clean cells
SOLUTION FOR BIOLOGICS

Please find herinbelow the list of our services applicable for R&D and GMP assays in biosafety level L2.
We can also perform those tests in L3 environment.
For more information about our services,
do not hesitate to contact our sales team or to visit our website:
www.clean-cells.com

CODIFICATION	DESIGNATION
1.	**Mycoplasma**
	Non regulatory
01.001	PCR mycoplasma detection kit (including Taq polymerase) R&D use - 25 tests in monoplicate
01.002	PCR mycoplasma detection kit (including Taq polymerase) R&D use - 50 tests in monoplicate
01.026	PCR detection kit for Mycoplasma (including a kit for the validation of the extracts and the positive controls) 12 samples
01.003	Mycoplasma detection – single validation by real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off) Excluding avian mycoplasma strains M gallicepticum and M imitans
01.004	Mycoplasma detection – single validation by real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off) – including avian mycoplasma strains M gallicepticum and M imitans
01.005	Mycoplasma detection – double validation by direct fluorescence microscopy and real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off) - excluding avian mycoplasma strains M gallicepticum and M imitans
01.006	Mycoplasma detection – double validation by direct fluorescence microscopy and real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off) –including avian mycoplasma strains M gallicepticum and M imitans
01.007	Mycoplasma detection – double validation by indirect. Fluorescence microscopy on indicator cells and real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off)
01.008	Mycoplasma identification by sequencing. *Subcontracted test*
01.009	Enter fee for decontamination and testing
01.010	Success fee : Exit of decontamination treatment and testing
	Pre-clinical and clinical grade - regulatory
01.011	Mycoplasma detection – single validation by real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off, internal validation of extract) Tests according to European Pharmacopoeia (§ 2.6.7) and US Pharmacopoeia (USP63) Excluding avian strains M gallisepticum and M imitans.
01.012	Mycoplasma detection – single validation by real-time PCR PCR (C- water, C- cells, plasmid 3x positivity cut-off, internal validation of extract) according to European Pharmacopoeia (§ 2.6.7) and US Pharmacopoeia (USP63). Including avian strains M gallisepticum et M imitans
01.013	Mycoplasma detection – single validation by real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off, internal validation of extract) - tests according to European Pharmacopoeia (§ 2.6.7) and US Pharmacopoeia (USP63) - excluding avian strains M gallisepticum and M imitans. Mycoplasma spiking for validation
01.014	Mycoplasma detection – Single validation by indirect fluorescence microscopy on indicator cells - Test according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP63).
01.020	Mycoplasma detection according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997 – excluding avian mycoplasma strains M gallisepticum and M imitans - real-time PCR and indirect culture on Vero cells (read out by PCR and epifluorescence)

CODIFICATION	DESIGNATION
01.021	Mycoplasma detection according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997 Including avian mycoplasma strains M gallisepticum and M imitans - real-time PCR and indirect culture on Vero cells (read out by PCR and epifluorescence)
01.027	Detection of mycoplasma - Culture direct according to Indian Pharmacopoeia (§ 2.6.7) Excluding avian mycoplasma strains - condition aerobic and microaerophilic and 4 sub cultures. Inoculated 10 mL in 100 mL.
01.028	Spiroplasma detection – single validation by real-time PCR (C- water, C- cells, plasmid 3x positivity cut-off, internal validation of extract). Tests according to European Pharmacopoeia (§ 2.6.16)
01.030	Mycoplasma detection in sample for human use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997– excluding avian mycoplasma strains. Direct and indirect culture. Test under microaerophilic conditions and 4 sub-cultures. Inoculation 10mL in 100mL. Including a centrifugation step in case of M Pneumoniae
01.031	Mycoplasma detection in sample for human use – Single validation by indirect fluorescence microscopy on indicator cells. Test according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP63), and PTC1993 and 1997.
01.034	Evaluation of inhibitory effect of a sample on the detection of mycoplasma by direct culture.
01.036	Mycoplasma detection by direct culture - additional condition M *orale* under anaerobic condition. Inoculation 1mL in 10mL
01.037	Mycoplasma detection by direct culture - additional condition M *orale* under anaerobic condition. Inoculation 10mL in 100mL
01.038	Mycoplasma detection in sample for human use – direct culture according to European Pharmacopoeia (§ 2.6.7), excluding avian mycoplasma strains -M *orale* and M *pneumoniae* strain. Test under microaerophilic conditions and 4 sub-cultures. Inoculation 1mL in 10mL
01.039	Mycoplasma detection in sample for human use – direct culture according to European Pharmacopoeia (§ 2.6.7), excluding avian mycoplasma strains -M *orale* and M *pneumoniae* strain. Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL
01.040	Mycoplasma detection in sample for human use – direct culture according to European Pharmacopoeia (§ 2.6.7), including 3 reference mycoplasma strains. Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL
01.041	Mycoplasma detection in sample for human use – direct culture according to European Pharmacopoeia (§ 2.6.7), including 3 reference mycoplasma strains- test under microaerophilic conditions and 4 sub-cultures of sample - inoculation 10mL in 100mL
01.042	Mycoplasma detection in sample for human use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, excluding avian mycoplasma strains - direct and indirect culture. Direct culture: 2 strains (one dextrose fermenter and one arginine hydrolyser) Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL. Indirect culture: M *orale* and M *hyorhinis*
01.043	Mycoplasma detection in sample for human use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, excluding avian mycoplasma strains. Direct and indirect culture. Direct culture: 2 strains (one dextrose fermenter and one arginine hydrolyser) Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL. Indirect culture: M *orale* and M *hyorhinis*

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01.046	Mycoplasma detection in sample for veterinary use – direct culture according to European Pharmacopoeia (§ 2.6.7), excluding avian mycoplasma strains -M *orale* and M *hyorhinis* strain. Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL
01.047	Mycoplasma detection in sample for veterinary use – direct culture according to European Pharmacopoeia (§ 2.6.7), excluding avian mycoplasma strains -M *orale* *and* M *hyorhinis* strain. Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL
01.048	Mycoplasma detection in sample for veterinary use – direct culture according to European Pharmacopoeia (§ 2.6.7), including 3 reference mycoplasma strains. Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL
01.049	Mycoplasma detection in sample for veterinary use – direct culture according to European Pharmacopoeia (§ 2.6.7), including 3 reference mycoplasma strains- test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL
01.050	Mycoplasma detection in sample for veterinary use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, excluding avian mycoplasma strains. Direct and indirect culture. direct culture: 2 strains (one dextrose fermenter and one arginine hydrolyser). Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL. indirect culture: M *orale* and M *hyorhinis*
01.052	Mycoplasma detection in sample for veterinary use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, excluding avian mycoplasma strains - direct and indirect culture. direct culture: 2 strains (one dextrose fermenter and one arginine hydrolyser) Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL. Indirect culture: M *orale* and M *hyorhinis*.
01.054	Mycoplasma detection in sample for human use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, including avian mycoplasma strains. Direct and indirect culture. Direct culture: 3 strains (one dextrose fermenter and one arginine hydrolyser and one avian). Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL. indirect culture: M *orale* and M *hyorhinis*
01.055	Mycoplasma detection in sample for human use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, including avian mycoplasma strains. Direct and indirect culture. Direct culture: 3 strains (one dextrose fermenter and one arginine hydrolyser and one avian). Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL indirect culture: M *orale* and M *hyorhinis*
01.056	Mycoplasma detection in sample for veterinary use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, including avian mycoplasma strains - direct and indirect culture. Direct culture: 3 strains (one dextrose fermenter and one arginine hydrolyser and one avian). Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 1mL in 10mL. Indirect culture: M *orale* and M *hyorhinis*.

CODIFICATION	DESIGNATION
01.057	Mycoplasma detection in sample for veterinary use according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP 63), PTC1993 and 1997, including avian mycoplasma strains - direct and indirect culture. Direct culture: 3 strains (one dextrose fermenter and one arginine hydrolyser and one avian). Test under microaerophilic conditions and 4 sub-cultures of sample. Inoculation 10mL in 100mL. Indirect culture: M *orale* and M *hyorhinis*.
01.058	Mycoplasma detection in sample for human use. Single validation by indirect fluorescence microscopy on indicator cells. Test according to European Pharmacopoeia (§ 2.6.7), US Pharmacopoeia (USP63), and PTC1993 and 1997. Including an Inhibition test.
2.	**"Bioburden" - Sterility - Endotoxins**
	§2.6.1 et USP71
02.001	Bacteriostatic and fungistatic substance test (anti-microbial activity tests). Inoculation 10 in 100mL inoculation.
02.002I2	Sterility assay by direct inoculation over a period of 7 days.
02.003I2	Sterility assay by direct inoculation over a period of 14 days, according to European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71). Inoculation 1 in 10 mL
02.003G2	Sterility assay over a period of 14 days, in compliance with European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71). Inoculation 1 in 10 mL. Test applicable on product sample manufactured under aseptic conditions (eg: injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias)
02.004I2	Sterility assay by direct inoculation over a period of 14 days, according to European Pharmacopoeia (§ 2.6.1) et US Pharmacopoeia (USP 71). Inoculation 10 in 100 mL
02.004G2	Sterility assay over a period of 14 days, in compliance with European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71). Inoculation 10 in 100 mL. Test applicable on product sample manufactured under aseptic conditions (eg: injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias.
02.005I	Sterility test over a period of 14 days, according to European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including antimicrobial activity test (method suitability test). Inoculation 1 in 10 mL.
02.005B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test (method suitability test). Inoculation 1 in 10 mL. Test applicable on product sample manufactured under aseptic conditions (eg: injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias.
02.006I2	Sterility test over a period of 14 days, according to European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test (method suitability test). Inoculation 10 in 100 mL.
02.006B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 10 in 100 mL. Test applicable on product sample manufactured under aseptic conditions (eg:injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias.
02.030B-G	Additional cost due to sampling and representativeness (up to 10 inoculations per medium)
02.031B-G	Additional cost due to sampling and representativeness (over 10 inoculations per medium)
02.026B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 10 in 100 mL on pool for sterility assay, and inoculation 1 in 10 mL for antimicrobial activity test. Test applicable on product sample manufactured under aseptic conditions (eg: injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias . Sample pooling in aseptic conditions (see related reference 02.032 or 02.033)

CODIFICATION	DESIGNATION
02.032B-G	Sample pooling in aseptic conditions (up to 20 tubes or bags)
02.033B-G	Sample pooling in aseptic conditions (over 20 tubes or bags)
02.007I2	Sterility assay by membrane filtering "STERITEST" over a period of 14 days, according to European Pharmacopoeia (§2.6.1) and US Pharmacopoeia (USP 71) .
02.007G2	Sterility assay by membrane filtering "STERITEST" over a period of 14 days, compliant with European Pharmacopoeia (§2.6.1) and US Pharmacopoeia (USP 71) . Test applicable on product sample manufactured under aseptic conditions (eg: injectable product) number of units submitted to assay compliant to tables of Pharmacopoeias.
02.008I2	Test assay by membrane filtering "STERITEST" over a period of 14 days, according to European Pharmacopoeia (§2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test.
02.008B-G	Sterility test by membrane filtering "STERITEST" over a period of 14 days, compliant with European Pharmacopoeia (§2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Test applicable on product sample manufactured under aseptic conditions (eg: injectable product). Number of units submitted to assay compliant to tables of Pharmacopoeias.
	§5.2.3
02.027B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 5.2.3); test performed according to the method described in European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 10 in 100 mL. Test applicable on cell bank for human use. Number of units submitted to the assay: 8% of vials (see related reference 02.032 or 02.033) and qsp 80 mL of culture supernatant, pooled before inoculation.
02.028B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 5.2.3) for the percentage of tested vials ; test performed according to the method described in European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 10 in 100 mL. Test applicable on cell bank for human use. Number of units submitted to the assay: 8% of vials, pooled (see related reference 02.032 or 02.033) qsp NaCl 0.9% before inoculation
	§5.2.4
02.029B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 5.2.4) for the percentage of tested vials ; test performed according to the method described in European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 1 in 10 mL. Test applicable on cell bank for veterinary use, on supernatant of flask ≥70 cm^2 obtanied after a culture phase without antibiotic of 1% of cell bank.
02.034B-G	Sterility test over a period of 14 days, in compliance with European Pharmacopoeia (§ 5.2.4) for the percentage of tested vials ; test performed according to the method described in European Pharmacopoeia (§ 2.6.1) and US Pharmacopoeia (USP 71), including anti-microbial activity test. Inoculation 10 in 100 mL. Test applicable on cell bank for veterinary use, on supernatant of flask ≥70 cm^2 obtanied after a culture phase without antibiotic of 1% of cell bank.
	Bacterial identification and decontamination
02.009	Identification of bacteria, fungi and yeast using Vitek system. *Subcontracted test*
02.010	Additional identification of bacteria, fungi and yeast by microseq system. *Subcontracted test*
02.011	Eradication of other contaminants (bacteria, fungi, yeast)
02.012	Validation on new product and detection of bacterial endotoxin, compliant with European Pharmacopoeia (§ 2.6.14) and US Pharmacopoeia (USP85).
02.013	Routine detection of bacterial endotoxins by kinetics (after validation), compliant with European Pharmacopoeia (§ 2.6.14) and US Pharmacopoeia (USP85).

CODIFICATION	DESIGNATION
02.014	Bioburden testing by membrane filtration, compliant with European Pharmacopoeia (§ 2.6.12) and US Pharmacopoeia (USP61) including anti-microbial activity tests.
02.015	Bioburden testing by plate count method for a maximum volume of 10mL, compliant with European Pharmacopoeia (§ 2.6.12) and US Pharmacopoeia (USP61) including anti-microbial activity tests.
02.016	Bioburden assay by membrane filtration, compliant with European Pharmacopoeia (§ 2.6.12) and US Pharmacopoeia (USP61)
02.018	Bioburden assay by plate count method for a maximum volume of 10mL, compliant with European Pharmacopoeia (§ 2.6.12) and US Pharmacopoeia (USP61)
02.019	Bacteriostatic and fungistatic substance test (anti-microbial activity tests). Inoculation 1 in 10mL
	§2.6.27
02.023I	Sterility assay by Bact/Alert system according to European Pharmacopoeia §2.6.27. Version 9.2
02.023G	Sterility assay by Bact/Alert system in compliance with European Pharmacopoeia §2.6.27. Version 9.2
02.024I	Sterility test by Bact/Alert system according to European Pharmacopoeia §2.6.27. Version 9.2
02.024B-G	Sterility test by Bact/Alert system in compliance with European Pharmacopoeia §2.6.27. Version 9.2
02.025	Validation of the suitability of sterility test by Bact/Alert system in compliance with European Pharmacopoeia §2.6.27. Version 9.2
03.	**Residual DNA (7+2 spe)**
03.001	Residual CHO DNA - Qualification and test (real-time PCR)
03.002	Residual human DNA - Qualification and test (real-time PCR)
03.003	Residual E.coli DNA - Qualification and test (real-time PCR)
03.004	Residual mice DNA - Qualification and test (real-time PCR
03.005	Residual Vero DNA - Qualification and test (real-time PCR)
03.006	Residual duck DNA - Qualification and test (real -time PCR)
03.007	Residual DNA of insect Sf+ - Qualification and test (real-time PCR)
03.012	Residual mice DNA – Routine test (real-time PCR) after qualification
03.013	Residual CHO DNA – (Routine test – real-time PCR) after qualification
03.014	Residual human DNA – Routine test (real-time PCR) after qualification
03.015	Residual E.coli DNA – Routine test (real-time PCR) after qualification
03.016	Residual Vero DNA – Routine test (real-time PCR) after qualification
03.017	Residual duck DNA – Routine test (real-time PCR) after qualification
03.018	Residual DNA of insect Sf+ – Routine test (real-time PCR) after qualification
03.020	Residual P. acnes DNA - Qualification and test (real-time PCR)
03.023	Residual P. acnes DNA – Routine test (real-time PCR) after qualification
04.	**Residual Proteins**
04.001I2	Determination of host protein profile by western blot
04.002	Residual E Coli protein quantification. Qualification of the working dilution for a new sample without initial western blot
04.003	Residual E Coli protein quantification. Routine testing from a qualified working dilution *(See REF. 04.001B2 or 04.002B2)*
04.007	Residual HEK 293 Host Cell Protein quantification by ELISA method: Qualification of sample working dilutions and measurement of the HCP

CODIFICATION	DESIGNATION
04.008	Residual HEK 293 Host Cell Protein quantification by ELISA method : Routine testing for the measurement of the HCP quantity on a previously qualified sample (See REF. 04.007B2)
04.015	Optional: Integration of an ELISA kit. Checking of analytical performances on controls included in the CYGNUS kitrification des performances analytiques sur les contrôles
04.016	Western Blot analysis to determine protein profile of PG13 cells
04.017	Quantification of residual proteins of PG13 cells by ELISA using a NS/0 or SP2 kit from Cygnus Technologies with determination of the working conditions
04.018	Quantification of residual proteins of PG13 cells by ELISA using a NS/0 or SP2 kit from Cygnus Technologies for routine analysis on a qualified sample (REF: 04.017)
	Viruses (in vitro)
05.	**None-specific viral detection**
	RT activity and retroviruses
05.001	Detection of Reverse Transcriptase activity (Q-PERT)
05.001b	Detection of Reverse Transcriptase activity (Q-PERT) for additional samples (2-4)
05.002	Detection of Reverse Transcriptase activity (Q-PERT) and transmissibility test on target cells with Q-PERT read out at day 7, 14 and 21
05.002a	Detection of Reverse Transcriptase activity (Q-PERT) and transmissibility test on target cells with Q-PERT read out at day 7, 14 and 21. This test includes a positive control.
05.003	Detection of Reverse Transcriptase activity (Q-PERT) and transmissibility test on target cells with Q-PERT read out at day 7, 14 and 21 for additional samples (2-4)
05.009	Virus detection by transmission electron microscopy (TEM) - 100 profiles *Subcontracted Test*
05.010	Virus detection by transmission electron microscopy (TEM) - 200 profiles *Subcontracted Test*
05.011	Virus particule quantitation by negative staining using electron microscopy *Subcontracted Test*
05.053	Determination of RT activity by Q-PERT after inoculation on H9 detector cells
05.054	Determination of RT activity by Q-PERT after inoculation on H9 detector cells - samples 2-4
05.055	Detection of Reverse Transcriptase activity (Q-PERT) on protein extracts using a spike of thymus DNA
05.061	Detection of Reverse Transcriptase activity (Q-PERT) with and without a spike of thymus DNA
05.062	Detection of ecotropic murine viruses including Moloney virus by Q-PERT activity after amplification on permissive SC-1 cells.
05.068	Detection of infectious retroviruses: Transmissibility test on target cells with Q-PERT read out at day 7, 14 and 21
05.068a	Detection of infectious retroviruses: Transmissibility test on target cells with Q-PERT read out at day 21
05.068b	Detection of infectious retrovirus : additional analysis on sample collected at day 7 and day 14 of transmissibility test
05.070	Detection of retrovirus after amplification on Mus dunni cells with a single endpoint assay PG4 S+L- (Positive controle included)

CODIFICATION	DESIGNATION
05.102	Detection of retrovirus after amplification on Mus dunni cells with a single endpoint assay PG4 S+L-
05.105	Detection of retrovirus with a single endpoint assay PG4 S+L-
05.114	Virus detection by transmission electron microscopy (TEM) - 200 profiles. This test is subcontracted to a certified GMP partner with the issue of a certificate of analysis.
05.115	Virus particle quantitation by negative staining using electron microscopy. This test is subcontracted to a certified GMP partner with the issue of a certificate.
05.116	Bovine virus detection on MRC, VERO and MDBK cells. In vitro assay (28 days) according to Chinese Pharmacopoeia: - Hemadsorption test - Hemagglutination test - Specific virus detection by real-time PCR following culture step on MDBK cells : REO3, BPI3, BHV1 + BHV5, BAV3, BAVD (4, 5 and 8) BVDV, Rabies * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) *PCR Infectious Bovine Rhinotracheitis Virus (real-time PCR) * PCR Bovine Adenovirus 3, 4, 5 and 8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR)
	Cytopathic effect detection - human use
	Harmonized approach
05.004	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin -Hemadsorption effects and hemagglutination effects. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52.
05.005	Cytopathogenic effects on additional cell line - Hemadsorption effects and hemagglutination effects. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52.
05.006	Cytopathogenic effects on bovine indicator cells - Hemadsorption and hemagglutination effects. In vitro assay (minimum 21 days)
05.007	Cytopathogenic effects on porcine indicator cells - Hemadsorption and hemagglutination effects. In vitro assay (minimum 21 days)
05.104	Cytopathogenic effects on simian indicator cells - Hemadsorption and hemagglutination effects. In vitro assay (minimum 21 days)

CODIFICATION	DESIGNATION
05.012	ECL004A-GB Bovine virus detection on MDBK cells. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 : - Hemadsorption test - Hemagglutination test - Specific virus detection by real-time PCR (9CFR and EMEA) : REO3, BPI3, BHV1 + BHV5, BAV3, BAVD (4, 5 and 8) BVDV, Rabies * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * PCR Infectious Bovine Rhinotracheitis Virus (real-time PCR) * PCR Bovine Adenovirus 3, 4, 5 and 8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR)
05.013	Bovine virus detection on MDBK, In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 (full list) : - Hemadsorption test - Hemagglutination test - Extended specific virus detection by real-time PCR (9CFR and EMEA) : REO3, BPI3, BHV1 + BHV5, BAV3, BAVD (4, 5 and 8), BVDV, Rabies, BRSV, BTV and BPV * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * PCR Infectious Bovine Rhinotracheitis Virus (real-time PCR) * PCRs Bovine Adenovirus 3, 4, 5 and8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR) * RT-PCR Bovine respiratory Syncitial virus (real-time PCR) * RT-PCR Bluetongue virus (real-time PCR) * PCR Bovine Parvovirus Virus (real-time PCR)
05.015	ECL004A-GB and ECL005A-GB Bovine and porcine virus detection on MDBK and ST cells. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 : - Hemadsorption test - Hemagglutination test - Specific virus detection by real-time PCR (9CFR and EMEA) : -> *Bovine* : REO3, BPI3, BHV1 + BHV5, BAV3, BAVD (4, 5 and 8), BVDV, Rabies * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * PCR Bovine Herpesvirus 1 and 5 (real-time PCR) * PCRs Bovine Adenovirus 3, 4, 5 and 8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus -> *Porcine* : * PPV * PCR Porcine Parvovirus (real-time PCR)
05.038	ECL003A-GB Cytopathogenic effects on MRC-5, VERO,3T3 and CHO-K1 - Hemadsorption effects and hemagglutination effect. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52.

CODIFICATION	DESIGNATION
05.039	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 1 cell model. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.040	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin - Hemadsorption effects and hemagglutination effects. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. Inoculation of neutralized sample with a volume of 50 mL.
05.041	ECL005A-GB Porcine virus detection on ST cells. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 : - Hemadsorption test - Hemagglutination test - Specific virus detection by real-time PCR (9CFR) : PPV
05.042	Cytopathogenic effects on MRC-5 and VERO target cell lines - Hemadsorption effects and hemagglutination effects. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52
05.044	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects and hemagglutination effects. In vitro assay (14 days)according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52.
05.047	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects and hemagglutination effects. In vitro assay (14 days)according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. Including assay with human erythrocytes
05.048	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects and hemagglutination effects. In vitro assay (42 days – subculture on fresh cells at day 28) according to Guidance for Industry : Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications. *Note* : As the possibility of contamination with human or simian cytomegalovirus is a consideration , the first phase of culture is extended to 28 days (instead of 14 days) before re-inoculation onto fresh cells.
05.049	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects. In vitro assay (14 days)according to European Pharmacopoeia (§2.6.16). Inoculation of 10mL of supernatant pool collecting from control cells.

CODIFICATION	DESIGNATION
05.050	In vitro assay (14 days minimum) for detection of viral contaminants in the control cells (ECP,Hemadsorption) according to WHO TRS 993 Annex3. This test includes a culture of 10F75, 2 passages (with supernatant harvest) at D5 and D10, and a final read out at D14 and D17. The Hemadsorption is performed with red cells from guinea pigs. The work performed during the week end and bank holidays is not included.
05.051	Cytopathogenic effects on MRC-5 and VERO target cell lines. Hemadsorption effects. In vitro assay (14 days) compliant with European Pharmacopoeia (§2.6.16). Inoculation of 10mL of supernatant pool collecting from control cells.
05.052	Porcine virus detection on ST cells. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 (full porcine list): * Hemadsorption test * Hemagglutination test * Extended specific virus detection by real-time PCR (9CFR) : BVDV(CSFV), REO3, Rabies, PPV, PHEV, TGEV, PAV * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR) * PCR Porcine Parvovirus Virus (real-time PCR) * RT-PCR Bluetongue virus (real-time PCR) * RT-PCR Porcine Hemagglutinating Encephalomyelitis Virus (real-time PCR) * RT-PCR Transmissible gastroenteritis coronavirus (real-time PCR) * PCR Porcine adenovirus (real-time PCR)
05.056	Infectivity assay for viral detection (except HCV) on indicator cells
05.060	Porcine virus detection on ST cells, (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 : - Hemadsorption test - Hemagglutination test - Specific virus detection by PCR (9CFR) : PPV, PCV, TGEV, PHEV, PAV (A, B, C and W)

CODIFICATION	DESIGNATION
05.065	Bovine and porcine virus detection on MDBK and ST cells. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52, 113.46 and 113.47 (full bovine list): - Hemadsorption test - Hemagglutination test - Extended specific virus detection by real-time PCR (9CFR and EMEA) : -> *Bovine* : BVDV, BHV1 + BHV5, BAV3, BPI3, BAVD (4,5,8), REO3,Rabies, BRSV, BTV, BPV * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * PCR Infectious Bovine Herpesvirus 1 et 5 (real-time PCR) * PCR Bovine Adenovirus 3,4, 5 et 8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR) * RT-PCR Bovine respiratory Syncitial virus (real-time PCR) * RT-PCR Bluetongue virus (real-time PCR) * PCR Bovine Parvovirus Virus (real-time PCR) -> *Porcine* : PPV, PHEV, TGEV et PAV * PCR Porcine Parvovirus (real-time PCR) * RT-PCR Porcine Hemagglutinating Encephalomyelitis Virus (real-time PCR) * RT-PCR Transmissible gastroenteritis coronavirus (real-time PCR) * PCR porcine Adenovirus (Real-time PCR) - 4 independent PCR assays
05.100	Feasibility study to check the absence of cytopathic or interfering effect of a test sample on one indicator cell line. The feasibility study will be performed according to the design of the reference 05.004, but will be limited to a duration of 17 days. Hemadsorption and hemagglutination with chicken and guinea red blood cells will be assessed.
05.101	General protocol ECL003A-14D-GB, Cytopathogenic effects on MRC-5, VERO,3T3 and CHO-K1. Hemadsorption effects and hemagglutination effect. In vitro assay (14 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52.

CODIFICATION	DESIGNATION
05.106	General protocol - 210-010-ECL01 : Cytopathogenic effects on MRC-5, VERO,3T3 and CHO-K1. Hemadsorption effects and hemagglutination effect. In vitro assay (28 days) according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. With inhibition control
	EP2.6.16
05.072	In vitro assay (up to 14 days) for the detection of viral contaminant in control cells (CPE and hemadsorption with guinea-pig red blood cells) compliant to European Pharmacopoeia (§2.6.16)
05.073	Cytopathogenic effects on MRC-5 and VERO target cell lines - Hemadsorption effects. In vitro assay (28 days) compliant to European Pharmacopoeia (§2.6.16). Inoculation of 5mL of supernatant pool collecting from control cells per cell line.
05.071	Cytopathogenic effects on MRC-5 and VERO target cell lines. In vitro assay (day 14) compliant to European Pharmacopoeia (§2.6.16). Inoculation of 5mL of supernatant pool collecting from control cells per cell line.
05.074	Cytopathogenic effects on one additional cell line - Hemadsorption effects. In vitro assay (28 days) according to European Pharmacopoeia (§2.6.16). Inoculation of 5mL of supernatant pool collecting from control cells.
05.095	Cytopathogenic effects on one additinal cell line In vitro assay (-day 14) compliant to European Pharmacopoeia (§2.6.16). Inoculation of 5mL of supernatant pool collecting from control cells.
05.077	Cytopathogenic effects on cell line of the same origin1- Hemadsorption effects. In vitro assay (14 days) compliant to European Pharmacopoeia (§2.6.16). Inoculation of 5 mL of supernatant pool collected from control cells.
05.075	Detection of avian leucosis virus compliant with European Pharmacopoeia (§2.6.16). Culture of sample on DF1 cells for 5 passages followed by ALV detection by PCR
05.076	Cytopathogenic effects on MRC-5 and VERO target cell lines - Hemadsorption effects. In vitro assay (28 days) compliant with European Pharmacopoeia (§2.6.16). Inoculation of 50mL of crude harvest equally divided between the indicator cells.
05.078	Cytopathogenic effects on Hela/Hep2 and VERO target cell lines - Hemadsorption effects. In vitro assay (14 days) compliant with European Pharmacopoeia (§2.6.16). Inoculation of 5 mL of crude harvest + 5 mL of antiserum per cell line.
05.113	Additional interference control (one positive control mixed with the sample) for testing for the presence of avian leucosis virus compliant with European Pharmacopoeia §2.6.16
	Bulk harvest
05.096	Sample preparation before viadventitious dtection on indicator cells: neutralization step (antiserum will be provided by the sponsor)
05.083	Cytopathogenic effects on MRC-5 and VERO target cell lines. Hemadsorption effects with guinea-pig red blood cells effects. In vitro assay (28 days - subculture at day 14) compliant with European Pharmacopoeia (§2.6.16). Inoculation of a maximum volume of 60 mL neutralized sample per cell line (corresponding to 50mL of sample before neutralization)

CODIFICATION	DESIGNATION
05.084	Cytopathogenic effects on one additional target cell line. Hemadsorption effects with guinea-pig red blood cells effects. In vitro assay (28 days - subculture at day 14) compliant with European Pharmacopoeia (§2.6.16). Inoculation of a maximum volume of 60 mL neutralized sample onto the cell line (corresponding to 50mL of sample before neutralization)
05.085	Cytopathogenic effects on MRC-5 and VERO target cell lines. Hemadsorption effects with guinea-pig red blood cells. In vitro assay (28 days - subculture at day 14) compliant with European Pharmacopoeia (§2.6.16). Inoculation of a maximum volume of 5 mL neutralized sample per cell line.
05.086	Cytopathogenic effects on one additional target cell line. Hemadsorption effects with guinea-pig red blood cells. In vitro assay (28 days - subculture at day 14) compliant with European Pharmacopoeia (§2.6.16). Inoculation of a maximum volume of 5 mL neutralized sample onto the cell line.
	EP 5.2.3
05.087	Cytopathogenic effects on MRC-5 and VERO target cell lines. Haemagglutination effects with guinea-pig red blood cells . In vitro assay (14 days) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto each cell line.
05.088	Cytopathogenic effects on MRC-5 and VERO target cell lines. Haemagglutination effects . In vitro assay (28 days- with subculture of lysate/supernatant on fresh monolayers at day 14) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto each cell line.
05.089	Cytopathogenic effects on one additional cell line. Haemagglutination effects with guinea-pig red blood cells. In vitro assay (14 days) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto the cell line.
05.090	Cytopathogenic effects on one additional cell line. Haemagglutination effects with guinea-pig red blood cells. In vitro assay (28 days- with subculture of lysate/supernatant on fresh monolayers at day 14) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto each cell line.
05.091	Cytopathogenic effects on BHK21 cell line (case of insect cells). Hemadsorption effects with guinea-pig red blood cells. In vitro assay (14 days) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto the cell line.
05.092	Cytopathogenic effects on BHK21 cell line (case of insect cells). Hemadsorption effects with guinea-pig red blood cells. In vitro assay (28 days- with subculture of lysate/supernatant on fresh monolayers at day 14) compliant with European Pharmacopoeia (§5.2.3). Inoculation of a lysate equivalent to at least 10 millions of cells in culture supernatant onto the cell line.
	9CFR113.52 -9CFR113.55
05.093	In vitro assay (21 days) for the detection of viral contaminant in control cells (CPE and hemadsorption with guinea-pig red and chicken blood cells) compliant with 9CFR113.52 and 113.46

CODIFICATION	DESIGNATION
05.094	Cytopathogenic effects on MRC-5 and VERO target cell lines. Hemadsorption effects with guinea-pig and chicken red blood cells and hemagglutination effects. In vitro assay (14 days) compliant with 9CFR113.52 and 113.46. Inoculation of a lysate equivalent to one F75 onto each cell line.
05.097	Cytopathogenic effects on one additional cell line. Hemadsorption effects with guinea-pig and chicken red blood cells and hemagglutination effects. In vitro assay (14 days) compliant with 9CFR113.52 and 113.46. Inoculation of a lysate equivalent to one F75 onto the cell line.
05.098	Cytopathogenic effects on MRC-5 and VERO target cell lines. Hemadsorbtion effects with guinea-pig and chicken red blood cells and hemagglutination effects. In vitro assay (14 days) according to 9CFR113.55 and 113.46. Inoculation of 1 ml of virus seed (neutralized if necessary) onto each cell line.
05.099	Cytopathogenic effects on one additional cell line. Hemadsorbtion effects with guinea-pig and chicken red blood cells and hemagglutination effects. In vitro assay (14 days) according to 9CFR113.55 and 113.46. Inoculation of 1 ml of virus seed (neutralized, if necessary)
	Cytopathic effect detection - veterinary use
05.018	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 1 model of primary cells. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46
05.019	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 1 cell model. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.47
05.020	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 2 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.021	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 3 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.022	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 4 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.023	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 5 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.024	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 6 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.025	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 7 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.046	Detection of cytopathic and haemadsorbing agents by coculture for 14 days with 8 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§5.2.4) and FDA 9CFR 113.52, 113.46 and 113.47
05.064	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 1 unusual model of primary cells. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47

CODIFICATION	DESIGNATION
05.066	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 1 classic model of primary cells.Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46
05.067	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 1 cell model. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.47
05.026	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 2 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.027	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 3 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.028	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 4 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.029	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 5 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.030	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 6 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.031	Detection of cytopathic and haemadsorbing agents by coculture for 28 days with 7 cell models including (if necessary) one model for pestivirus detection. Test according to European pharmacopoeia (§0062) and FDA 9CFR 113.52, 113.46 and 113.47
05.032	Detection of cythopathic and haemadsorbing effects by culture of sample for 28 days. Test according to European pharmacopoeia (§5.2.4)
05.035	Test in chicken embryo kidney cells (CEKC) performed according to European Pharmacopoeia (§ 2.6.24)
05.036	Test for avian leucosis viruses performed according to European Pharmacopoeia (§ 2.6.24)
05.037	Test for avian reticuloendotheliosis virus performed according to European Pharmacopoeia (§ 2.6.24)
	Serum and neutralisation efficacy assessment of an antiserum

CODIFICATION	DESIGNATION
05.033	Bovine virus detection using 21 days of coculture on MDBK and Vero cells, according to European Pharmacopoeia (bovine serum : §2262) , EMEA (CPMP/BWP/1793/02 , CVMP/743/00rev2) and FDA 9CFR113.53, 113.46 and 113.47. - Detection of cytopathic effects - Hemadsorption test - Hemagglutination test - Specific virus detection by real-time PCR at the end of coculture: REO3, BPI3, BHV1 + BHV5, BAV3, BAVD (4, 5 and 8), BVDV, Rabies, BRSV, BTV and BPV * RT-PCR Bovine Viral Diarrhea Virus (real-time PCR) * PCR Infectious Bovine Rhinotracheitis Virus (real-time PCR) * PCRs Bovine Adenovirus 3, 4, 5 and8 (real-time PCR) * RT-PCR Bovine Parainfluenza 3 (real-time PCR) * RT-PCR Bovine Reovirus 3 (real-time PCR) * RT-PCR Rabies Virus (real-time PCR) * RT-PCR Bovine respiratory Syncitial virus (real-time PCR) * RT-PCR Bluetongue virus (real-time PCR) * PCR Bovine Parvovirus Virus (real-time PCR)
05.063	Preliminary study to assess the efficacy of antiserum to neutralize the virus bank for its use in an in vitro assay (14 days - to exclude any cytopathic effects on 1 detector cell line) – R&D grade
05.080	Preliminary study to assess the efficacy of antiserum to neutralize the virus bank for its use in an in vitro assay (28 days - to exclude any cytopathic effects on 1 detector cell line) – R&D grade.
05.103	Feasibility study to check the absence of cytopathic or interfering effect of a test sample at one concentration on 2 indicators cell line. This assay is performed in order to determine analysis conditions for further adventitious agents detection in vitro assay. Cells will be observed for 7 days. An assay report will be provided.
05.107	Preliminary study to assess the efficacy of antiserum to neutralize the virus bank for its use in an in vitro assay (Mycoplasma detection by indirect culture on indicator VERO cells) during 7 days (to exclude any cytotoxicity and inhibitory effects on 1 detector cell line)
	RCL and RCAAV test
05.057	Detection of Replication Competent Lentivirus (RCL) in vector supernatant using infectivity assay with P24 ELISA endpoint titration assay.
05.058	Feasibility study: Determination of the experimental conditions to be applied for P24 ELISA endpoint titration assay on samples of lentiviral vectors.
05.059a	P24 ELISA endpoint titration assay on samples of lentiviral vectors.
05.059b	P24 ELISA endpoint titration assay on samples of lentiviral vectors - for additional samples (2-5)
05.069	Replication Competent Lentivirus (RCL) detection after infectivity assay on indicator cells and with titration of p24 by ELISA. Test is performed in duplicate (2 x F75) - in BSL3 with a negative control and without a positive or inhibition control.
05.079	Detection of serotype 2 replication-competent AAV particles (rcAAV-2) via an infectivity assay on HeLa cells (three 72-hour rounds) and detection of Rep2 gene by qPCR assay at the end of each amplification round.
05.081	Replication Competent Lentivirus (RCL) detection after infectivity assay on indicator cells and with titration of p24 by ELISA. Test is performed in duplicate (2 x F75) - in BSL3 with a positive and negative controls and without an inhibition control.

CODIFICATION	DESIGNATION
05.082	Replication Competent Lentivirus (RCL) detection after infectivity assay on indicator cells and with titration of p24 by ELISA. Test is performed in duplicate (2 x F75) - in BSL3 with a positive, negative and inhibition controls.
05.108	Detection of Replication Competent Lentivirus (RCL) on supernatant from cell culture (maximum of 50 mL of supernatant tested corresponding to a maximum volume of production of 1L) using infectivity assay with P24 ELISA endpoint titration assay
05.109	Detection of Replication Competent Lentivirus (RCL) on supernatant from cell culture (maximum of 100 mL of supernatant tested to a maximum volume of production of 2L) using infectivity assay with P24 ELISA endpoint titration assay
05.110	Detection of Replication Competent Lentivirus (RCL) in cell culture using infectivity assay with P24 ELISA endpoint titration assay
05.111	Detection of Replication Competent Lentivirus (RCL) in vector supernatant using infectivity assay with P24 ELISA endpoint titration assay and with preliminary sample toxicity study
05.112	Detection of Replication Competent Lentivirus (RCL) in vector supernatant or cell culture supernatant (maximum of 300 ml or 450 µg P24) using pooling-format infectivity assay with P24 ELISA endpoint titration assay
06.	**Human viruses**
06.001	PCR Adeno Associated Virus – consensus (real-time PCR)
06.002	PCR Adenovirus 5 (real-time PCR)
06.003	PCR Erythrovirus B19 – Parvovirus (real-time PCR)
06.004	PCR CMV (HHV-5) (real-time PCR)
06.005	PCR EBV (HHV-4) (real-time PCR)
06.006	Enterovirus Consensus RT-PCR by real-time PCR (except Bovine enteroviruses)
06.007	RT-PCR HAV (real-time PCR)
06.008	PCR HBV (real-time PCR)
06.009	RT-PCR HCV (real-time PCR)
06.010	PCR HHV-6A (real-time PCR)
06.011	PCR HHV-6B (real-time PCR)
06.012	PCR HHV-7 (real-time PCR)
06.013	PCR HHV-8 (real-time PCR)
06.014	PCR HIV-1 (real-time PCR)
06.015	RT-PCR HIV-1 (real-time PCR)
06.016	PCR HIV-2 (real-time PCR)
06.017	RT-PCR HIV-2 (real-time PCR)
06.018	PCR Papillomavirus (HPV serotypes 16 & 18) (real time PCR)
06.019	PCR Human Polyomavirus - BK polyomavirus ; JC polyomavirus ; Human polyomavirus type 6 ; Human polyomavirus type 7 ; Human polyomavirus type 9 ; KI polyomavirus ; Merkel cell polyomavirus ; Trichodysplasia spinulosa-associated polyomavirus ; WU polyomavirus (6 real time PCR)
06.020	PCR HSV1 (real-time PCR)
06.021	PCR HSV2 (real-time PCR)
06.022	PCR HTLV-1 (real-time PCR)
06.023	RT-PCR HTLV-1 (real-time PCR)
06.024	PCR HTLV-2 (real-time PCR)

CODIFICATION	DESIGNATION
06.025	RT-PCR HTLV-2 (real-time PCR)
06.026	PCR detection of human viruses (HIV1, HIV2, HTLV1, HTLV2, HBV, HCV) (real-time PCR)
06.027	PCR detection of human viruses (RT-HIV1,RT-HIV2,RT- HTLV1, RT-HTLV2, HBV, HCV) (real-time PCR)
06.029	PCR detection of human viruses (HIV1, HIV2, HTLV1, HTLV2, HBV, HCV, HAV, HSV1, HSV2, CMV, EBV, VZV, HHV6A, HHV6B, HHV7, HHV8, B19 and Papilloma virus HPV16&18, Enterovirus,hPolyomavirus,adenovirus5) (real-time PCR) *Note* : the detection of hPolyomavirus covers the following viruses: BK polyomavirus; JC polyomavirus; Human polyomavirus type 6; Human polyomavirus type 7; Human polyomavirus type 9; KI polyomavirus; Merkel cell polyomavirus; Trichodysplasia spinulosa-associated polyomavirus; WU polyomavirus (6 real-time PCR)
06.033	PCR VZV (HHV-3) (real-time PCR)
06.034	RT-PCR Rubella Virus (RUB) (real-time PCR)
06.035	PCR Human adenovirus type F (40&41) (real-time PCR)
06.036	RT-PCR Measle Virus (real-time PCR)
06.037	RT-PCR Mumps Virus (real-time PCR
06.038	PCR Human Adenovirus groupe A (12,18,31,61) (real-time PCR)
07.	**Animal viruses (multiple species)**
07.001	RT-PCR Bornavirus (real-time PCR)
07.002	RT-PCR Encephalomyocarditis Virus (real-time PCR)
07.003	RT-PCR Feline Foamy Virus (real-time PCR)
07.004	RT-PCR Influenza Virus type A (real-time PCR)
07.005	RT-PCR Japanese B encephalitis virus & West Nile Virus (real-time PCR)
07.006	RT-PCR Rabies Virus (real-time PCR)
07.007	RT-PCR Rift Valley Fever Virus (real-time PCR)
07.008	RT-PCR Reovirus 3 (real-time PCR)
07.009	RT-PCR Vesivirus or Calicivirus 2117 (real-time PCR)
07.010	RT-PCR Hepatitis E (human and porcine) (real-time PCR)
07.011	RT-PCR Tick-borne encephalitis virus (real-time PCR)
07.012	PCR Rabbit bocaparvovirus (real-time PCR)
07.013	RT-PCR Rabbit hemorrhagic disease virus (real-time PCR)
08.	**Bovine viruses**
08.001	RT-PCR Akabane Virus (real-time PCR)
08.002	PCR Bovine Adenovirus 3 (real-time PCR)
08.003	PCR Bovine adenovirus 4, 5 and 8 (real-time PCR)
08.004	RT-PCR Bovine Enterovirus (real-time PCR)
08.005	RT-PCR Bovine Coronavirus & Porcine Hemagglutinating (real-time PCR)
08.006	PCR Bovine herpesvirus type 1 (or BHV1 + BHV5), 2, 4 and 5 (real-time PCR)
08.007	PCR Bovine herpesvirus type 2 (real-time PCR)
08.008	PCR Bovine herpesvirus type 4 (real-time PCR)
08.009	PCR Bovine Herpesvirus 1 (or Infectious Bovine Rhinotracheitis Virus), Bovine Herpesvirus 5 and Caprine Herpesvirus type 1 (real-time PCR)
08.010	RT-PCR Bovine Leukaemia Virus (real-time PCR)
08.011	RT-PCR Bovine Parainfluenza 3 (real-time PCR)
08.012	PCR Bovine Papular Stomatitis Virus (real-time PCR)

CODIFICATION	DESIGNATION
08.014	PCR Bovine Polyomavirus (real-time PCR)
08.015	RT-PCR Bovine Respiratory Syncytial Virus(real-time PCR)
08.016	RT-PCR Blue Tongue Virus (real-time PCR)
08.017	Detection of Pestivirus by RT-PCR (real time PCR): Bovine Viral Diarrhea Virus, Classical Swine Fever Virus, Border Disease Virus
08.018	Determination of the number of BVDV particles. Qualification of the method for a new sample. Establishing a standard curve of BVDV in TCID50. Establishing a standard curve of gene copy number using a plasmid.
08.021	PCR Cowpoxvirus (real-time PCR)
08.022	RT-PCR Epizootic Hemorraghic Disease Virus (real-time PCR)
08.023	RT-PCR Foot-and Mouth Disease Virus (real-time PCR)
08.025	PCR Lumpy Skin Disease Virus (real-time PCR)
08.026	RT-PCR Rinderpest Virus (real-time PCR)
08.027	RT-PCR Vesicular Stomatitis Virus Indiana and New Jersey strains (real-time PCR)
08.028	RT-PCR Vesicular Stomatitis Virus New Jersey strain (real-time PCR)
08.029	PCR Alcelaphine herpesvirus 1 or Malignant catarrhal fever virus (African form) or Bovine herpesvirus 3 (real-time PCR)
08.031	PCR Bovine Papillomavirus type 1 to 13 (8 real-time PCR)
08.035	PCR Bovine parvovirus Type 1, bovine bocavirus and Bovine Parvovirus type 2 (2 real-time PCR)
08.036	RT-qPCR Bovine Rhinitis Virus type A and B (2 PCR)
08.037	RTqPCR Bovine Jena virus (or Norwalk virus subtype Norovirus GIII)
08.038	RT-PCR Rotavirus bovins A, B et C (3 real-time PCR)
09.	**Porcine viruses**
09.001	PCR African Swine Fever Virus (real-time PCR)
09.002	PCR Porcine Cytomegalovirus (real-time PCR)
09.003	RT-PCR Porcine epidemic diarrhea virus (real time PCR)
09.004	RT-PCR Porcine Encephalomyelitis Virus hemagglutinating (real time)
09.005	PCR Porcine Parvovirus (real-time PCR)
09.006	PCR Pseudorabies Virus (real-time PCR) (Aujeszky's Disease)
09.007	RT-PCR Porcine Respiratory and Reproductive Syndrome Virus (real-time PCR)
09.008	PCR Swinepox virus (real-time PCR)
09.009	RT-PCR Transmissible Gastroenteritis Virus (real-time PCR)
09.010	PCR Porcine Circovirus 1 & 2, Bovine circovirus (real-time PCR)
09.012	PCR Porcine Adenovirus type A, B, C and W (4 real-time PCR)
09.014	RT-PCR Consensus Teschovirus (including Porcine Teschovirus type 1) (real time)
09.015	RT-PCR Porcine coronavirus HKU15
09.016	RT-PCR Porcine rotavirus A, B, C and H (4 individual RT-PCRs)
09.017	PCR Porcine Circovirus 1,2 & 3, Bovine circovirus (real-time PCR)
10.	**Murine viruses**

CODIFICATION	DESIGNATION
10.001	RT-PCR Murine Rotavirus - Epizootic Diarrhea of Infant Mice (real-time PCR)
10.002	PCR Ectromelia Virus (real-time PCR)
10.003	RT-PCR Hantaan Virus (real-time PCR)
10.004	PCR Kilham Rat Virus (real-time PCR)
10.005	RT-PCR Lymphocytic Choriomeningitis Virus (real-time PCR)
10.006	RT-PCR Lactate Dehydrogenase-elevating Virus (real-time PCR)
10.007	PCR Murine Adenovirus - strain FL (real-time PCR)
10.008	PCR Murine Adenovirus K87 (real-time PCR)
10.009	PCR Murine Cytomegalovirus (real-time PCR)
10.010	PCR Murine Herpes Virus 68 (real-time PCR)
10.011	RT-PCR Murine Hepatitis Virus (real-time PCR)
10.012	PCR Murine Kilham Virus (real-time PCR)
10.013	Murine Norovirus RT-PCR (real time PCR).
10.014	PCR Murine Polyoma Virus (real-time PCR)
10.015	PCR Murine Parvovirus (real-time PCR)
10.016	PCR Pneumoniae Virus of Mice (real-time PCR)
10.017	RT-PCR Sialodacryoadenitis Virus (real-time PCR)
10.018	RT-PCR Sendai Virus / Murine Parainfluenza 1 (real-time PCR)
10.019	RT-PCR for the detection of Simian Virus 5 and canine parainfluenza type 2 virus (real-time PCR)
10.020	PCR Toolan's H1 Virus (real-time PCR)
10.021	RT-PCR Theiler's Murine Encephalomyelitis Virus / GD VII virus (real-time PCR)
10.022	Detection of murine virus by PCR (EV, EDIM, HANV, LCMV, LDV, MVM, Mouse adenovirus, MCMV, TMEV, MHV, PVM, MPOV, REO3, Sendai virus, MKV) (real-time PCR)
10.023	Detection of virus from hamster origin LCMV, PVM, REO3, SENDAI, SV5 by PCR (real-time PCR)
10.024	Mouse Thymic Virus PCR (Real Time PCR) Subcontracted test
11.	**Avian viruses**
11.001	RT-PCR Encephalomyelitis Avian Virus (real-time PCR)
11.002	RT-PCR Avian Leucosis Viruses – consensus (real-time PCR)
11.003	RT-PCR Avian Leucosis Virus genotype A (real-time PCR)
11.004	RT-PCR Avian Leucosis Virus genotype B & C (real-time PCR)
11.005	RT-PCR Avian Leucosis Virus genotype D (real-time PCR)
11.006	RT-PCR Avian Leucosis Virus genotype J (real-time PCR)
11.007	RT-PCR Avian Leucosis Virus genotype E (real-time PCR)
11.008	RT-PCR Avian Leucosis Virus Genotype A with specific probe (real time PCR)
11.009	RT-PCR Avian Leucosis Virus Genotype B & C with specific probe (real time PCR)
11.010	RT-PCR Avian Leucosis Virus Genotype D with specific probe (real time PCR)
11.011	RT-PCR Avian Leucosis Virus Genotype J with specific probe (real time PCR
11.012	RT-PCR Avian Leucosis Virus Genotype E with specific probe (real time PCR)
11.013	RT-PCR Avian ParaMyxovirus type 2 (real-time PCR)
11.014	RT-PCR Avian Reovirus (real-time PCR)

CODIFICATION	DESIGNATION
11.015	PCR Chicken Anaemia Virus (real-time PCR)
11.016	PCR Egg Drop Syndrome Virus (real-time PCR)
11.017	PCR Fowl Adenovirus Type 1 (real-time PCR)
11.018	PCR Hemorrhagic Enteritis Virus (real-time PCR)
11.019	RT-PCR Influenza Virus type A (real-time PCR)
11.020	RT-PCR Infectious Bronchitis Virus (real-time PCR)
11.021	RT-PCR Infectious Bursal Disease Virus (real-time PCR)-consensus detection of serotypes IBDV1 and IBDV2 (Gumboro)
11.022	PCR Infectious laryngotracheitis Virus (real-time PCR)
11.023	PCR Marek's Disease Virus (real-time PCR)
11.024	RT-PCR Newcastle Disease Virus group II (real-time PCR)
11.025	RT-PCR Avian Reticuloendotheliosis Virus (real-time PCR)
11.026	Quantification of the avian flu virus H9N2 by RT-qPCR method
11.027	RT-PCR Consensus Avian Nephritis Virus type 1 & 2 et Chicken Astrovirus) (real time)
11.028	RT-PCR Avian metapneumovirus - including Turkey rhinotracheitis virus (2 real-time PCR)
12.	**Equine viruses**
12.001	RT-PCR African Horse Sickness Virus (real-time PCR)
12.002	RT-PCR Equine encephalomyelitis virus - eastern, western, venezuelian (real time PCR)
12.004	RT-PCR Equine infectious anemia virus (real time PCR)
12.005	RT-PCR Equine viral arteritis virus (real time PCR)
12.006	PCR Equine adenovirus type 1&2 (real time PCR)
12.007	PCR Equine herpesvirus type 1&4 (or Equine rhinopneumitis herpesvirus type 1 and 4) (real time PCR)
12.008	RT-PCR Equine rotavirus (real-time PCR)
12.009	RT-PCR Hendra Virus and Nipah Virus (real-time PCR)
13.	**Caprine / Ovine viruses**
13.001	RT-PCR Caprine Arthritis Encephalitis Virus (real-time PCR)
13.002	PCR Caprine adenovirus 2 (real time PCR)
13.003	RT-PCR Louping Ill Virus (real-time PCR)
13.004	RT-PCR Nairobi sheep disease virus (real-time PCR)
13.005	PCR Ovine adenovirus A (Bovine adenovirus type 2, Ovine adenovirus 2, 3, 4 & 5) (real-time PCR)
13.006	PCR Ovine adenovirus B (ovine adenovirus 1 et caprine adenovirus type 2) (real-time PCR)
13.007	PCR Ovine adenovirus c (ovine adenovirus 6) (real-time PCR)
13.008	PCR Ovine adenovirus D (goat adenovirus 1 & Ovine adenovirus 7) (real-time PCR)
13.009	PCR Ovine herpesvirus 2 (real-time PCR)
13.010	RT- PCR Ovine Respiratory Syncytial Virus (real time PCR)
13.011	PCR Ovine Papillomavirus (type 1, 2 et 3) (real-time PCR)
13.012	PCR ORF Virus or Echtyma Poxvirus (real-time PCR)
13.013	RT-PCR Peste-des-petits-ruminants (real-time PCR)
13.014	PCR Caprine herpesvirus 2 (real-time PCR)
14.	**Simian viruses**
14.001	PCR Simian Cytomegalovirus (real-time PCR)
14.002	RT-PCR Simian Foamy Virus (real-time PCR)

CODIFICATION	DESIGNATION
14.003	PCR Monkey B or Simian Herpes B Virus (real-timpe PCR)
14.004	RT-PCR Simian Immunodeficiency Virus (real-time PCR)
14.005	RT-PCR Squirrel Monkey Retrovirus (real-time PCR)
14.006	RT-PCR Simian Lymphotropic Virus (real-time PCR)
14.007	PCR SV40 (real-time PCR)
14.008	Package simian viruses (simian Lymphotropic virus detection by real-time RT-PCR, simian immunodeficiency virus detection by real-time RT-PCR, simian and human foamy virus detection by real-time RT-PCR SV40 virus detection by real-time PCR)
14.009	PCR SV40 VP2 target (real-time PCR) – specific for sample of Hek293T cells
15.	**Insect viruses**
15.001	RT-PCR Insect alphanodavirus: Black beetle virus, Boolara Virus, Flock house virus (real-time PCR)
15.002	RT-PCR Insect alphanodavirus: Nodamura virus, Pariacato virus (real-time PCR)
16.	**Feline viruses**
16.002	PCR FLV (real-time PCR) *Subcontracted test*
16.003	PCR FIV (real-time PCR) *Subcontracted test*
16.004	RT-PCR Feline/Canine coronavirus (real-time PCR). This test is subcontracted to a non GMP partner with the issue of a report of analysis (RoA) non verified by our Qualified Person
16.005	RT-PCR Feline Calicivirus (real-time PCR) *Subcontracted test*
16.006	PCR Feline Panleucopenia (real-time PCR) *Subcontracted test*
17.	**Canine viruses**
17.001	PCR Canine oral papillomavirus (real-time PCR)
17.002	PCR canine parvovirus (real-time PCR) This test is subcontracted to a non GMP partner but with the issue of a certificate of analysis. *Subcontracted test*
17.003	RT-PCR Canine distemper virus (real-time PCR) This test is subcontracted to a non GMP partner with the issue of a report of analysis (RoA) non verified by our Qualified Person
18.	**Other microbial contaminants**
18.001	Test for Mycobacterium spp by direct culture - According to European Pharmacopoeia (§ 2.6.2).
18.002	PCR mycobacterium (real-time PCR)
18.003	PCR Brucella (real-time PCR) *Subcontracted test*
18.004	PCR Coxiella burnetii (real-time PCR) *Subcontracted test*

CODIFICATION	DESIGNATION
18.005	PCR Chlamydia (Chlamydophila psittaci, abortus, felis caviae) (real-time PCR) *Subcontracted test*
18.007	PCR Toxoplasma gondii (real-time-PCR)
18.008	PCR Trypanosoma sp (real-time-PCR)
18.009	Consensus PCR Burkholderia mallei et Burkholderia pseudomallei (real-time PCR)
18.010	PCR Treponema pallidum (real-time PCR)
18.011	qPCR Helicobacter spp *Subcontracted test*
18.012	PCR Cilia-Associated Respiratory Bacillus (Filobacterium rodentium) (real-time PCR)
18.013	PCR Chlamydia (Chlamydophila psittaci, abortus, felis caviae) (real-time PCR)
18.014	PCR Leptospira (pathogenic) (real-time PCR)
18.015	PCR Salmonella sp – consensus (real-time PCR) *Subcontracted test*
19.	**Viruses (in vivo) and other tests**
19.001	Abnormal toxicity *Subcontracted test*
19.002	FDA In vivo tumorigenicity assay in Nude mice + Cell expansion for tumorigenicity assay *Subcontracted test*
19.003	HAP – Hamster virus detection by injection on the animal and ELISA technique on serum *Subcontracted test*
19.004	MAP – Mice virus detection by injection on the animal and ELISA technique on serum *Subcontracted test*
19.006	In vivo assay for detection of adventitious agents on animals (adult and suckling mice embryonated hen eggs). According to European Pharmacopoeia (§5.2.3) *Subcontracted test*
19.007	In vivo assay for detection of adventitious agents on animals (adult and suckling mice embryonated hen eggs and guinea pigs). According to European Pharmacopoeia (§2.6.16). *Subcontracted test*
19.008	In vivo adventitious agent assays– adult & suckling mice, embryonated eggs to EP Sec 5.2.3. (Plus guinea pigs as 2.6.16)
19.009	In vivo adventitious agent assays– adult & suckling mice, and guinea pigs to EP Sec 2.6.16
19.010	General Safety Test (USP) *Subcontracted test*
19.011	In vivo assay for detection of adventitious agents on animals (adult and suckling mice). According to European Pharmacopoeia (§5.2.3) but excluding assay on eggs. *Subcontracted test*
19.012	In vivo assay for detection of adventitious agents on animals – adult & suckling mice, embryonated eggs as outlined in ICH Q5A. Test compliant with the current version of the European Pharmacopoeia (§5.2.3) and USP C 1050. *Subcontracted test*
19.013	In vivo assay for detection of adventitious agent on animals – adult & suckling mice, embryonated eggs and guinea pigs as outlined in ICH Q5A. *Subcontracted test*
19.014	In vivo assay for detection of adventitious agent on animals (adult & suckling mice, guinea pigs and embryonated eggs) according to FDA "Guidance for Industry" (2010) guidelines. *Subcontracted test*

CODIFICATION	DESIGNATION
19.015	Vaccin Viral Aviaire : Test pour recherche d'agents adventices sur des lots de semences selon la Pharmacopée Européenne §2.6.24 (test pour agents adventices utilisant des œufs embryonnés). *Subcontracted test*
19.016	In vivo assay for detection of adventitious agent on animals - adult & suckling mice and Guinea Pigs according to FDA PTC guidelines *Subcontracted test*
19.017	In vivo assay for detection of adventitious agents on animals (suckling mice). According to European Pharmacopoeia (§5.2.3). *Subcontracted test*
19.018	In vivo adventitious agent assays– suckling mice, embryonated eggs according to EP Sec 5.2.3. *Subcontracted test*
19.019	In vivo assay for detection of adventitious agents on animals (adult & suckling mice, guinea pigs and embryonated eggs) according to FDA "Guidance for Industry" (2010) guidelines and compliant with the current version of the European Pharmacopoeia (§5.2.3). *Subcontracted test*
19.020	In vivo adventitious agent assays (suckling mice) according to the current version of the European Pharmacopoeia (§2.6.16) *Subcontracted test*
19.021	In vivo adventitious agent assays (suckling mice, embryonated eggs) according to the current version of the European Pharmacopoeia (§2.6.16). *Subcontracted test*
19.022	In vivo adventitious agents assays- embryonated eggs to E.P. 5.2.3. *Subcontracted test*
19.023	In vivo tumorigenicity assay according to European Pharmacopoeia (§5.2.3) including cell expansion needed for the assay. *Subcontracted test*
20.	**Other impurities and gene therapy process**
20.001	Residual BSA quantification by ELISA method: qualification of sample working dilutions and measurement
20.002	Residual BSA quantification by ELISA method: routine testing for the measurement on a previously qualified sample (Ref. 20.001).
20.003	Residual Benzonase® Protein quantification by ELISA method: qualification of sample working dilutions and measurement.
20.004	Residual Benzonase Protein quantification by ELISA method: routine testing for the measurement on a previously qualified sample (Ref. 20.003).
20.005	Quantitative PCR method for quantification of sequence of the plasmid gene for kanamycine resistance Qualification and test
20.006	Quantitative PCR method for quantification of sequence of the plasmid gene for VSV-G Qualification and test
20.007	Quantitative PCR method for quantification of sequence of the plasmid gene for HIV-GAG Qualification and test
20.008	Quantitative PCR method for quantification of sequence of the genomic DNA for Adeno E1 Qualification and test
20.009	Quantitative PCR method for quantification of sequence of the genomic DNA for SV40 Qualification and test
20.010	Quantitative PCR method for quantification of sequence of the plasmid gene for HIV-PSI Qualification and test

CODIFICATION	DESIGNATION
20.011	Quantitative PCR method for quantification of sequence of the plasmid gene for kanamycine resistance
20.012	Quantitative PCR method for quantification of sequence of the plasmid gene for VSV-G
20.013	Quantitative PCR method for quantification of sequence of the plasmid gene for HIV-GAG
20.014	Quantitative PCR method for quantification of sequence of the genomic DNA for Adeno E1
20.015	Quantitative PCR method for quantification of sequence of the genomic DNA for SV40
20.016	Quantitative PCR method for quantification of sequence of the plasmid gene for HIV-PSI
20.017	E1a sequence detection by PCR
20.018	Quantitative PCR method for quantification of sequence pol gene of HIV1. Qualification and test
20.019	Quantitative PCR method for detection of sequence of the plasmid gene for kanamycine resistance
20.020	Quantitative PCR method for detection of sequence of the plasmid gene for VSV-G
20.021	Quantitative PCR method for quantification of sequence REP of AAV. Qualification and test
20.022	Quantitative PCR method for quantification of sequence REP of AAV. Routine Testing
21.	**Characterisation / Identity**
21.001a	DNA finger printing (STR) on cells of human origin. Comparison to bibliographic data or reference data. *Subcontracted test*
21.001	DNA finger printing (STR) on cells of human origin *Subcontracted test*
21.009	Species authentication by PCR with 8 to 13 specific species: The standard assay includes detection of 8 to 13 specific species among: human, mouse, rat, hamster, monkey (AGM*), dog, cat, rabbit, horse, duck, chicken, beef, pig. **African green monkey*
21.010	Species authentication by PCR with 2 to 7 specific species: The standard assay includes detection of 2 to 7 specific species among: human, mouse, rat, hamster, monkey (AGM*), dog, cat, rabbit, horse, duck, chicken, beef, pig, insect. **African green monkey*
21.011	Species authentication by PCR for 14 specific species: The standard assay includes detection of 14 specific species: human, mouse, rat, hamster, monkey (AGM*), dog, cat, rabbit, horse, duck, chicken, beef, pig, insect. **African green monkey*
21.056	Species authentication by PCR for 15 specific species : The standard assay includes detection of 15 specific species: human, mouse, rat, hamster, monkey (AGM*, M**), dog, cat, rabbit, horse, duck, chicken, beef, pig, insect. * *African green monkey* ** *Macaca*
21.031	Cells identity test by RAPD-PCR fingerprinting (against a reference profile)
21.034	Cells characterization by RAPD-PCR fingerprinting (Determination of a reference profile)

CODIFICATION	DESIGNATION
21.048	qPCR assay development for the determination of Gene copy number (1 target) : 1) Primers design (3 set of primers) 2) Evaluation of primers performances and selection of a suitable primers set for the assay
21.049	qPCR assay development for the determination of Gene copy number (2 targets) : 1) Primers design (3 set of primers) 2) Evaluation of primers performances and selection of a suitable primers set for the assay
21.050	qPCR based assay for gene copy number determination from cellular sample (1 target) : - Normalization with a reference gene of the host cell to be tested - Gene copy Number determined from 2 independent qPCR assay
21.051	qPCR based assay for gene copy number determination from cellular sample (2 targets) : - Normalization with a reference gene of the host cell to be tested - Gene copy Number determined from 2 independent qPCR assay
21.052	qPCR based assay for gene copy number determination from genomic DNA sample (1 target) : - Normalization with a reference gene of the host cell to be tested - Gene copy Number determined from 2 independent qPCR assay
21.053	qPCR based assay for gene copy number determination from genomic DNA sample (2 targets) : - Normalization with a reference gene of the host cell to be tested - Gene copy Number determined from 2 independent qPCR assay
21.054	Real Time qPCR assay for the determination of VCN (Vector Copy Number)
21.055	qPCR assay development and validation in agreement with ICH Q2(R1) guideline for the determination of Gene copy number (1 target = “test” gene) by quantitative real-time PCR with SYBRGreen technology. 1) Primers design (3 set of primers) 2) Evaluation of primers performances and selection of a suitable primers set for the assay 3) Validation of accuracy, precision, specificity and linearity (range) of the assay
	Caryotype et fish
21.002a	Feasibility study on cell line : - checking that culture condition allow proliferation of cells - checking of the anysable number of metaphases - checking of the chromosome quality (spreading and size) - checking of G-banding staining quality (optional, depending of cell model)
21.002b	Customized feasibility study on specif cell models : - checking that culture condition allow proliferation of cells - checking of the anysable number of metaphases - checking of the chromosome quality (spreading and size) - checking of G-banding staining quality (optional, depending of cell model)
21.005	Karyotype analysis on 50 metaphases : - ploidy level and modal chromosome number determination. *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.

CODIFICATION	DESIGNATION
21.006I2	Karyotype study on 1000 metaphases. - ploidy level & modal chromosome number determination on 950 metaphases - ploidy level & modal chromosome number and structural chromosome aberration determination on 50 metaphases *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.007I2	Karyotype study on 500 metaphases. - ploidy level & modal chromosome number determination on 450 metaphases - ploidy level & modal chromosome number and structural chromosome aberration determination on 50 metaphases *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.024	Karyotype analysis on 20 metaphases by G-banding : - ploidy level and modal chromosome number determination - determination of structural chomosome aberrations *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.025	Karyotype analysis on 30 metaphases by G-banding : - ploidy level and modal chromosome number determination - determination of structural chomosome aberrations Note: The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.026	Karyotype analysis on 50 metaphases by G-banding : - ploidy level and modal chromosome number determination - determination of structural chomosome aberrations *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.029	Karyotype study on 100 metaphases : - ploidy level & modal chromosome number determination on 95 metaphases - ploidy level & modal chromosome number and structural chromosome aberration determination on 5 metaphases *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.030	Karyotype study on 105 metaphases (according to the WHO Technical Report Series No. 978) : - ploidy level & modal chromosome number determination on 100 metaphases - ploidy level & modal chromosome number and structural chromosome aberration determination on 5 metaphases *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.035	Karyotype analysis on 100 metaphases : - ploidy level and modal chromosome number determination *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.036	Karyotype study on 100 metaphases : - ploidy level & modal chromosome number determination on 80 metaphases - ploidy level & modal chromosome number and structural chromosome aberration determination on20 metaphases *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.037	Thawing , culture and fixation of non-genetically modified human T lymphocytes
21.038	Thawing of UCART cells and activation

CODIFICATION	DESIGNATION
21.058	Identity test of CSEh - cell phenotype analysis by flux cytometry (FACS)
21.059	Characterization of keratinocytes - Detection of CSEh by flux cytometry (FACS)
21.060	Identity test of keratinocytes - cell phenotype analysis by flux cytometry (FACS)
21.061	Detection of structural aberrations and gene rearrangements using the FISH (fluorescent in situ hybridization) method.
21.062	Detection of aneuploidies using the FISH (fluorescent in situ hybridization) method.
21.064	Karyotype analysis on 100 metaphases by G-banding : - ploidy level and modal chromosome number determination - determination of structural chomosome aberrations *Note* : The analytical method is limited by the number of metaphases. If the target metaphase number is not achieved, the conclusion would be based on reduced number of metaphases.
21.070	Identity Assay by analysis of positive pluripotency markers by RTqPCR (analysis of 2 markers)
21.071	Identity Assay by analysis of positive pluripotency markers by FACS (analysis of 2 markers)
	Other analyses
21.012	Morphology and doubling time
21.014	FACS analysis with one antibody (antibody supply cost not included)
21.016	Titration of interferon alpha. Titration of anti-viral activity using A549 cells and EMC virus according to European Pharmacopoeia (§ 5.6)
21.018**a**	Quantification of the telomerase activity
21.018**b**	Quantification of the telomerase activity using Roche kit
21.018**c**	Telomerase testing of EB66 cells using the TELOTAGGG kit (Roche) including: - Validation of the cellular positive controls provided with the kit - Generation and validation of additional cellular positive controls (STO and HuH7) - Routine GMP testing on one sample - Cost of one kit
21.032G2	Routine immunosuppression assay
21.063	PCR test for detection of specific sequence of pCAS9
21.065	Report for sequencing in non-regulatory grade *Subcontracted service*
21.067	Sanger sequencing: Price for 2-fold sequencing of **100 bp** – this service is outsourced
21.068	Sanger sequencing: Price for 4-fold sequencing of **100 bp** – this service is outsourced
21.069	PCR product migration
21.072	Study management of sequencing project (including sample preparation and shipment to subcontractor). Price per sample tested in one study. This test is subcontracted to a GMP partner with the issue of a certificate of Analysis (CoA).

CODIFICATION	DESIGNATION
21.073	PCR test for detection of specific sequence of pgRNA
21.074	Validation of primers used for sequencing activity. Price for 2-fold sequencing of 100 bp. This service is outsourced. This test is subcontracted to a certified GMP partner with the issue of a certificate of analysis.
22.	**Process validation**
22.001	Fertility test on agarose medium
22.002	Fertility test on liquid medium
23.	**Production**
	Production of frozen cells
23.001	Customised cell production of secured cell banks (depending on cell type and number of vials to be produced)
23.002	Customised cell production of 3 vials + 1 free test vial (1 to 5 million cells per vial)
23.003	Customised cell production of 5 vials + 1 free test vial (1 to 5 million cells per vial)
23.004	Customised cell production of 10 vials + 1 free test vial (1 to 5 million cells per vial)
23.005	Customised cell production of 15 vials + 1 free test vial (1 to 5 million cells per vial)
23.006	Customised cell production of 20 vials + 1 free test vial (1 to 5 million cells per vial)
23.007	Customised cell production of 25 vials + 1 free test vial (1 to 5 million cells per vial)
23.008	Customised cell production of 30 vials + 1 free test vial (1 to 5 million cells per vial)
23.008aI2	First batch of production of 30 vials (5x106 cells by vial) + 1 vial for testing and mycoplasma detection
23.008bI2	2nd batch of production of 30 vials (5x106 cells by vial) + 1 vial for testing and mycoplasma detection
23.009	Customised cell production of 40 vials + 1 free test vial (1 to 5 million cells per vial)
23.010	Customised cell production of 50 vials + 1 free test vial (1 to 5 million cells per vial)
23.011	Pilot study for a cell bank production
23.012	GMP Campaign MCB production (100 vials - up to 10 millions cells/vial) over three weeks period
23.013	GMP Campaign MCB production (additional vial)
23.014	GMP Campaign WCB production (100 vials - up to 10 millions cells/vial) over three weeks period
23.015	GMP Campaign WCB production (additional vial)
23.016	Optional: Additional week of GMP production
23.017	Reservation fee for GMP compliant manufacturing of cell bank or Virus seed
23.018	Environmental additional controls in C Class by : - particular and microbial analysis (biocollector, flow plate and contact plate)
23.019	Environmental additional controls in A Class A by: - particular and microbial analysis by biocollector (start and end of the handling), operator controls (touch gloves), flow plate and contact plate.
	Production of growing cells
23.101	Customised production of growing cells (depending on cell quantity and production system specifications)
23.201	GMP production of Master Virus Bank

CODIFICATION	DESIGNATION
23.201I2	Production of a virus bank non GMP compliant
23.102	Customised production of growing cells - 1 flask of 25cm²
23.103	Customised production of growing cells - 1 flask of 75cm²
23.104	Customised production of growing cells - 1 flask of 150cm²
23.105	Customised production of growing cells - 2 flasks of 150cm²
23.106	Customised production of growing cells - 3 flasks of 150cm²
23.107	Customised production of growing cells - 4 flasks of 150cm²
23.108	Customised production of growing cells - 5 flasks of 150cm²
23.109	Customised production of growing cells - 10 flasks of 150cm²
23.110	Customised production of growing cells - 15 flasks of 150cm²
23.111	Preparation of growing cells - 20 F150
	Production of frozen virus
24.	**Biobanking**
	Non dedicated storage (secured tank)
24.001I2	Access fee for deposit in shared container in liquid nitrogen or -80°C per bank. Until 10 banks in the same shipment
24.001G2	Access fee for deposit in shared container for GMP grade storage (liquid nitrogen in vapor phase or -80°C) per bank – for the first 10 banks in the same shipment
24.002I2	Monthly rental fee / vial (shared storage in liquid nitrogen)
24.003G2	Exit fee for GMP shared storage (liquid nitrogen in vapor phase or -80°C) per bank per shipment
24.003I2	Exit fee for shared storage (liquid nitrogen or -80°C) per bank per shipment.
24.009G2	Annual cost for GMP shared storage in liquid nitrogen in vapor phase per standard box (13x13x5cm)
24.018I2	Shared storage at minus 80 degrees (cost per box per year). Standard box (13 cm x 13 cm x 5 cm)of 81 or 100 vials of 2 mL
24.018G2	Annual cost for GMP Shared storage at minus 80 degrees per standard box (13x13x5cm)
24.019I2	Customised storage
24.019G2	Customised storage
24.029G2	Annual cost for GMP Shared storage at minus 80 degrees. Area storage allocated equivalent to one shelf in a shared container.
24.030I2	Annual cost for Shared storage at minus 20 degrees. Area storage allocated equivalent to one shelf in a shared container.
24.030G2	Annual cost for GMP Shared storage at minus 20 degrees. Area storage allocated equivalent to one shelf in a shared container.
24.031G2	Annual cost for GMP Shared storage at +5°C ±3°C per standard box (13x13x5cm)
24.032G2	Annual cost for GMP Shared storage at at minus 80 degrees per box (13,3x13,3x9,5cm)
24.033G	Package for the transfer of vials until 5 Clean Cells standard size boxes (13x13x5 cm). *Note* : for GMP storage, different samples cannot be gathered in a same box.
24.034G2	Additional costs for dividing the storage at two enclosures
	Dedicated storage (specific tank)
24.004I2	Access fee for deposit in dedicated container in liquid nitrogen or -80°C per bank (per box of 100 vials maximum). Until 10 banks in the same shipment.

CODIFICATION	DESIGNATION
24.004G2	Access fee for deposit in GMP dedicated container in liquid nitrogen or -80°C per bank (per box of 100 vials maximum) Until 10 banks in the same shipment.
24.005	Monthly rental fee / vial (dedicated storage)
24.005aI2	Annual cost for dedicated storage in container of small size in liquid nitrogen (2000 vials) or liquid nitrogen in vapor phase (1600 vials)
24.005aG2	Annual cost for GMP dedicated storage in container of small size in liquid nitrogen (2000 vials) or vapor of liquide nitrogen (1600 vials)
24.005bI2	Annual cost for dedicated storage in container of medium size in liquid nitrogen (4800 vials) or liquid nitrogen in vapor phase (4200 vials)
24.005bG2	Annual cost for GMP dedicated storage in container of medium size in liquid nitrogen (4800 vials) or vapor of liquid nitrogen (4200 vials)
24.005cI2	Annual cost for dedicated storage in container of large size in liquid nitrogen (6000 vials) or liquid nitrogen in vapor phase (5400 vials)
24.005cG2	Annual cost for GMP dedicated storage in container of large size in liquid nitrogen (6000 vials) or vapor of liquid nitrogen (5400 vials)
24.007	Report (1/year) for storage in liquid nitrogen (liquid or vapor phase) or -80°C
24.035	Report (1/year) for storage in liquid nitrogen (liquid or vapor phase) or -80°C for 2 enclosures divided storage
24.008G2	Exit fee for dedicated storage per cell bank (per group of 1 to 10 vials)
24.008I2	Exit fee for dedicated storage (liquid nitrogen or -80°C) per bank
24.013G2	Container qualification according to client specifications
24.016	Bank destruction
24.020I2	Annual cost for dedicated storage at -80°C (until 4 shelves)
24.020G2	Annual cost for GMP dedicated storage at -80°C (until 4 shelves)
24.021	Standard Qualification of a container for GMP storage: - Setting up Qualification - Operational Qualification * Follow up of evaporation of liquid nitrogen over 1 month minimum * Temperature stability * Temperature increase (simulation of opening of container due to activity) * Follow up of temperature : Measurement at two points * Alarm for the temperature probe If the sponsor wish to add some other qualification parameters to those usually performed, there will be a cost related to the additional work performed.
24.024	Report for transfer between two containers in Clean Cells site
24.025	Annual fee for storage (including maintenance and service) at -150 degrees Celsius (cost per freezer) for a minimum storage of 5 years
24.026	Access fee for deposit in dedicated freezer (in GMP) per bundle for storage for dedicated storage
25.	**Sample preparation prior testing**
25.001	Cell thawing and culture (2 passages or around 7 days)
25.002	Preparation of sample by cell culture amplification

CODIFICATION	DESIGNATION
25.003	Viability test after thawing performed on vials collected at 3 different points during the filling
25.004	Preparation and extraction of DNA for the detection of mycoplasma or other bacterial contaminants on cell-free samples (serum, plasma, microsomes, etc.): Centrifugation step up to 200 ml.
25.005	Preparation and DNA extraction for the detection of mycoplasma and bacterial contaminants on acellular sample (serum, plasma, microsomes, …) : centrifugation step on a sample volume between 200mL and 500mL.
25.006	Preparation and extraction of nucleic acids for the detection of virus in acellular samples (serum, plasma, microsomes…)
25.007	Vivaspin ultrafiltration
25.008	Preparation and extraction of nucleic acids for the detection of virus in tissular samples
25.009	Feasibility study Determination of suitable extraction condition for nucleic acids (RNA or DNA) 2 evaluated methods
25.010	Thawing and culture of sample from the production cell bank (microscopy analysis with photography before and after Giemsa staining, determination of doubling time and observation of polynucleated cells and others cells abnormalities) 15 days culture without antibiotics
25.011	Preparation of sample
25.012	Recovery assay: Viability and cell number determination after thawing of each single vial + determination of viability cell density after 4 days of culture (reference is valid upto 3 cryovials of a single bank)
25.013	Cell count - Viability
25.014	Feasibility study in order to evaluate the DNA extraction process efficiency for 1 product as a prerequisite for a GMP study. Evaluation of a maximum of 3 experimental conditions. - Management of the study - Experiments (Extraction genetic material, PCR runs) - Result analysis and review - Generation of Report and review by RCQ
25.015	Feasibility study in order to evaluate the RNA extraction process efficiency for 1 product as a prerequisite for a GMP study. Evaluation of a maximum of 3 experimental conditions. - Management of the study - Experiments (Extraction genetic material, PCR runs) - Result analysis and review - Generation of Report and review by RCQ
26.	**Other services**
26.001	“Good Cell Culture Practices” training over 2 days / delegate Max. 4 persons (accommodation and meals included)
26.002	“Good Cell Culture Practices” training on site / 2 days Max. 10-15 persons (accommodation and meals excluded)
26.003	Contract R&D program

CODIFICATION	DESIGNATION
26.005	Consulting service - daily rate
26.026	Custom Project Management – Full time equivalent per hour
26.027	Custom Project Management – Full time equivalent per day
26.006	Supply of a cell line from ATCC and realization of mycoplasma test (test offered by Clean-Cells)
26.007	Measurement of ADCC activity using Chromium 51, one sample + one reference antibody
26.008	Measurement of ADCC activity using Chromium 51, for each additional sample (max 6 additional samples)
26.011	Measurement of ADCC activity using exclusive luminescence method, one sample + one reference antibody
26.012	Measurement of ADCC activity using exclusive luminescence method, for each additional sample (max 6 additional samples)
26.013	Purchase of a virus model
26.014	5 vials of CD16 T cell effector cells 20x10e6 cells / vial
26.015	10 vials of CD16 T cell effector cells 20x10e6 cells / vial
26.016	20 vials of CD16 T cell effector cells 20x10e6 cells / vial
26.017	50 vials of CD16 T cell effector cells 20x10e6 cells / vial
26.018	Measurement of CDC activity using Chromium 51, one sample + one reference antibody
26.019	Measurement of CDC activity using Chromium 51, for each additional sample (max 6 additional samples)
26.020	Measurement of CDC activity using exclusive luminescence method, one sample + one reference antibody
26.021	Measurement of CDC activity using exclusive luminescence method, for each additional sample (max 6 additional samples)
26.022	1 vial of CD16 T cell effector cells 20x10e6 cells / vial
26.023	Purchase of bacteria strains
26.024	Purchase of medium and reagents
26.025	Purchase of virus strain
26.030	Measurement of transfection efficiency by flow cytometry
27.	**Development**
	Qualification/ validation of PCR method under ISO or GMP conditions
27.001	Development of contaminant (bacteria, virus) specific PCR test
27.002	Development of contaminant (bacteria, virus) specific RT-PCR test
27.004a	**Simple Qualification on 1 batch** Determination of the preparation and extraction process in 1 experiment - Crude or diluted sample + spike with nucleic acids (x1 replicate) or endogenous target The experiment is performed once - Interference study, checking of the absence of inhibitory effects
27.004b	**Extended Qualification on 1 batch** Determination of the preparation and extraction process in 1 experiment - Sample + spike 1 with nucleic acids + spike 2 with targeted contaminants (x3 replicates) The experiment is performed once - Determination of the status "mycoplasma-free" of the sample - Interference study, checking of the absence of inhibitory effects **Conclusion on the sample suitability for the detection process**

CODIFICATION	DESIGNATION
27.005	**Validation -first level on 1 batch** Determination of the LOD in 3 experiments - Sample + spike 1 with nucleic acids + spike 2 with targeted contaminants (x8 replicates) The experiment is performed 3 times with 2 different operators - Determination of the status "mycoplasma-free" of the sample - Interference study on the sample **Validation of the LOD for the sample**
27.006	**Validation - second level on 3 batches** Determination of the LOD in 3 experiments - Sample (batch 1) + spike 1 with nucleic acids + spike 2 with targeted contaminants (x8 replicates) - Sample (batch 2/3) + spike 1 + spike 2 (x3 replicates) The experiment is performed 3 times with 2 different operators for the batch 1 (ie 24 determinations) and once for each of the other batches (3 determinations per batch) - Determination of the status "contaminant-free" of the sample - Interference study on the sample **Validation of the LOD for the sample and Inter-batch complementary study**
27.007	**Validation - third level on 3 batches** Full LOD determination in 3 experimentations - Sample + spike 1 with nucleic acids + spike 2 with targeted contaminants (x8 replicates) The experiment repeated 3 times with 2 different operators for each batch of sample (ie 3x24 determinations with 2 operators) - Determination of the status "contaminant-free" of the sample - Interference study on the sample **Validation of the extended LOD for the sample**
	Qualification/ validation of mycoplasma detection by indirect culture
27.008	Test for absence of interference of sample for mycoplasma detection assay by indirect culture : C neg, C pos (Mh), C pos (Mo), C inh (sample + Mh) and C inh (sample + Mo). Assay with one sample dilution. Feasibility report included.
27.009	Validation of mycoplasma test by indirect culture (indicator cells) for sample for human use according to European Pharmacopoeia (§2.6.7), US Pharmacopoeia (USP 63), FDA 21CFR610.30 and PTC1993 et 1997. Validation limited to detection of absence of interference effects. Test performed on 3 samples lots. Validation report included.
27.010	Validation of mycoplasma test by indirect culture (indicator cells) for sample for human use according to European Pharmacopoeia (§2.6.7), US Pharmacopoeia (USP 63), FDA 21CFR610.30 and PTC1993 et 1997. Validation for detection of absence of interference effects including the mycoplasma test results. Test performed on 3 samples lots. Validation report included.
	Qualification/ validation of mycoplasma detection by direct culture

CODIFICATION	DESIGNATION
27.011	Test for absence of interference of sample for mycoplasma detection assay by direct culture according to European Pharmacopoeia (§2.6.7), US Pharmacopoeia (USP 63) and PTC1993 et 1997: µareobie - C neg, C pos (Mp), C pos (Ma), C inh (sample + Mp) and C inh (sample + Ma). Anaerobie - C neg, C pos (Mo), C inh (sample + Mo) Assay with one sample dilution. Inoculation 10mL in 100 mL. Feasibility report included.
27.012	Validation of mycoplasma test by direct culture for sample for human use according to European Pharmacopoeia (§2.6.7), US Pharmacopoeia (USP 63), and PTC1993 et 1997. Validation limited for detection of absence of interference effects. Test performed on 3 samples lots. Validation report included.
27.013	Validation of mycoplasma test by direct culture (indicator cells) for sample for human use according to European Pharmacopoeia (§2.6.7), US Pharmacopoeia (USP 63), FDA 21CFR610.30 and PTC1993 et 1997. Validation for detection of absence of interference effects including the mycoplasma test results. Test performed on 3 samples lots. Validation report included.
27.017	Validation of the mycoplasma test by direct and indirect culture according to European pharmacopoeia (§2.6.7) and US Pharmacopoeia (USP63). Validation of the method on the sponsor'product. This validation include the detection of interference and inhibitory effects of the sample versus positives controls used. 3 lots tested. Inoculation 10 mL sample in 100 mL of culture medium. The Bulk Harvest samples are processed without centrifugation step for the M. Pneumoniae test in direct culture. The control strains used for the indirect culture : M.Orale and M.Hyorinis - The control strains used for the direct culture are : * Micro-aerobic conditions : M. Arginini (or M.Orale if possible) and M.Pneumoniae * Anaerobic conditions : M.Orale Including a validation protocol and report
	Qualification/ validation of adventitious agent detection using indicator
27.014	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects and hemagglutination effects. In vitro assay (14 days)according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. Including assay with human erythrocytes.
27.015	Cytopathogenic effects on MRC-5 and VERO target cell lines and on cell line of the same origin. Hemadsorption effects and hemagglutination effects. In vitro assay (14 days)according to European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. Including assay with human erythrocytes
27.016	Validation of test for detection of cytopathic effects on cell lines MRC5, VERO, a cell line of the same origin that the test article and a complementary cell line. Detection of Hemadsorption and hemagglutination effects (in vitro 28 days assay) according to the European Pharmacopoeia (§5.2.3 and 2.6.16) and FDA 9CFR113.52. The validation include the detection of interference effects of the sample verus the positif controls used. Test performed on 3 sample lots. Validation protocol and report included
27.017	Validation of the sterility test for cell products for therapeutic use in compliance with European Pharmacopoeia §2.6.27 using Bact'alert system. This validation will be performed in presence of the sample. A protocol and a validation report for this validation phase will be issued by Clean Cells. Validation performed in triplicate, with 9 control strains, and determination of LOD between 10 - 100 CFU.

CODIFICATION	DESIGNATION
28.	**Adventitious agent detection by PCR**
28.001	Contaminant (bacteria, virus) specific PCR test
28.002	Contaminant (bacteria, virus) specific RT-PCR test
29.	**Bacteriophages**
29.001	Filter integrity test by bubble point method
29.002	Quantification of total protein by BCA assay - assay according to the European Pharmacopoeia (§ 2.5.33)
29.003	Bacteriophage titration
29.004	pH Determination - assay according to the European Pharmacopoeia (§ 2.2.3)
29.005	Detection of anti-E.coli bacteriophages in an acellular sample. Qualification and test of the sample on 4 E.coli strains permissive to the anti-E.coli bacteriophages. - Culture step of the sample in E.Coli bacterial solution. - Titration on plate of bacteriophages in the sample before and after cultivation step.
29.006	Visual aspect observation of a solution. 1) Clarity and degree of opalescence of solution - assay according to the European Pharmacopoeia (§ 2.2.1) 2) Degree of coloration of liquids - assay according to the European Pharmacopoeia (§ 2.2.2)
29.007	Particulate Matters (EP 2.9.19 USP <788>) *Subcontracted test*
29.008	Osmolality (EP 2.2.35)
29.009	Extractable volume by gravimetry (EP 2.9.17) *Subcontracted test*
29.011	Detection and quantification of phage by qPCR (panel of 3 phages)
29.013	Identity test of phage by qPCR (panel of 5 phages)
29.014	Identity and quantification test of phage by qPCR (panel of 5 phages)
30.	**Transport** *Prices provided as a guide and that may be reassessed regarding the transportor price list*
30.002	Transport of biological samples in dry ice in France TSE - Box 8L
30.003	Transport of biological samples in dry ice in France TSE - Box 15L
30.004	Transport of biological samples in dry ice in France TSE - Box 49L

CODIFICATION	DESIGNATION
30.005	Transport of biological samples +5°C +/- 3°C in France TSE - Box 4L
30.006	Transport of biological samples +5°C +/- 3°C in France TSE - Box 8L
30.007	Transport of biological samples +5°C +/- 3°C in France TSE - Box 15L
30.008	Transport of biological samples +5°C +/- 3°C in France TSE - Box 49L
30.009	Transport of biological samples in ambient temperature in France TSE - Box 4L
30.010	Transport of biological samples in ambient temperature in France TSE - Box 8L
30.011	Transport of biological samples in ambient temperature in France TSE - Box 15L
30.012	Transport of biological samples in ambient temperature in France TSE - Box 49L
30.013	Transport of biological samples in a dry-shipper (nitrogen vapor) in France
30.014	Transport of biological samples in Europe (EU) in dry ice Cryo Express
30.015	Transport of biological samples in Europe (EU) in a dry-shipper (nitrogen vapor)
30.016	Transport of biological samples outside of the EU in dry ice
30.017	Transport of biological samples outside of the EU in a dry-shipper (nitrogen vapor)
30.018	Documentation management for the **export** of biological materials - outside of the EU
30.019	Documentation management for the **export** of biological materials and documentation on the protection of animal species - outside of the EU (DDPP + CITES)
30.020	Documentation management for the **import** of biological materials - outside of the EU (DDPP)
30.021	Documentation management for the **import** of biological materials and documentation on the protection of animal species - outside of the EU (DDPP + CITES)
30.022	Temperature recorder - TSE
30.023	Shipment cost of biological samples for 24h delivery at 4°C - TSE
30.024	Shipment cost of biological samples using dry ice within Europe - QUICKSTAT
30.025	Shipment documentation management for the export of biological materials and documentation on the protection of animal species - outside of the EU
30.026	Management of samples shipment in France
30.027	Custom taxes
31.	**Documentation management**
31.001A	Setting of a fast track management of the documentation per test (price of test < 5000 €)
31.001B	Setting of a fast track management of the documentation per test (price of test > 5000 €)
31.002	Setting of a customized SDS per test
31.003	Writing of a protocol and a report for a feasibility study
31.004	Writing of intermediate report of analysis (IR)
31.005	Cost for any major modifications out of the standard documents : Technical Protocol and Certificate of Analysis
32.	**Additional services**
32.001	Mobilisation of technical staff during the weekend and/or bank holidays. Price of half a working day