



HLT08 INFECT-MET

## A) Questionnaire for manufacturers and suppliers on

## Nucleic acid tests (NAT) for diagnostics of patients with infectious diseases

1 What do you supply ?							
instrumentation	reagents / kits instruments and kits						
2 On which methods are the NATs based ?							
temperature cycling PCR	isothermal amplification techniques						
3 Is micro system technology used for liquid handling?							
☐ yes	🔲 no						
4 Target bacteria / viruses							
L tuberculosis	☐ MRSA						
Cytomegalovirus (CMV)	adenovirus	🔲 influenza A/B					
□ HIV	EBV	HBV / HCV					
other targets, i.e.							
5 Type of sample							
🔲 blood / plasma	🔲 swab	bioptic tissue					
other samples, i.e.							
6 Workflow for handling / sar	nple preparation and ampl	ification					
manual preparation (DNA extraction, purification, etc.) required before amplification							
<ul> <li>complete tests, automated p</li> <li>complete tests, all reagents</li> </ul>	•	one / different instruments					
7 Measurement time for nucle	eic acid amplification						
□ < 5 min	🔲 < 10 min	🔲 < 15 min					
□ < 20 min	□ < 25 min	□ > 25 min					
8 Turnaround time for bacter	ia / virus detection (includ	ing sample preparation)					
□ < 15 min	□ < 30 min	🔲 < 1 h					
□ < 2 h	□ > 2 h						



## **INSTAND e.V.**

Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V.





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9 Total volume us	ed in NAT ar	nplification	chamber / cuv	vette		
□ < 2µL	<u> </u>		□ < 10µL			
□ < 20μL		□ < 50µL		> 50µL		
10 Detection limit	or analytical	sensitivity	(in pure test s	amples)		
target organism	DNA / RNA copy number / mL					
e.g. CMV	□ < 10	□ < 50	□ < 100	□ < 200	□ < 500	
	□ < 10	□ < 50	□ < 100	□ < 200	□ < 500	
	□ < 10	□ < 50	□ < 100	□ < 200	□ < 500	
	□ < 10	□ < 50	□ < 100	□ < 200	□ < 500	
11 Average price	per test for s	elected targ	ets			
target organism	price per test					
e.g. CMV	<b>□</b> < 1€	<u> </u>	€ □ 2€ - 4€	<b>□</b> 4€ - 8€	] >8€	
	<b>□</b> < 1€	<u> </u>	€ □ 2€ - 4€	<b>□</b> 4€ - 8€	] >8€	
	<u> </u>	<u> </u>	€ □ 2€ - 4€	<b>□</b> 4€ - 8€	] >8€	
	<u> </u>	<u> </u>	2€-4€	□ 4€ - 8€	<b>□</b> >8€	
12 Typical numbe	r of analyses	s per month	for selected ta	argets		
target organism		number of a	inalyses per te	st		
e.g. CMV	$\Box$ < 100 / month $\Box$ 100 - 1000 /			month	> 1000 / month	
	🔲 < 100 / month		$\Box$ 100 - 1000 / month $\Box$ > 1000 /		> 1000 / month	
	🔲 < 100 / month		□ 100 - 1000 / month □ > 100		> 1000 / month	
< 100 / month		month [	] 100 - 1000 /	month 🔲 :	> 1000 / month	
13 Company / inst	rument / kit					
company name		_				
instrument series /	model	_				
test kit / test kits		-				
		_				
date						

