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Ref. No.:- F.02(82)/RMSCL/S&S/RT-PCR Test Kit/NIB-14/2020/346

Dated:-8 10 2020

Corrigendum - I

Subject: - Amendment in Date/ technical specification

Ref.:- NIB No. F.02(82)/RMSCL/S&S/RT-PCR Test Kit/NIB-14/2020/338 Dated:-30.09.2020

(Technical bid opening due on dated -08.10.2020)

re T	S. Existing date / technical specification					
No No	Existing date / technical specification			Amended date / technical sp	pecificat	ion
14/2	(82)/RMSCL/S&S/RT-PCR 020/338 Dated:-30.09.2020	Test	Kit/NIB-	F.02(82)/RMSCL/S&S/RT-PCR 14/2020/338 Dated:-30.09.2020	Test	Kit/NIB-
Las of control EM through the control EM con	t date and time of submission online bids D, Tender fees, RISL fees ough challan and Physically e and time of opening of ine technical bids DF SPECIFICATION OF RT-PCR TO EXURE - VI CR Test Kit on Regent Basis	3.00 P 08.10.3 3.00 P 08.10.3 04.00 I	2020 at M 2020 at PM	Last date and time of submission of online bids EMD, Tender fees, RISL fees through challan and Physically Date and time of opening of Online technical bids LIST OF SPECIFICATION OF RT-PCR TE ANNEXURE – VI RT PCR Test Kit on Regent Basis	3.00 PM 13.10.2 3.00 PM 13.10.2 04.00 F EST KIT-	2020 at M 2020 at PM
	approval by DGCI and intimation to ICMR). Compatible with all Real time PCR systems of ABI, Biorrad, Qiagen and Roche. Master mix, Primer probes for screening and confirmation of SARS-COV2. Single tube multiplex kits 9more than three genes) as larg number of samples have to be processed in our lab. To have internal control/housekeeping gene to know the validity of run. To have positive control. PCR tube and caps. To quote for all pack sizes available 100/500/1000 reactions. The kit will be validated as per the guidelines of ICMR and sensitively of the assay shall be >94.7% and specifivity >98.8%. Q.C. and validation of each batch of approved kit will be done before use.		 Kits should be approved by D India/NIV Pune /ICMR. US FDA, EUA/CC approved approval by DGCI and intima ICMR Approved. Compatible with all Real time including of ABI, Biorrad, Qi Roche. Master mix, Primer probes for confirmation of SARS-COV2. Single tube multiplex kits (thr genes) as larg number of samp processed in our lab. To have internal control/house to know the validity of run. To have positive control. PCR tube and caps. To quote for all pack sizes av reactions. The kit will be validated as per guidelines of ICMR and sensiti assay shall be >94.7% and spec >98.8%. Q.C. and validation of each bat approved kit will be done before Validation of kits can be done in presence of expert from company 	(after dution to 10 PCR syagen and screening les have keeping ailable the lively of the use, in the	cmr)/ estems d ng and ore e to be. gene	

of Was - WA



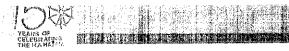


S. No	Existing date / technical specification	Amended date / technical specification
2	LIST OF SPECIFICATION OF RT-PCR TEST KIT- ANNEXURE - VI RT PCR Test Kit on Regent Rental Basis for Covid-19 (A) • Kits should be approved by DGCI, India/NIV Pune /ICMR. • US FDA, EUA/CC approved (after due approval by DGCI and intimation to ICMR). • Compatible with all Real time PCR systems of ABI, Biorrad, Qiagen and Roche. • Master mix, Primer probes for screening and confirmation of SARS-COV2. • Single tube multiplex kits 9more than three genes) as larg number of samples have to be processed in our lab. • To have internal control/housekeeping gene to know the validity of run. • To have positive control. • PCR tube and caps. • To quote for all pack sizes available 100/500/1000 reactions. • The kit will be validated as per the guidelines of ICMR and sensitively of the assay shall be >94.7% and specifivity >98.8%. • Q.C. and validation of each batch of approved kit will be done before use. • Validation of kits can be done in the presence of expert from company.	LIST OF SPECIFICATION OF RT-PCR TEST KIT- ANNEXURE – VI RT PCR Test Kit on Regent Rental Basis for Covid-19 (A) • Kits should be approved by DGCI, India/NIV Pune /ICMR. • US FDA, EUA/CC approved (after due approval by DGCI and intimation to ICMR)/ ICMR Approved. • Compatible with all Real time PCR systems including of ABI, Biorrad, Qiagen and Roche. • Master mix, Primer probes for screening and confirmation of SARS-COV2. • Single tube multiplex kits (three or more genes) as larg number of samples have to be processed in our lab. • To have internal control/housekeeping gene to know the validity of run. • To have positive control. • PCR tube and caps. • To quote for all pack sizes available reactions. • The kit will be validated as per the guidelines of ICMR and sensitively of the assay shall be >94.7% and specifivity >98.8%. • Q.C. and validation of each batch of approved kit will be done before use. • Validation of kits can be done in the presence of expert from company.
		 (B) Technical specification for Real Time PCR Machine Table Top Model. Complete system including basic system, essential accessories, the state of art computer workstation, acquisition and analysis software. Open System to accommodate Taqman, SYBR green and all other fluorescent dye based chemistries. Peltier based 96 well block RT PCR System. The instrument should be compatible to use standard optical 96 well plates,0.2ml 8 tube strips, 0.2ml tubes without need of any additional hardware and/or requirement of selecting block for different formatthroughput. The plates & tubes should be available from other manufacturers.

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S. No	Existing date / technical specification	Amended date / technical specification
		SNP Genotyping assays.
		Software applications: Comparative Ct,
-		standard curve, relative standard curve,
		allelic discrimination/SNP Genotyping,
		Plus/Minus, Dissociation.
		· ·
		The instrument should have 21 CFR part
		11/MIQE compliance.
		The instrument should come along with
		three years warranty.
		A compatible 2KVA online UPS with 30
		minute backup must be provided.
		Note: - Demonstration of PCR Machines (Except
		:- ABI, Biorrad, Qiagen and Roche) will be part of
		technical evaluation and will be done in the
		presence of technical experts.
3	2(b) - ELIGIBILITY CRITERIA and	2(b) - ELIGIBILITY CRITERIA and
,	ANNEXURE-III Ref. Clause No. 5 (m) Average Annual turnover (for drug and	ANNEXURE-III Ref. Clause No. 5 (m) Average Annual turnover (for drug and
	medicines or Medical Devices) in the last three	medicines or Medical Devices) in the last three
	financial years (2016-17, 2017-18, 2018-19 or	financial years (2016-17, 2017-18, 2018-19 or
	2017-18, 2018-19 2019-20) shall not be less	2017-18, 2018-19 2019-20) shall not be less
	than Rs. 5 crores. For MSME Units of	than Rs. 1 crores. For MSME Units of
	Rajasthan, the average annual turnover (for	Rajasthan, the average annual turnover (for
İ	drug and medicines or Medical Devices) in the	drug and medicines or Medical Devices) in the
	last three financial years (2016-17, 2017-18,	last three financial years (2016-17, 2017-18,
	2018-19 or 2017-18, 2018-19 2019-20) shall not	2018-19 or 2017-18, 2018-19 2019-20) shall not
	be less than Rs. 1 Cr. The same should be	be less than Rs. 50 Lakh. The same should
ļ	supported by audited annual accounts &	be supported by audited annual accounts &
	certified by a practicing Chartered	certified by a practicing Chartered
	accountant, based on audited accounts.	accountant, based on audited accounts.
4	Some specific Condition for tender of RT-PCR	Some specific Condition for tender of RT-PCR
	TEST KIT.	TEST KIT.
	1. Bidder has to submit past performance /	1. Deleted
.	experience for supply of at least 50000 RT-	2. The bidder should have monthly
	PCR TEST during COVID 19 to ICMR / any	manufacturing capacity and
	Central Government / State government institution along with copy of purchase order.	commitment to supply of RT-PCR
	2. The bidder should have monthly	TEST at least 5 lacs RT-PCR TEST
	manufacturing capacity and	Per month, for this undertaking to this
	commitment to supply of RT-PCR	effect will be submitted by the bidder.
	TEST at least 5 lacs RT-PCR TEST Per	A format of the same has been
	month, for this undertaking to this effect	prescribed at Annexure X.
1	will be submitted by the bidder. A	3. SMS medical college shall be nodal
	format of the same has been prescribed	for the QC of the kits procured by
ĺ	at Annexure X.	RMSCL. QC shall be done for each
.	3. SMS medical college shall be nodal for	batch of supply. If RT-PCR TEST
	the QC of the kits procured by RMSCL.	KIT fails in quality control the entire
1	QC shall be done for each batch of	lot of testing kits shall be returned.

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S.	Existing date / technical specification	Amended date / technical specification
S. No	Existing date / technical specification	Amended date / technical specification sample volume requirement between 1-50 ml or more. The instrument must have white or filtered. LED/Tungsten Halogen for excitation of day. Multiplexing ability of 5 or more dyes in a single run. The instrument must be compatible to use 96 well plates, 8 tube strips and individual tubes. The instrument must be capable of performing (six) colour multiplexing in a single tube. The instrument should come along with calibrated dyes at installation. Should be compatible with FAM/SYBR Green, Jun/Texas redX/VIC/JOE, NED/TAMRA/Cy3,ROX/Texas Red ®, and CY5 should offer flexibility in dye selection. The instrument must be cloud/email based access to result enabled platform and come up with free access to secured cloud based server for remote monitoring and access of data. Cloud/email based access to result based data analysis module must be available. Facility to calibrate new dye within the wavelength range without addition of new filters.
		 server for remote monitoring and access of data. Cloud/email based access to result based data analysis module must be available. Facility to calibrate new dye within the wavelength range without addition of new
	-	 calibrated dye and should be optional. Option for melt curve analysis. Temperature range 4° C to 100°C System should have on board memory of 10GB or more. The system must have block ramp rate of 5°C or better. The instrument must be capable to detect
	Q W _0	differences as small as 1.5 fold in target quantities. • System should be standardized for Taqman and SYBR Green chemistry with prevalidated and functionally tested Taqman Gene Expression assays as well as Taqman

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S. No	Existing date / technical specification	Amended date / technical specification
	supply. If RT-PCR TEST KIT fails in quality control the entire lot of testing kits shall be returned.	4. RT-PCR Machines on regent rental basis, cost of supplied and installed RT PCR Machine will be on cost of supplier which will be required to be installed before the date of start of supply of reagents. No payments will be made by the RMSCL against RT PCR Machine including precautionary maintenance features/facilities against electric fluctuations and break – down supporting with voltage controller and UPS facilities.

1. Note:- RT-PCR Test kit procured on regent basis will be installed by supplier with own cost in the districts of Jodhpur/ Bikaner / Udaipur division as required.

Rate should be quoted per test

2. Note:-

- It may be noted that if any further amendments are issued then a corrigendum will be published and informed.
- Rest of the terms and conditions will remain the same.

(Shriniwas Meena) Executive Director (Prod

Executive Director (Proc.)
RMSCL

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