

Scope of Services

This scope of services reflects the PEI's inhouse test methods that are continuously updated within the framework of flexible accreditation granted by the German Accreditation body DAkkS. In addition test methods are highlighted which are reviewed by the EDQM in the Mutual Joint Audit. For complete external traceability, the document also contains the former document keys in addition to the current ones. The internal expertise on specific test methods of research functions is not covered by this list in total. Testing fields highlighted with ** allow the modification and development of test assays validated and accredited by DAkkS through conformity assessments. This means that newly validated methods in flexibly accredited areas shall not be considered as accredited before a successful internal audit has been conducted on the new method involved and no further deviations have been established, i.e. any possible deviations have been eliminated.

Testing field – Chemical and physical analytics of medicinal products and active pharmaceutical ingredients

1 Photometry **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00301_R1	Assay for poly-ribosyl-ribitolphosphate: assay for ribose (orcinol test)	1/2-A-020	Photometer	Haemophilus influenzae Type B Vaccines	2007	
QM-00302_R1	Resorcinol Assay	1/2-S-052	Photometer	Pneumococcal conjugate vaccine (monovalent bulks)	2010	
QM-00322_R1	Nephelometry for measuring antigen content	1/2-S-058	Nephelometer	Multivalent pneumococcal polysaccharide conjugate vaccine from 10 different polysaccharides of different serotypes of S. pneumoniae	2016	2022

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00330_R2	O-Acetyl determination of Meningococcal vaccines	1/2-S-069	Photometer	Meningococcal vaccines (monovalent Bulks)	2022	
QM-00001_R3	Protein determination using the optical method at 280 nm	3/1-A-004	Photometer	Immunglobulins	2001	2022
QM-00004_R2	Colorimetric determination of the Formaldehyde content	3/1-A-007	Photometer	Test and Therapy Allergens, Immunglobulins and Vaccines	2008	
QM-00005_R2	Colorimetric determination of the phenol content	3/1-A-008	Photometer	Test and Therapy Allergens, Antitoxins, Immunoserum, Vaccines	2002	
QM-00029_R2	Total protein by BCA	3/1-A-162	Photometer	Vaccines	2010	
QM-00192_R1	Protein Determination I according to Bradford; Range: 25 µg/ml- 300 µg/ml	5/1-A-001	Photometer	Test and Therapy Allergens	2007	2022
QM-00193_R1	Protein Determination II according to Bradford; Range: 200 µg/ml - 1,000 µg/ml	5/1-A-002	Photometer	Test and Therapy Allergens	2007	2022
QM-00204_R1	Protein Determination I according to Kjeldahl; Range: 2,5 - 40 µg/ml	5/1-A-034	Photometer (AutoAnalyzer)	Test and Therapy Allergens	2012	2022
QM-00205_R1	Protein Determination II according to Kjeldahl; Range: 30 - 1000 µg/ml	5/1-A-035	Photometer (AutoAnalyzer)	Test and Therapy Allergens	2012	2022
QM-00210_R1	Hyaluronidase-Activity test	5/1-A-040	Photometer	Test and Therapy Allergens (bee and wasp venom preparations)	2014	2022

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00230_R1	Factor XIII-potency determination	7/3-A-003	Automatic coagulator	Factor XIII concentrates, Fibrin Sealants	2006	2022
QM-00238_R1	Determination of Fibrinogen as clottable protein by Biuret-reaction	7/3-A-014	Photometer	Fibrin Sealants	2012	2022
QM-00249_R1	Determination of Fibrinogen quantity in sealing matrices	7/3-A-038	Photometer	Fibrin Sealants	2021	2022
QM-00252_R1	Determination of Ristocetin-Cofactor-Activity of von-Willebrand-Factor using the coagulation analyzer BCS-XP	7/3-A-063	Automatic coagulator	Factor XIII concentrates, vWF concentrates	2019	2022
QM-00253_R1	Protein determination according to biuret in microplate reader and in coagulation analyzer BCS-XP	7/3-A-064	Photometer	Albumines, Plasma	2008	

2 High Performance Liquid Chromatography (HPLC) **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00011_R1	Molecular size distribution	3/1-A-032	HPLC	Immunoglobulins Monoclonal Antibodies	2001	2022

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QM-00247_R2	HPLC: Gel-filtration chromatography for albumins	7/3-A-033	HPLC	Albumins	2017	2022
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3 Potentiometry **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00008_R1 and QM-00034_R1	pH - determination	3/1-A-025 and 3/1-A-180	pH meter	Determination of Tri-n-butyl phosphate by gas chromatography	2001	
QM-00021_R1	Potentiometric determination of the chloride content	3/1-A-114	Automatic Titrator	Determination of Tri-n-butyl phosphate by gas chromatography	2004	

4 Gas Chromatography **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00023_R1	Determination of Tri-n-butyl phosphate by gas chromatography	3/1-A-121	Gas chromatography	Immunglobulins	2010	

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5 Agar diffusion test **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00096_R1	Influenza SRD test	2/1-A-007	Transmitted light scanner	Inactivated influenza vaccines	2002	

6 Electrophoresis **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00019_R1	SDS Electrophoresis	3/1-A-096	Elektrophoresis unit	Immunoglobulins, monoclonal Antibodies	2004	
QM-00027_R2	Protein composition by capillary zone electrophoresis of serum proteins and immunoglobulins	3/1-A-144	Capillary electrophoresis	Immunosera und Immunoglobulins	2010	2022
QM-00037_R1	Purity: Protein composition by zone electrophoresis	3/1-A-194	Elektrophoresis unit	Immunoglobulins (human)	2003	
QM-00201_R1	Identification of allergen extracts by SDS PAGE	5/1-A-030	Elektrophoresis unit & imager	Test and Therapy Allergens	2004	2022
QM-00203_R2	Isoelectric Focusing (IEF) of proteins in modified allergens extracts	5/1-A-033	Elektrophoresis unit & Imager	Therapy Allergens	2004	2022

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7 Osmometry **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00003_R1	Cryoscopic determination of osmolality	3/1-A-006	Osmomat	Albumin and immunoglobulin containing products, sera, immunosera, vaccines ad.us.hum and ad. us.vet.	2001	

8 Rheology **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00145_R1	Rotating viscosimeter method	4/3-S-061	Viscosimeter	Vaccines ad.us.vet.	2010	

9 Emmissionsspectrometry with inductive linked plasma **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00043_R1	Determination of aluminium with ICP-OES	3/1-A-202	ICP-OES	Allergens and vaccines	2021	

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10 Visual Inspections **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00314_R2	Appearance testing of vaccines	1/2-S-032	Apparatus for visible particles	Polycaccharide vaccines and adsorbed vaccines	2016	2022
QM-00349_R1	Appearance testing of Vaxchora samples	1/3-S-015	Petri dish, white and black background	Cholera vaccines	2021	
QM-00211_R1	Particle-size analysis by laser light diffraction	5/1-A-041	Laser diffractometer	Therapy Allergens	2019	2022

11 Refractive index **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00209_R1	Determination of refractive index of glycerine-containing Test and Therapy Allergens	5/1-A-039	Refractometer	Test and Therapy Allergens	2019	2022

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Testing field – Biological analytics of medicinal products, active pharmaceutical ingredients and excipients

12 Microbiological potency determination **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00317_R1	Sandwich ELISA (free poly-ribitol-ribosylphosphate)	1/2-S-041	ELISA Reader	Haemophilus influenzae Typ B Vaccines	2007	
QM-00318_R1	Sandwich ELISA: Assay for free pneumococcal polysaccharide	1/2-S-054	ELISA Reader	Pneumococcal conjugate vaccine (monovalent bulks)	2010	
QM-00325_R2	Multiplex-Immunoassay by MSD U-PLEX®	1/2-S-066	Multiarray ECL reader	Toxoid and combined vaccines: diphtheria, tetanus and pertussis	2020	2022
QM-00329_R2	Efficacy of DTaP-Vaccines	1/2-S-068	Multiarray ECL reader	Toxoid and combined vaccines: diphtheria, tetanus and pertussis	none	2022
QM-00347_R1	Live bacteria count	1/3-S-013	Colony count (visual)	Cholera Vaccine	2021	
QM-00093_R1	IPV ELISA Method B	2/1-A-002	ELISA Reader	IPV Vaccines	2019	
QM-00094_R1	HAV ELISA Method B	2/1-A-003	ELISA Reader	Hepatitis A Vaccine	2005	
QM-00095_R1	HAV ELISA Method A	2/1-A-004	ELISA Reader	Hepatitis A Vaccines	2017	2022
QM-00098_R1	Hepatitis B ELISA Method A	2/1-A-023	ELISA Reader	Hepatitis B Vaccines	2007	
QM-00099_R1	HPV-16 und HPV-18 ELISA Method A	2/1-A-026	ELISA Reader	Human Papillomavirus Vaccines (HPV): Type 16 und 18	2015	

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00101_R1	Vaccinia Live Virus Vaccines - Titration on embryonated hen's eggs	2/1-A-038	Visual identification of plaques	Vaccinia Live Virus Vaccines	2003	
QM-00109_R1	Indirect immunofluorescence technique for titration of human Rotavirus in Live Vaccines	2/1-A-061	Microscope (Fluorescence microscope)	Rotavirus Live Vaccines	2016	
QM-00110_R1	HPV IVRP-ELISA Method B	2/1-A-062	ELISA Reader	Human Papillomavirus Vaccines, Type 6, 11, 16 und 18	2021	
QM-00062_R1	Anti-Tetanus ELISA	3/1-A-412	ELISA Reader	Anti-Tetanus Immunoglobulins and Immunoserä	2003	
QM-00071_R1	Anti-HBV ELISA	3/1-A-438	ELISA Reader	Anti-HbsAg Immunoglobulins	2006	
QM-00072_R1	Anti-CMV ELISA	3/1-A-439	ELISA Reader	Anti-CMV Immunoglobulins	2005	
QM-00073_R1	Anti-VZV ELISA	3/1-A-440	ELISA Reader	Anti-VZV Immunoglobulins	2017	
QM-00137_R1	RFFIT (rapid fluorescent focus inhibition test)	4/3-S-018	Fluorescence microscope	Anti-Rabies Immunoglobulins	2002	
QM-00138_R1	CCID50 determination: Cell titration for measuring antigen in Live Vaccines ad. us. vet	4/3-S-040	Microscope (Light microscope, Fluorescence microscope)	Live Vaccines ad. us. vet: Canin. Parainfluenza Canin. Parvovirus (CPV) EHV-1 Distemper Live Virus Vaccine	2003 2003 2004 2005	

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
				Lawsonia intracellularis PRRSV BHV Rabies Myxomatosis BVDV	2005 2002 2002 2002 2004 2008	
QM-00139_R2	Hemagglutination inhibition test (HI)	4/3-S-041	Visual assessment	Determination of antibodies against equine influenza strains	2012	2022
QM-00141_R1	Challenge test	4/3-S-044	Visual assessment	Inactivated Rabies Vaccines for human use	2007	
QM-00142_R1	Serum neutralisation test to determine the potency of rabies vaccines for animal use	4/3-S-048	Fluorescence microscope	Inactivated Rabies Vaccines for animal use	2008	
QM-00143_R1	Indirect ELISA to determine anti-erysipelas antibodies	4/3-S-057	ELISA-Reader	Inactivated Erysipelas vaccines	2002	
QM-00149_R1	Live bacteria count: Spatula method	4/3-S-076	Visual assessment	Mycoplasma gallisepticum Live Vaccine Bacterial live vaccines (Salmonella)	2003; 2012; 2004	2022
QM-00153_R1	Titration on embryonated SPF-hen's eggs	4/3-S-083	Visual assessment	Newcastle-disease (ND) Live Vaccines	2002, 2004	2022

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
				Infectious Bursitis (IBD) Live Vaccines Infectious Bronchitis (IB) Live Vaccines		
QM-00155_R1	ND-Antigen-ELISA	4/3-S-085	ELISA-Reader	Inactivated ND Vaccines ad. us. vet	2006	2022
QM-00156_R1	Haemagglutination Inhibition-Test (HI)	4/3-S-086	Visual assessment	Determination of ND antibodies in chicken sera	2007	2022
QM-00157_R1	AE-Antigen-ELISA (Indirect Sandwich ELISA)	4/3-S-087	ELISA-Reader	Aviäre Enzephalomyelitis (AE)-Lebendimpfstoffe	2014	
QM-00158_R1	CCID50 determination: Titration on primary chicken embryo fibroblasts	4/3-S-088	Microscope (Light microscope, Fluorescence microscope)	IBD und MD Lebendimpfstoffe rCP Influenza rCP FeLV rCP Tollwut	2002, 2003 2003 2003 2016	2022
QM-00423_R2	Antigen quantification by AlphaLISA	n.a.	Microplate reader (Luminescence measurement)	Inactivated rabies vaccines for animal use	2022	

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13 Serological determination of potency / content **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00065_R2	Anti-D-Purity, Haemagglutination	3/1-A-426	Visual assessment	Normal human Immunoglobulins	2007	2022
QM-00067_R1	Test for anti-A and Anti-B Haemagglutinins, Haemagglutination	3/1-A-432	Visual assessment	Normal human Immunoglobulins	2014	2022
QM-00194_R1	Western Blot	5/1-A-003	Electrophoresis unit, Western Blot chamber & Imager	Test und Therapy Allergens	2008	2022
QM-00198_R1	Determination of the allergenic activity of test allergens using FEIA inhibition	5/1-A-023	ImmunoCAP device	Test Allergens	2005	2022
QM-00208_R1	Determination of the allergenic activity of therapy allergens using FEIA inhibition	5/1-A-038	ImmunoCAP device	Therapy Allergens	2012	2022

14 Determination of Bacterial Endotoxins **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00344_R1	Bacterial endotoxin test (BET) Routine test (Method A + B) & testing for disturbing factors (gel clot)	1/3-S-008	Visual assessment	Vaccines ad us. hum. and vet. Solutions and media	2001	

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00345_R1	Bacterial endotoxins – kinetic-turbidimetric Method	1/3-S-012	Photometer	Vaccines ad us. hum. and vet. Solutions and media	2019	2022

15 Monocyte activation test **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00338_R1	Monocyte-Activation-Test (MAT), Method B	1/3-S-010	ELISA-Reader	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2022
QM-00339_R1	Dicytokine-(IL-1 β ;IL-6)-ELISA within the scope of MAT	1/3-S-011	ELISA-Reader	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2022

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16 Purity **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00248_R1	Serological identity check	1/3-S-014	Visual assessment	Cholera vaccines	2021	
QM-00144_R1	Purity testing of bacterial life vaccines	4/3-S-060	Visual assessment	Bacterial Life Vaccines	2007	

17 Chromogenic Tests **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00229_R2	Activity of prekallikrein activator- chromogenic test	7/3-A-002	Photometer	Human Albumin	2005	2022
QM-00231_R1	Antithrombin-chromogenic test	7/3-A-006	Photometer	Plasma, Plasmaproteinconcentrates	2004	2022
QM-00235_R1	Protein C activity – chromogenic test	7/3-A-010	Photometer	Protein-C-Concentrates	2007	2022
QM-00244_R1	C1-Inhibitor - chromogenic test	7/3-A-024	Photometer	C1-Inhibitor Concentrates	2006	2022
QM-00256_R1	Alpha 1-Proteinase-Inhibitor chromogenicElastase-Inhibitor-Test	7/3-A-069	Photometer	Alpha1-Proteinase-Inhibitor Concentrates, Plasma	2014	2022

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Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00259_R1	Factor VIII – Chromogenic Test	7/3-A-072	Automatic coagulator	Factor VIII Concentrates, Plasma	2005	2022
QM-00260_R1	Factor X – Chromogenic Test	7/3-A-073	Automatic coagulator	Factor X products	2019	2022

18 Coagulation tests **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00232_R1	Factor IX potency determination	7/3-A-007	Automatic coagulator	Factor IX concentrates, Prothrombincomplex-Concentrates, plasma protein concentrates	2006	2022
QM-00237_R1	Thrombin potency determination	7/3-A-012	Automatic coagulator	Fibrin Sealants	2005	2022
QM-00239_R1	Factor II potency determination	7/3-A-018	Automatic coagulator	Prothrombincomplex-Concentrates	2021	2022
QM-00242_R1	Factor V potency determination	7/3-A-022	Automatic coagulator	Plasma	2005	2022
QM-00246_R1	Factor XI-clotting assay	7/3-A-028	Automatic coagulator	Plasma	2010	2022
QM-00250_R1	Determination of Thrombin in sealing matrices	7/3-A-039	Automatic coagulator	Fibrin Sealants	2021	2022

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19 Amplification techniques **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00350_R1	Proof of deletion of toxin component by PCR	1/3-S-016	PCR-Cycler	Cholera vaccines	2021	
QM-00148_R1	Identity und quantification of equine Influenza strains by qPCR	4/3-S-075	qPCR-Cycler	rCP Influenza vaccines	2020	2022
QM-00150_R1	Detection of Virus contaminations by PCR	4/3-S-079	PCR-Cycler	Poultry Vaccines (CAV and MDV contaminations) Bovine Live Vaccines (BVDV contaminations)	2010 2007	2022