Features	Mycoplasma Testing Service				Virology Testing Service
	Prime	**Intego**	**MaxVolume**	**VitalAmp**	**HAV, HBV, HCV, HIV-1, HIV-2, Parvo B19**
Interest Group	Research & Development	ATMP manufacturer	Pharmaceutical industry	Pharmaceutical industry, media manufacturer	R&D, ATMPs, Pharmaceutical industry, media manufacturer
Description	Basic testing service providing fast, reliable, and affordable results, but does not comply with official regulations.	Direct testing method especially designed for cell culture materials and ATMPs according to EP 2.6.7.	Designed for highest sensitivity by using a maximum of sample. With special concentration tools the intact mycoplasma particles from up to 18 ml sample are concentrated and the extracted DNA tested completely by qPCR. Residual DNA is usually not detected by this method.	Utilizing the cell culture enhancement step as recommended by EP 2.6.7 a minute amount of vital mycoplasma can be detected. Most mycoplasma can be propagated in cell culture to titers easily detectable by the following qPCR.	Direct testing service providing fast and reliable results. Automated extraction, followed by qPCR
Recommended Sample Material	Cells, cell culture supernatant, cryo stocks	Cell cultures, cryo stocks, sera, antibody formulations and autologous chondrocytes	in process control, lot release	media components	Cell culture supernatant, serum, plasma (different matrices on request)
Method	qPCR	qPCR	concentration by filtration followed by qPCR	cell culture enrichment on VERO cells followed by qPCR	Qualitative Real-Time PCR
Applied PCR Kit	Microsart RESEARCH Mycoplasma	Microsart ATMP Mycoplasma	Microsart AMP Mycoplasma	Microsart ATMP Mycoplasma	In-House
DNA Extraction	not included (15 € surcharge for PCR-inhibiting samples)	included	included	included	included
Process Control	amplification control	extractions and amplification control	extractions and amplification control	vital mycoplasma spike control	extraction and amplification control
Sample Volume / PCR	2 µl	10 µl	50 µl	10 µl	5 µl
Turnaround Time	24 to 48 hours after sample receipt	24 to 48 hours after sample receipt	24 to 48 hours after sample receipt	8 days after sample receipt	48 to 72 hours after sample receipt
Sensitivity of Method	< 20 CFU/ml	< 10 CFU/ml	< 10 CFU/sample volume; at least < 10 CFU/ml	theoretically 1 CFU/sample volume	Based on sample matrix
EP 2.6.7 conformity	no	yes, for ATMPs	yes	yes	n/a
Validation	**specificity, basic sensitivity**	for ATMP-related sample material (200 µl sample volume)	comprehensive	comprehensive	comprehensive
		Please note, that a validated procedure is available for standard sample materials only. For any other materials an individual validation may be required to demonstrate the efficiency of the pre-analytical procedure in means of sensitivity. Please contact us for further information.			
Sample Requirements	heat-inactivated, at least 600 µl	heat-inactivated, at least 600 µl	native, up to 18 ml	native, up to 100 ml	native, at least 1,5 ml
Order No.	41-1011	41-1012	41-1013	41-1014	on request
Volume Discount Available	yes, on request	yes, on request	yes, on request	yes, on request	available on request

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