DEPARTMENT OF GASTROENTEROLOGY ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Reference: 27/Gastro./Proprietary/RT Amplification Kit/NGB Diag./2016-17

November 17, 2016

Subject: Purchase of HCV-Genotype-FRT, HCV cDNA, RT Amplification Kit, Department of Gastro., AIIMS, New Delhi, on proprietary basis- Inviting comments thereon.

The Department of Gastroenterology has been procuring the above cited **HCV-Genotype-FRT**, **HCV cDNA**, **RT Amplification Kit**, Cat No. NGB-HCV-G02 with mentioned volumes from M/s Ecoli s.r.o., on proprietary basis. The proposal submitted by M/s NGB Diagnostics, and PAC certifications are attached & uploaded on website.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 days from the date of issue/uploading of the notification giving reference no. 27/Gastro./Proprietary/RT Amplification Kit/NGB Diag./2016-17.

The comments should be sent to Professor & Head, Department of Gastroenterology, Room No. 3111, Teaching Block, 3rd Floor, AIIMS, New Delhi on or before 05 December 2016 upto 5:00 p.m., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours sincerely,

Dr. Umesh Kapil Prof. & Head

Encl:

- 1. Quotation
- 2. PAC certificate

NGB DIAGNOSTICS PVT LTD PLOT NO: 120, 3rd Floor, Hargovind Enlcave, DELHI-110092, INDIA PH- 01142688435, +91-9717652828 Email: rakesh@ngbdx.com

Quotation for HCV 4 Genotypes

Buyer:

Dr. S K Acharya, Head, Dept of Gastroenterology

All India Institute of Medical Sciences New Delhi, India

Quotation No- 791-AIIMS-26102016

Dated: 26- Oct-2016

S.no.	Catalogue no.	Description	No of Reactions	Shelf Life	Price
01	CAT#NGB- HCV-G03	HCV-Genotype-FRT.HCV cDNA Real time Amplification Kit- Hepatitis C Genotyping (genotypes 1a, 1b, 2, 3a, 4,). 2		09	
		optical channels are required.	110	Months	150216
VAT @ 13.5%					22532.40
Total Amount					172748.00

Amount Chargeable (in words): One lakh seventy two thousand seven hundred forty eight.

Company Details: PAN no: AAECN4454E VAT no: 07776929551

Bank Name: Yes Bank Account Number:023983800001219 Account Name: NGB Diagnostics Private Limited IFSC code: YESB0000239 Account type: Current Branch Address: GROUND FLOOR, 195 RAM VIHAR NEW DELHI 110095.

This is a computer generated statement hence no signature is required.

Ecoli s.r.o.

Studenohorská 12 841 03 Bratislava 47 Slovak Republic

ecoli@ecoli.sk

Tel: +421 2 64 789 336 Fax: +421 2 64 789 040 Mobil: +421 903 160 701

Authorization Certificate

Date: 26th July, 2016

Reference no: AC-CE-406

To whomsoever it may concern

Subject: Distribution Authorization to M/s NGB Diagnostics Pvt Ltd

We E.coli s.r.o. having our registered office at *Studenohorská* 12, 84103 Bratislava 47, *Slovak republic*, do hereby authorize M/S NGB Diagnostics Pvt Ltd having there registered office at *Plot no:120, 3rd Floor, Hargovind Enclave, New Delhi: 110092, India* for all our bacterial/viral marker Detection Kits based on PCR, Real Time PCR and Capillary electrophoresis and for all other reagents including nucleic acid extraction, with effect from 1st April 2016 till 31st March 2017, to submit bids, negotiate, Quote, and receive orders on behalf of our products.

Authorised Signatory

enohors 031Brati tel fax bchodné oddelenie

Marek Kalnicky



EC declaration of confirmity (certificate no. 4122.58.01/0) for in vitro diagnostic medical device according to the Directive 98/79/EC. ISO certificate – EN ISO 13485. EC declaration of conformity for in vitro diagnostic medical devices according to Annex I, List B of the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex II. List B of the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex II. List B of the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to coli

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Studenohorská 12 841 03 Bratislava 47 Slovak Republic

ecoli@ecoli.sk

Tel: +421 2 64 789 336 Fax: +421 2 64 789 040 Mobil: +421 903 160 701

Proprietary Certificate

Reference no: SER-GA-340

Date: 26th July, 2016

Kit Items and respective contents:

AmpliSens®HCV-genotype-FRT: R-V1-G(1-6)-2x(RG,iQ,Mx,Dt,SC)-CE (genotypes 1a, 1b, 2, 3a, 4, 5a, 6)

This is to certify that:

AmpliSens® HCV Genotyping Real Time detection kits are based on proprietary designed & validated regions. No other company in our knowledge has such HCV genotypes detection methods in a single test. The methods are thoroughly investigated for specificity, sensitivity and reproducibility. Detection of HCV genotypes 1a, 1b, 2, 3a, 4, 5a, and 6 by RT-PCR is based on the amplification of a pathogen genome specific region using Proprietary short Oligos.

The amplified product is detected by using fluorescent dyes. These dyes are linked to Proprietory oligonucleotide probes which bind specifically to the amplified product. Monitoring of fluorescence intensities during the real-time PCR allows the detection of accumulating product without re-opening the reaction tubes after the PCR run. AmpliSens^D HCV-genotype-FRT PCR kit uses Proprietory "hot-start mastermix with modified Polymerase for high efficiency", which greatly reduces frequency of nonspecifically primed reactions.

Kit detection probe configuration.

HCV-genotype-FRT 1-6 PCR kit allows detection and discrimination of HCV genotypes 1a, 1b, 2, 3a, 4, 5a and 6. For detection, FAM/Green and JOE/Yellow/HEX/Cy3 channels are needed.

The analytical sensitivity depends on the clinical sample volume and is 100 IU/ml (if the sample volume is 100 ul) or 10 IU (if the sample volume is 1000 ul).

Authorised Signatory

dné oddelenie

Marek Kalnicky





EC declaration of confirmity (certificate no. 4122.58.01/0) for in vitro diagnostic medical device according to the Directive 98/79/EC. ISO certificate – EN ISO 13485. EC declaration of conformity for in vitro diagnostic medical devices according to Annex I, List B of the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I, List B of the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro diagnostic medical devices according to Annex I and the Directive 98/79/EC (IVD Directive). CE certificate (no.110040 QS/NB/c) for in vitro di