvettes across a wide range of temperatures for a longer duration.	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-95%	Annexure- VII Environmental consideration Point1- Should be able to perform in the temperature range of 10-40 deg centigrade. Point 2- Working humidity- 5-90% Shelf life for storage shall be at least 24 months for unopened vials/ packs from the date of manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.
		Change request: **Third party blood based liquid controls to be available for low, normal & high facility should be available.** Third party blood based liquid controls are more authentic.	**Annexure- VIIQuality controlPoint 2-** Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.	No Change
		Change request: **Service center in India should be of the original OEM and not of the distributor.** Ensures timely and genuine support to the user.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.** **• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**

		Change request: **i) Original Manufactures can apply.** **ii) Authorized Distributors/ Direct Importers with Authorization Letter from Original Manufacturer can apply.** To ensure wider participation from reputed manufacturer will help in sourcing quality product at competitive rates.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers only. Distributors/ agents/ loan licensees/contract manufacturers are not eligible to participate in the tender.	5. **GENERAL CONDITIONS** a) Tender bid is invited directly from Manufacturers or Direct Importers or Manufacturers as well as direct importers or **Distributor having authorization from OEM for participating in this tender.** **• In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under various clauses of the bid document.**
		Change request: **Bidders who are Manufacturers : The manufacturers have to provide documentary evidence certifying that he is manufacturing the item under consideration for the past five years. Not necessarily of the same specifications). Manufacturing Experience certified by CA along with supporting documents to be submitted. Bidders who are not Manufacturers: If the Bidder is not a Manufacturer then the Bidder should be duly authorized by the Manufacturer who meets the above Criteria(b.I). Bidder should have experience in supplying the quoted items to Central Government/ any state government / Government corporation/ any Central Government or State Government PSU.** To ensure wider participation from reputed manufacturer will help in sourcing quality product at competitive rates.	Clause 3(f) Bidders must have: - •Minimum three years old valid Manufacturing/ import License with latest license renewal certificate.•Must have three years of experience in manufacturing / Importing of the quoted item.•Must have three years of experience in supplying the quoted items to Central Government/ any state government/ Government corporation/ any Central Government or State Government PSU.• Bidder who are manufactures for all the floated items or bidder who are direct importers for all the floated items or bidder who are manufacturer for some of the floated items as well as importer for the remaining floated items are allowed to participate in the bidding process.Bidders shall submit self-attested copies of their manufacturing license (for manufacturer)/ import License (for	No Change in Clause 3(f)• **In case of Distributor, they will have to furnish all the requisite documents of the manufacturer's/ importers as required under clause 3(f).**

			direct importer)/ manufacturing & import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions.• In case of Importer, they will have to furnish the manufacturer's authorization form from the original equipment manufacturer (OEM) as per Annexure IX.	
		Change request: **To be deleted. B) Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets should be supplied along with COA and should be CE marked. The TIA has the right to get the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets tested at the laboratories of his choice for further verifications.** Understand NIB is not conducting Hb test. Haemoglobin meter machine, Test strips/ Cuvettes and Auto disable lancets should be supplied along with COA and should be CE marked.	**Clause 3(i)** The Test strips/ Cuvettes should be certified by the National Institutes of Biological (NIB), Govt. of India. Clause 25(d) All the batches of the Haemoglobinometer machine, Test strips/ Cuvettes and Auto disable lancets supplied shall be supported by test/analysis reports furnished by independent NABL Accredited Testing Laboratory/Central Medical device testing laboratory as applicable along with In House Quality Control report of the manufacturer as applicable. The TIA has the right to get the Haemoglobinometer machine, Test strips/ Cuvettes and Auto	Clause 3 (i) The Test strips/ Cuvettes should be certified **by the NABL Accredited Testing Laboratory.** **Clause 25(d)** - No Change

			disable lancets tested at the laboratories of his choice for further verifications.	

ANNEXURE-B			
REVISED TENDERED PRODUCT LIST			
S. N.	**Name of the Products**	**Pack size**	**Estimated Quantity for 2019-2021**
1.	Haemoglobinometer machine	1 Piece/ pack	23774Pieces
2.	Test strips/ Cuvettes	50 Strips/ pack	**713220**Packs
3.	Auto Disable Lancets	**50 Nos./ pack**	**713220** Packs

Note:

1) The device and test strips (per batch/packet) shall be quoted with 2 years of replacement warranty deliverable at the user site.
2) The bidders must have to quote the price of all individual item/ pack i.e., 1) Each Haemoglobinometer with required accessories as per the specification 2) Each Pack having **50 Nos.** of Test strips/ Cuvettes 3) Each Pack having **50 Nos.** of auto disable lancets in the respective rows of financial bid.
3) The tender inviting authority shall not be binding with any kind of offer for free supply of device based on specific quantity of order of strips or any such request to issue order for fixed or bulk quantity of the test strips. The price quoted for respective items in the price bid sheet shall be final. In case, the bidder offers free supply of device then there should not be any condition that the device is free against any specific quantity of strips and lancets. In that case, the device cost shall be taken as "zero" irrespective of the order quantity of strips/lancets.
4) **A lancet applicator/ lancet holder shall have to be supplied along with each machine.**

ANNEXURE-C

REVISED TECHNICAL SPECIFICATIONS OF DIGITAL HAEMOGLOBINOMETER

1. Clinical Purpose-Direct hand held battery operated mobile and portable device used for hemoglobin testing in clinical setting/population-based screening. The device is intended to be used for quantitative measurement of hemoglobin in capillary, venous or arterial whole blood samples taken from forearm, upper arm, hand thigh, calf, or finger.

Technical Characteristics

1. Working Principal-reflectance photometry/ absorbance photometry.
2. Parameter-blood hemoglobin level
3. Range of HB estimation 0-20gm/dl
4. On screen patients result display-Yes (LCD Display)
5. Maximum volume of Sample requited – Not more than 50ul (one full blood drop)
6. Sample Material- capillary, venous of arterial whole blood
7. Measuring Time-Less than one Minute
8. Auto calibration – Auto/Self Calibration.
9. Sensitivity- more than 80%
10. Specificity more than 80%
11. Bias (limit of agreement)-0.5gm/dl(+_1gm/dl)

User Interface

1. Memory to store Data- desirable-up to 500 tests with data and time.
2. Bluetooth connectivity-desirable.
3. Data transfer- desirable-provision for data transfer to printer and PC.

Physical Characteristics

1. Weight-should not be more than 500 gm.

Energy Source

1. Power requirement – preferably battery operated.
   Should also be able to work on direct connection with electricity source (AC). The manufacturer must provide the charger and cable for electricity power connection, wherever required by the equipment.
2. Battery 3.7 Volt Lithium polymer rechargeable battery 1.5 volt 4AA Batteries etc. should be able to perform up to 500 tests when full charge.
3. Automatic shut down- on battery power the device should turn off after approximately of 5 minutes of no use.

Environmental consideration

1. Should be able to perform in the temperature range of 10-40 dig centigrade.
2. Working humidity- **5-90**%
3. User's care/cleaning – the part of the equipment which comes in contact with blood should be easily cleanable.
   The factors which affect the hemoglobin estimation (ex. Haziness of lens) after replaced use should be clearly mention in the manual.
   The cleaning material for the less and cuvette/strip should be easily available.

Accessories

1. Cuvette/strip (working environment)- Disposable and stable specified
   Environmental (working temperature 40 dig C working humidity- **5-90**%) condition
2. Cuvette/Strip (Storage environment)- Should be stable at temperature of 25-30 dig C humidity- **5-90**%.
   Shelf life for storage shall be at least 24 months for unopened vials/ packs from the date of

manufacturing. Open vial stability shall be minimum of three (03) months from the date of opening.

Quality control

1. Intra sample Variation (Accuracy)- Should be less than 5%
2. Control Solution Check quality- Should be available for low, normal and high hemoglobin values. Calibration facility should be available.
3. Certification USA FDA/ European CE.

Service support

1. Service Support Contact details- Contact details of manufacturer, supplier and local service agent to be provided.
2. Free of cost onsite training should be provided for the doctor and ANM and Asha at least two trainings (one training at the time of installation and another training after six months i.e. refresher training.
3. A complete user operational guide shall have to be supplied along with each machine, printed in Hindi and English language.

ANNEXURE-D

PERFORMANCE STATEMENT (Self Declaration)

(For the period of last three years)

(Please furnish order copies of the client serially, the names of which are mentioned below)

Name of Bidder:

Name of Manufacturer:_____

Name of the Items:_____

Sl No.	**Order placed by (Address of purchaser (attach documentary proof) ***	**Order no. & Date**	**Qty**	**Value of Contract (Rs.)**	**Date of Completion**	**Have the items supplied satisfactorily (attach documentary proof) ****
1						
2						
3						

(Attach separate sheets if the space provided is not sufficient)

- The documentary proof will be copies of the purchase order (during the last 3 years) P.O. No. and date.
- The documentary proof will be certificate from the consignee/ and user indicating P.O. No. and date.

Signature of Bidder:

Date: **Official Seal:**

ANNEXURE-E

Production/ Import Capacity Statement(Self Declaration)

S N..	Item Name	PI. Mention Whether participating as a Manufacturer/ Importer/ Distributor	Mfg. / Import license number/ product registration certificate of number	Validity of Mfg. / Import License:	Shelf life of the quoted item (s)	Standard Batch Size of the quoted item (s)	Monthly Production Capacity of the quoted item (s)	Annual Production Capacity of the quoted item (s)
1	Haemoglobinometer machine				**NA**			
2	Test strips/ Cuvettes							
3	Auto Disable Lancets							

Signature of Bidder:

Date **Official Seal:**

ANNEXURE-F

MANUFACTURER'S AUTHORISATION FORM

*(to be submitted by bidder in a **letterhead** in case the bidder is the importer/ distributor of OEM)*

No. Dated:

To

The Managing Director

Bihar Medical Services and Infrastructure Corporation Limited

Dear Sir / Madam,

Bid Reference No: BMSIC/MEDICAL DEVICE/CONSUMABLE/19-05
Equipment Name:

1. We …… (name of the OEM) are the original manufacturers of the above equipment having registered office at …….. (full address with telephone number/fax number & email ID and website), having factories at _____ and _____ , do hereby authorize M/s._____ (Name and address of bidder) as _____(the importer/ distributor) to submit bids, and subsequently negotiate and sign the contract with you against the above bid no..

2. **No company or firm or individual** other than M/s._____ are authorized to bid, negotiate and conclude the contract in regard to this business against this specific bid reference no.

3. We also hereby undertake to provide full guarantee/warrantee /Calibration as agreed by the bidder in the event the bidder is changed as the importer/ distributor or the bidder fails to provide satisfactory after sales and service during such period of Comprehensive guarantee/warrantee /Calibration and to supply all the spares/reagents / consumables for 2 years.

4. We also hereby declare that we have the capacity to manufacture and supply the commission quantity of the Product bided within the stipulated time.

(Name)
for and on behalf of M/s._____
Date: (Name of manufacturers)
Place:
Seal

Note: *This letter of authority should be on the letterhead of the manufacturing concern and should be signed by a person competent and having the power of attorney to bind the manufacturer.*