

PROCUREMENT OF GOODS

DIRECT PROCUREMENT

**For Procurement under COVID-19 Emergency Response
Operations**

March 2020

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Direct Procurement of Goods

Procurement of:

In Vitro Diagnostic Equipment

Ref No: COVID19/G/DC-08

Project: P173911 – Georgia Emergency COVID-19 Respond

Purchaser: Ministry of IDP from the Occupied Territories, Labour, Health and Social Affairs

Country: Georgia

Issued on: June 22, 2020

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Invitation for Direct Contracting of Goods

Direct Contracting Ref No.: COVID19/G/DC-08

Direct Contracting Date: 22/06/2020

To: Roche Diagnostics Turkey A.Ş.

Dear Ayhan Isler

Invitation for Direct Contracting

The *Government of Georgia* has received financing from the World Bank (Bank) toward the cost of the Georgia Emergency COVID-19 Response Project and intends to apply part of the proceeds toward payments under the contract for Automated In Vitro Diagnostic Equipment.

The *Ministry of IDP from Occupied Territories, Labor, Health and Social Affairs (MoIDPLHSA)* now invites your offer for the Goods and the Related Services, described in Annex 1: Purchaser's Requirements, attached to this invitation.

Eligible Goods and Related Services

All the Goods and Related Services to be supplied under the Contract and financed by the Bank may have their origin in any country except for the following: none

Manufacturer's Authorization

If you do not manufacture or produce the Goods to be supplied, please submit a Manufacturer's Authorization using the form included to this invitation for direct contracting to demonstrate that you are authorized by the manufacturer or producer of the Goods to supply these Goods in the Purchaser's Country.

Performance Security

N/A

Validity of offers

Please indicate the validity of the offer.

Quoted Price

Prices shall be quoted in the following manner:

- (a) For Goods to be supplied from within the Purchaser's Country:
 - (i) the price of the Goods quoted EXW, including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;

- (ii) any Purchaser's Country sales tax and other taxes which will be payable on the Goods if the Contract is awarded to the Supplier; and
- (b) For Goods to be supplied from abroad:
 - (i) The price of the Goods, **quoted CIP** named place of destination in the Purchaser's Country: 144, Ak. Tsereteli ave, Tbilisi, Georgia
 - (ii) [IF REQUIRED] if CIP (named place of destination) delivery only] the price for inland transportation, insurance, and other local services required to convey the Goods from the named place of destination to their final destination (Project Site);
 - (c) for Related Services, other than inland transportation and other services required to convey the Goods to their final destination, whenever such Related Services are specified in the Schedule of Requirements, the price of each item comprising the Related Services (inclusive of any applicable taxes).

The offered unit prices shall be fixed during the performance of the Contract and not subject to adjustment.

You may quote your price in a freely convertible foreign currency of your choice in addition to the currency of the Purchaser's Country (for any local costs as applicable).

Clarifications

Any clarification request regarding this invitation for direct contracting may be sent in writing to **Giorgi Tsotskolaure** at info@moh.gov.ge before **June 25, 2020 16:00 hrs. of local time**.

Submission of Offer

- a. Please submit your offer within *seven (7) working days* using the form attached at Annex 2 and **by email**.
- b. The address for submission of Offer is:

Attention: *Giorgi Tsotskolaure*

E-mail address: info@moh.gov.ge ngvenetadze@moh.gov.ge

Contract negotiations and award of contract

The contract will be concluded subject to the satisfactory conclusion of negotiations, **in light of the circumstances, a negotiation is expected to be virtual**.

The Purchaser shall publish a contract award notice on its website with free access, if available, or in a newspaper of national circulation or UNDB online, within 15 days after award of contract or as soon as practicable thereafter. The information shall include the name of the successful Supplier, the Contract Price, the Contract duration and summary of its scope.

Fraud and Corruption

The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in the attachment to the Contract Conditions (Attachment A).

In further pursuance of this policy, the supplier shall permit and shall cause their agents (where declared or not), subcontractors, sub consultants, service providers, suppliers, and personnel, to permit the Bank to inspect all accounts, records and other documents relating to the RFQ and contract performance (in the case of award), and to have them audited by auditors appointed by the Bank.

On behalf of the Purchaser:

Signature:

Name: Giorgi Tsotskolaury

Title/position: Deputy Minister

Attachments:

Annex 1: Purchaser's Requirements

Annex 2: Supplier's Offer Form

Annex 3: Contract Forms

ANNEX 1: Purchaser's Requirements

1.1 List of Goods and Delivery Period

List of Goods and Delivery Period

Line Item N°	Description of Goods	Quantity required	Physical unit	Named Place of Destination (for CIP)	<i>[As applicable]</i> Place of Final Destination (Project Site)	Applicable Incoterms	Delivery Period
1	Molecular Testing Machine	1	1	Georgia (TBD)		CIP	March 2021

Delivery Schedule *[to be used if phased delivery is planned]*

Line Item N°	Description of Goods	Physical unit	Total Quantity required	Delivery period and minimum quantity requirements		
				Periods 1 <i>[insert period 1, e.g. within 15 days from the specified appropriate milestone]</i>	Period 2 <i>[insert period 2, e.g. within 20 days from the end of period 1]</i>	Period 3 (insert period 3, e.g. within 30 days from the end of period 2]

				Minimum acceptable quantity	Maximum quantity required for period	Minimum acceptable quantity	Maximum quantity required for period	Minimum acceptable quantity	Maximum quantity required for period

1.2 List of Related Services and Completion Schedule

Service	Description of Service	Quantity required	Physical Unit	Place where Services shall be performed	Completion Period of Services
<i>1</i>	<i>In-person user training or on-line training adequate to meet the needs of all operators.</i>	<i>1</i>	<i>1</i>	<i>TBD</i>	<i>Within 10 days from acceptance of the good</i>

1.3 Technical Specifications

PURPOSE OF USE		
1	Clinical or other purpose	Qualitative and/or quantitative in vitro nucleic acid testing using real-time PCR technology.
2	Level of use	Health center, high output laboratories. specialized hospital, blood institutes.
3	Overview of functional requirements	Automatic preparation and analysis of samples for quantitative and qualitative nucleic acid testing using real-time PCR technology. Using instrumentation, consumables, reagents, software and data management, interpretations Produces results through a connection to a computer and / or on integrated screen and printer
TECHNICAL CHARACTERISTICS		
4	Detailed requirements	* Tests to include: Infectious diseases and viral load monitoring: HIV HBV HCV CMV Blood screening: MPX WNV DOX HEV Respiratory: Sars cov 2 Sexual health: HPV CT/NG * Capacity for at least 50 specimens tested per hour. * Internal memory capacity for >5,000 samples. * Quality control routines to be user friendly with results recorded internally * Bar code reader facility required for automated registering of samples * * LCD display for testing parameters visualization.
5	Displayed parameters	Digital display of test results, as per configuration.
6	User adjustable settings	User calibration and quality control to be possible with test samples / objects and easy to use interface
PHYSICAL/CHEMICAL CHARACTERISTICS		
7	Components	Desktop mounted unit, with tube connections for water supply and drainage Sample tray mounting and access to be by quick and simple procedure Moving parts to be covered and quiet in operation Supplied with cover for protection from spray and dust At least one complete set for automatic calibration.
8	Mobility, portability	Tabletop
UTILITY REQUIREMENTS		

10	Electrical, water and/or gas supply (if relevant)	110-220 V, 60-50 Hz, $\pm 10\%$. Electrical protection provided by fuses in both live and neutral supply lines. Mains cable to be at least 3m in length. Protections against over-voltage and over-current line conditions. Compliance with applicable standards and regulations. Equipment provided with an adequate Uninterruptible Power Supply (UPS) system with not less than 20 minutes of back-up.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
11	Accessories (if relevant)	
12	Sterilization process for accessories (if relevant)	
13	Consumables / reagents (if relevant)	Reagents for the tests configured Calibration controls
14	Spare parts (if relevant)	Two sets of spare fuses (if non-resettable fuses used)
15	Other components (if relevant)	
PACKAGING		
16	Sterility status on delivery (if relevant)	N/A
17	Shelf life (if relevant)	Variable
18	Transportation and storage (if relevant)	N/A
19	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
20	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
21	Pre-installation requirements	Local clinical staff to affirm completion of installation
22	Requirements for commissioning	Supplier to perform installation (including water supply and drainage), safety and operation checks before handover Local clinical staff to affirm completion of installation
23	Training of user/s	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented
24	User care	Casing to be cleanable with alcohol and chlorine wipes
WARRANTY AND MAINTENANCE		
25	Warranty	14 months

26	Maintenance tasks	Calibration routines clearly described.
27	Type of service contract	Comprehensive contract
28	Spare parts availability post-warranty	
29	Software / Hardware upgrade availability	integrated Computer with software and connections for immediate use
DOCUMENTATION		
30	Documentation requirements	User, technical and maintenance manuals to be supplied in local language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Trade-in with manufacturer if available
DECOMMISSIONING		
31	Estimated Life Span	At least 5 years
SAFETY AND STANDARDS		
32	Risk Classification	Class A (GHTF Rule 4); Class II (USA); Class I (EU, Japan, Canada and Australia)
33	Regulatory Approval / Certification	Should be FDA, CE or UL approved product. "Manufacturer / supplier should have ISO certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1 Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility).
34	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
35	Reginal / Local Standards	
36	Regulations	

ANNEX 2: Offer Forms

Supplier's Offer Form

From:	Roche Diagnostics Turkey A.Ş.
Supplier's Representative:	[Ayhan ISLER]
Title/Position:	[Export Sales Specialist]
Address:	[Esentepe Mahallesi, Kırğülü Sokak, No: 4, 34394, Şişli İstanbul, Turkey]
Email:	[ayhan.isler@roche.com]

To:	Ministry of IDP from Occupied Territories, Labor, Health and Social Affairs.
Purchaser's Representative:	Giorgi Tsotskolaure
Title/Position:	Deputy Minister
Address :	144 Ak. Tsereteli ave., Tbilisi 0119 Georgia
Invitation for Direct Contracting Ref No.:	COVID19/G/DC-08
Date of Offer:	

Dear Mr. Tsotskolaure

SUBMISSION OF OFFER

1. Conformity and no reservations

In response to the above invitation for direct contracting, we offer to supply the Goods, **[add if applicable: "and deliver the Related Services,"]** as per this invitation subject to any negotiations that may be carried out to finalize the contract.

2. Eligibility

If awarded the Contract, the Goods **[add if applicable: "and Related Services,"]** that we supply shall be sourced from an eligible country.

We, along with any of our subcontractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the World Bank Group or a debarment imposed by the World Bank Group in accordance with the

Agreement for Mutual Enforcement of Debarment Decisions between the World Bank and other development banks. Further, we are not ineligible under the Purchaser's Country laws or official regulations or pursuant to a decision of the United Nations Security Council.

3. Offered Price

The total price of our offer is [Fourhundredfourthousandseuros / 440.000 EUR].

4. Validity of the Offer

Our offer shall be valid until [01.08.2020].

5. Performance Security N/A

6. Commissions, gratuities, fees

We have paid, or will pay the following commissions, gratuities, or fees with respect to this offer.

[If none has been paid or is to be paid, indicate "none."]

Name of Recipient	Address	Reason	Amount
"None"			

7. Not Bound to Accept

We understand that you reserve the right to:

- a. accept or reject the offer, and
- b. Annul the direct contracting process at any time prior to the award of the Contract.

8. Fraud and Corruption

We hereby certify that we have taken steps to ensure that no person acting for us, or on our behalf, engages in any type of Fraud and Corruption.

On behalf of the Supplier:

Name of the person duly authorized to sign the offer on behalf of the Supplier:

Doruk ORS[insert complete name of person duly authorized to sign the offer]

Title of the person signing the offer: [Head of Finance, Operations & IT]

Signature of the person named above: [insert signature of person whose name and capacity are shown above]

Date signed [01.07.2020]

Price Schedules

[The following forms may be used by the Supplier for submitting its offer. The forms may also be used for the contract subsequent to any negotiations.]

Price Schedule 1

Goods to be supplied from outside the Purchaser's country

1	2	3	4	5	6	7	8	9
Line Item N°	Description of Goods	Country of Origin	Delivery Date as defined by Incoterms	Quantity and physical unit	Unit price CIP [insert place of destination] [as applicable, FCA (named place0]	CIP (or FCA as applicable) Price per line item (Col. 5x6)	[FOR CIP, IF REQUIRED] Price per line item for inland transportation and other services required in the Purchaser's Country to convey the Goods to their final destination specified in the invitation for direct contracting	Total Price per Line item (Col. 7+8)
[1]	[Cobas 6800 PCR Analyzer]	[Switzerland / CH]	[March-2021]	[1 unit, Cobas6800 PCR Analyzer]	[440.000 EUR / CIP-Tbilisi]	[440.000 EUR]	[insert the corresponding price per line item]	[440.000 EUR]
							Offered Price	440.000,00 EUR

Price Schedule 2

Goods to be supplied from within the Purchaser's country

1	2	3	4	5	6	7	8	9
Line Item N°	Description of Goods	Delivery Date as defined by Incoterms	Quantity and physical unit	Unit price EXW	Total EXW price per line item (Col. 4x5)	<i>[IF REQUIRED]</i> Price per line item for inland transportation and other services required in the Purchaser's Country to convey the Goods to their final destination as specified in the invitation for direct contracting	Sales and other taxes payable per line item if Contract is awarded	Total Price per line item (Col. 6+7)
<i>[insert number of the item]</i>	<i>[insert name of Good]</i>	<i>[insert quoted Delivery Date/ quoted phased Delivery dates if applicable]</i>	<i>[insert number of units to be supplied and name of the physical unit]</i>	<i>[insert EXW unit price]</i>	<i>[insert total EXW price per line item]</i>	<i>[insert the corresponding price per line item]</i>	<i>[insert sales and other taxes payable per line item if Contract is awarded]</i>	<i>[insert total price per item]</i>
							Offered Price	

Price Schedule 3

Related Services *[If applicable]*

1		2	3	4	5	6	7
Item No.	Item description	Description of Services (excludes inland transportation and other services required in the Purchaser's Country to convey the goods to their final destination)	Country of Origin	Completion Period at place of Final destination	Quantity and physical unit	Unit price	Total Price per Service (Col. 5*6 or estimate)
<i>[insert number of the item]</i>		<i>[insert name of Services]</i>	<i>[insert country of origin of the Services]</i>	<i>[insert Delivery Period at place of final destination per Service]</i>	<i>[insert number of items to be supplied and name of the physical unit]</i>	<i>[insert unit price per item]</i>	<i>[insert total price per item]</i>
Offered Price							

Price Schedule 4

Total Price

The total cost for the supply and delivery of the Goods, and related Services is as follows:

Price Schedule	Amount
Goods: Price Schedule 1	440.000 EUR
Goods: Price Schedule 2	
Related Services: Price Schedule 3	
Total Price	440.000 EUR

Manufacturer's Authorization

[The Supplier shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer.]

Date: *[01.07.2020]*

Request for Invitation for Direct Contracting No.: *[insert reference number if applicable]*

To: *[Ministry of IDP from the Occupied Territories, Labour, Health and Social Affairs]*

WHEREAS

We *[Roche Diagnostics Switzerland]*, who are official manufacturers of *[Cobas 6800]*, having factories at *[Roche Diagnostics International Ltd. Forrenstrasse 2; 6343 Rotkreuz; Switzerland]*, do hereby authorize *[Roche Diagnostics Turkey]* to submit an offer the purpose of which is to provide the following Goods, manufactured by us *[Cobas 6800 PCR Analyzer]*, and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 20 of the Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: *[insert signature(s) of authorized representative(s) of the Manufacturer]*

Name: *[Doruk ORS]*

Title: *[Head of Finance, Operations & IT]*

Dated on 1st day of July, 2020