

Equipment Specification Data Sheet

Equipment Name: RT PCR

Document No.: DS-RT PCR 01




Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	QC	Q1-PCR-01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
<b>Prepared by</b>			
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<b>Checked by</b>			
Mr. Sridhar Babu	Sr. Engineer - Process		6/7/2015
<b>Approved by</b>			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015

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HLL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
R. SANJEEV KUMAR	MANAGER		8/7/2015
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Approved by			
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HLL Biotech Limited, Chennai		
nne pharmanplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
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1	Process requirements	
1.1	Real Time PCR machine will be used to perform real time amplification of DNA/RNA samples by polymerase chain reaction. Real Time PCR machine is to be supported with PC with inbuilt software for data analysis.	
2	Equipment ID	
2.1	Q1-PCR-01	
3	Technical Specification	
3.1	Block format	to hold 96 samples
3.2	Reaction volume	20 to 50µl reaction volume
3.3	Dynamic Range:	10 orders of magnitude/9 logs
3.4	Temperature Range:	ambient to 99°C
3.5	Temperature Uniformity:	±0.50°C
3.6	Temperature Ramp Rate:	up to 2.5°C/second
3.7	Heated lid temperature	100 °C for peltier based thermo cycler
3.8	Multiplexing capabilities:	2 to 5
3.9	Sensitivity	to detect 1 copy of target sequence
3.10	Heating/ cooling method	peltier based or rotary format
3.11	Excitation source:	Tungsten-halogen lamp or LED
3.12	Detector:	CCD/photodiodes/photomultiplier
3.13	Memory (Storage of programs and Program runs)	on board- vendor to specify
3.14	Dimension, mm	vendor to specify
3.15	Power Requirement	to be compatible for standard Indian Power Socket
3.16	Weight	vendor to specify
4	Material of Construction	
4.1	MOC	vendor to specify
5	Specific Equipment requirement	
5.1	Equipment shall facilitate easy cleaning and maintenance with standard disinfectant	
5.2	PC based result viewing and interpretation of results. Hence standalone PC and UPS to be provided with inbuilt software.	

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5.3	Software to control the instrument operation, and collect and analyze the data generated	
5.4	Suitable to run experiment based on Taqman probe, Sybr green assay	
6	<b>Other requirement</b>	
6.1	Training and demo for user on operation and cleaning to be provided	
6.2	Software to support Multiplex analysis Up to 2 targets per well, Data analysis of PCR quantification through standard curve; melt curve analysis; gene expression analysis by relative quantity, end point analysis, etc	
6.3	Consumable and accessories to be provided with the machine, along with ordering information.	
7	<b>Regulatory aspects</b>	
7.1	CE Certification	
7.2	21 CFR Part 11	
8	<b>Safety requirements</b>	
	<b>Following facilities must be provided to protect personnel and equipment:</b>	
8.1	The equipment should be integrated with audio or visual alarm in case of any failure/errors	
8.2	Appropriate closure of all parts	
8.3	Proper earthing is necessary	
9	<b>Documents</b>	
	<b>Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.</b>	
9.1	IOQ documents.	
9.2	Operation and maintenance manuals shall be provided along with IOQ Documents during installation at site.	
9.3	Warranty certificate for one year from date of supply.	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	Vendor should provide list of standard spare parts with ordering information.	
10	<b>Timelines</b>	
10.1	Not Applicable	
11	<b>Preferred list of Makes</b>	
11.1	AB, BIORAD, QUAIGEN	
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor	

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<b>Table-1: Equipment location</b>					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-PCR-01	QC	Immuno Chemistry Lab	Q1S026	5248 X 5470	24000
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Niharika Ruhela	00		New document	
06-05-2015	Niharika Ruhela	01	All	Changes as per comments received from clients on 27-02-2015 and 02-05-2015	
<b>Table-3: Annexure</b>					
Not applicable					