

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_R3	Assay for poly-ribosyl-ribitolphosphate: assay for ribose (orcinol test)	1/2-A-020	Photometer	Haemophilus influenzae Type B Vaccines	2007	---
QM-00302_R2	Resorcinol Assay	1/2-S-052	Photometer	Pneumococcal conjugate vaccine (monovalent bulks)	2010	---
QM-00322_R2	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_R4	O-Acetyl determination of Meningococcal vaccines	1/2-S-069	Photometer	Meningococcal vaccines (monovalent Bulks)	2022	---
QM-00001_R6	Protein determination using the optical method at 280 nm	3/1-A-004	Photometer	Immunglobulins	2001	2022
QM-00004_R3	Colorimetric determination of the Formaldehyde content	3/1-A-007	Photometer	Test and Therapy Allergens, Immunglobulins and Vaccines	2008	---
QM-00005_R4	Colorimetric determination of the phenol content	3/1-A-008	Photometer	Test and Therapy Allergens, Antitoxins, Immunosera, Vaccines	2002	---
QM-00029_R4	Total protein by BCA	3/1-A-162	Photometer	Vaccines	2010	---
QM-00192_R3	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_R3	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_R3	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_R3	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_R3	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_R3	Factor XIII-potency determination	7/3-A-003	Automatic coagulator	Factor XIII concentrates, Fibrin Sealants	2006	2022
QM-00238_R2	Determination of Fibrinogen as clottable protein by Biuret-reaction	7/3-A-014	Photometer	Fibrin Sealants	2012	2022
QM-00249_R2	Determination of Fibrinogen quantity in sealing matrices	7/3-A-038	Photometer	Fibrin Sealants	2021	2022
QM-00252_R3	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_R2	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_R3	Molecular size distribution	3/1-A-032	HPLC	Immunoglobulins Monoclonal Antibodies	2001	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-00247_R4	HPLC: Gel-filtration chromatography for albumins	7/3-A-033	HPLC	Albumins	2017	2022

3 Potentiometry **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00008_R4	pH – determination, manually	3/1-A-025	pH meter	Albumin and immunoglobulin containing products, immunosera, monoclonal antibodies, plasma products, vaccines ad. us. hum and ad. us. vet.	2001	---
QM-00034_R3	pH – determination, automatically	3/1-A-180	pH meter	Albumin and immunoglobulin containing products, immunosera	2021	---
QM-00021_R3	Potentiometric determination of the chloride content	3/1-A-114	Automatic Titrator	Immunglobulins, sera	2004	---

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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_R5	Determination of Tri-n-butyl phosphate by gas chromatography	3/1-A-121	Gas chromatography	Immunglobulins	2010	---

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_R3	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_R2	SDS Electrophoresis	3/1-A-096	Elektrophoresis unit	Immunoglobulins, monoclonal Antibodies	2004	---

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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-00027_R4	Protein composition by capillary zone electrophoresis of serum proteins and immunoglobulins	3/1-A-144	Capillary electrophoresis	Immunosera und Immunoglobulins	2010	2022
QM-00037_R2	Purity: Protein composition by zone electrophoresis	3/1-A-194	Elektrophoresis unit	Immunoglobulins (human)	2003	---
QM-00057_R4	RNA Integrity of BNT162b2	3/1-A-216	Capillary electrophoresis	mRNA vaccines	2022	---
QM-00201_R3	Identification of allergen extracts by SDS PAGE	5/1-A-030	Elektrophoresis unit & imager	Test and Therapy Allergens	2004	2022
QM-00203_R5	Isoelectric Focusing (IEF) of proteins in modified allergens extracts	5/1-A-033	Elektrophoresis unit & Imager	Therapy Allergens	2004	2022

7 Osmometry **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00003_R2	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	---

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8 Rheology **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00145_R3	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_R4	Determination of aluminium with ICP-OES	3/1-A-202	ICP-OES	Allergens and vaccines	2021	---

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_R3	Appearance testing of vaccines	1/2-S-032	Apparatus for visible particles	Polycaccharide vaccines and adsorbed vaccines	2016	2022
QM-00349_R3	Appearance testing of Vaxchora samples	1/3-S-015	Petri dish, white and black background	Cholera vaccines	2021	---

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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-00211_R2	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_R2	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_R2	Sandwich ELISA (free poly-ribitol-ribosylphosphate)	1/2-S-041	ELISA Reader	Haemophilus influenzae Typ B Vaccines	2007	---
QM-00318_R2	Sandwich ELISA: Assay for free pneumococcal polysaccharide	1/2-S-054	ELISA Reader	Pneumococcal conjugate vaccine (monovalent bulks)	2010	---
QM-00325_R3	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_R4	Efficacy of DTaP-Vaccines	1/2-S-068	Multiarray ECL reader	Toxoid and combined vaccines: diphtheria, tetanus and pertussis	---	2022
QM-00331_R4	Bestimmung des Antigengehaltes in Pneumokokkenkonjugatimpfstoffen mittels ELISA	1/2-S-070	Fluorescence spectrometer	Pneumococcal conjugate vaccine	2022	---
QM-00410_R3	Automatisierte Bestimmung des Antigengehaltes in Pneumokokkenkonjugatimpfstoffen mittels ELISA	n.a.	Fluorescence spectrometer with pipetting robot	Pneumococcal conjugate vaccine	2023	---
QM-00347_R3	Live bacteria count	1/3-S-013	Colony count (visual)	Cholera Vaccine	2021	---
QM-00351_R2	BCG bacteria count	n.a.	Colony count (visual)	BCG Live Vaccine	2023	---

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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-00093_R3	IPV ELISA Method B	2/1-A-002	ELISA Reader	IPV Vaccines	2019	---
QM-00094_R4	HAV ELISA Method B	2/1-A-003	ELISA Reader	Hepatitis A Vaccine	2005	---
QM-00095_R3	HAV ELISA Method A	2/1-A-004	ELISA Reader	Hepatitis A Vaccines	2017	2022
QM-00098_R3	Hepatitis B ELISA Method A	2/1-A-023	ELISA Reader	Hepatitis B Vaccines	2007	---
QM-00099_R2	HPV-16 und HPV-18 ELISA Method A	2/1-A-026	ELISA Reader	Human Papillomavirus Vaccines (HPV): Type 16 und 18	2015	---
QM-00101_R3	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_R2	Indirect immunofluorescence technique for titration of human Rotavirus in Live Vaccines	2/1-A-061	Microscope (Fluorescence microscope)	Rotavirus Live Vaccines	2016	---
QM-00110_R4	HPV IVRP-ELISA Method B	2/1-A-062	ELISA Reader	Human Papillomavirus Vaccines, Type 6, 11, 16 und 18	2021	---
QM-00111_R1	VSV Ebo	2/1-A-063	Visual assessment	VSV Ebola Vaccine	2024	---
QM-00113_R6	VZV-ELISA Method A	2/1-A-065	ELISA Reader	VZV (rDNA) Vaccines	2022	---
QM-00062_R2	Anti-Tetanus ELISA	3/1-A-412	ELISA Reader	Anti-Tetanus Immunoglobulins and Immunosera	2003	---
QM-00071_R3	Anti-HBV ELISA	3/1-A-438	ELISA Reader	Anti-HbsAg Immunoglobulins	2006	---

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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-00072_R2	Anti-CMV ELISA	3/1-A-439	ELISA Reader	Anti-CMV Immunoglobulins	2005	---
QM-00073_R2	Anti-VZV ELISA	3/1-A-440	ELISA Reader	Anti-VZV Immunoglobulins	2017	---
QM-00074_R4	Anti-HAV ELISA	3/1-A-441	ELISA Reader	Anti-HAV Immunoglobulins	2022	---
QM-00137_R2	RFFIT (rapid fluorescent focus inhibition test)	4/3-S-018	Fluorescence microscope	Anti-Rabies Immunoglobulins	2002	---
QM-00138_R2	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 Lawsonia intracellularis PRRSV BHV Rabies Myxomatosis BVDV	2003 2003 2004 2005 2005 2002 2002 2002 2004 2008	---
QM-00139_R3	Hemagglutination inhibition test (HI)	4/3-S-041	Visual assessment	Determination of antibodies against equine influenza strains	2012	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-00141_R2	Challenge test	4/3-S-044	Visual assessment	Inactivated Rabies Vaccines for human use	2007	---
QM-00142_R3	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_R2	Indirect ELISA to determine anti-erysipelas antibodies	4/3-S-057	ELISA-Reader	Inactivated Erysipelas vaccines	2002	---
QM-00149_R3	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_R3	Titration on embryonated SPF-hen's eggs	4/3-S-083	Visual assessment	Newcastle-disease (ND) Live Vaccines Infectious Bursitis (IBD) Live Vaccines Infectious Bronchitis (IB) Live Vaccines	2002, 2004	2022
QM-00155_R2	ND-Antigen-ELISA	4/3-S-085	ELISA-Reader	Inactivated ND Vaccines ad. us. vet	2006	2022
QM-00156_R2	Haemagglutination Inhibition-Test (HI)	4/3-S-086	Visual assessment	Determination of ND antibodies in chicken sera	2007	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-00157_R2	AE-Antigen-ELISA (Indirect Sandwich ELISA)	4/3-S-087	ELISA-Reader	Avian encephalomyelitis (AE)-Live Vaccines	2014	---
QM-00158_R3	CCID50 determination: Titration on primary chicken embryo fibroblasts	4/3-S-088	Microscope (Light microscope, Fluorescence microscope)	IBD und MD Live Vaccines rCP Influenza rCP FeLV rCP Tollwut	2002, 2003 2003 2003 2016	2022
QM-00160_R4	Efficacy test of recombinant ND live vaccine	4/3-S-090	Fluorescence microscope	Recombinant ND Live Vaccines	2023	---
QM-00404_R3	Antigen quantification by AlphaLISA	n.a.	Microplate reader (Luminescence measurement)	Inactivated rabies vaccines for animal use	2022	---

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_R3	Anti-D-Purity, Haemagglutination	3/1-A-426	Visual assessment	Normal human Immunoglobulins	2007	2022
QM-00067_R2	Test for anti-A and Anti-B Haemagglutinins, Haemagglutination	3/1-A-432	Visual assessment	Normal human Immunoglobulins	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-00194_R2	Western Blot	5/1-A-003	Electrophoresis unit, Western Blot chamber & Imager	Test und Therapy Allergens	2008	2022
QM-00198_R4	Determination of the allergenic activity of test allergens using FEIA inhibition	5/1-A-023	ImmunoCAP device	Test Allergens	2005	2022
QM-00208_R5	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-00345_R3	Bacterial endotoxins – kinetic-turbidimetric Method	1/3-S-012	Photometer	Vaccines ad us. hum. and vet. Solutions and media	2019	2022

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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_R2	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_R2	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

16 Purity **

Internal document	Title of test assay	former document key (intern)	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
QM-00348_R2	Serological identity check	1/3-S-014	Visual assessment	Cholera Vaccines	2021	---
QM-00352_R3	BCG Ziehl-Neelsen staining	n.a.	Visual assessment	BCG Live Vaccine	2023	---
QM-00144_R2	Purity testing of bacterial life vaccines	4/3-S-060	Visual assessment	Bacterial Life Vaccines	2007	---

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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_R4	Activity of prekallikrein activator- chromogenic test	7/3-A-002	Photometer	Human Albumin	2005	2022
QM-00231_R3	Antithrombin-chromogenic test	7/3-A-006	Photometer	Plasma, Plasmaproteinconcentrates	2004	2022
QM-00235_R2	Protein C activity – chromogenic test	7/3-A-010	Photometer	Protein-C-Concentrates	2007	2022
QM-00244_R2	C1-Inhibitor - chromogenic test	7/3-A-024	Photometer	C1-Inhibitor Concentrates	2006	2022
QM-00256_R3	Alpha 1-Proteinase-Inhibitor chromogenicElastase-Inhibitor-Test	7/3-A-069	Photometer	Alpha1-Proteinase-Inhibitor Concentrates, Plasma	2014	2022
QM-00259_R2	Factor VIII – Chromogenic Test	7/3-A-072	Automatic coagulator	Factor VIII Concentrates, Plasma	2005	2022
QM-00260_R2	Factor X – Chromogenic Test	7/3-A-073	Automatic coagulator	Factor X products	2019	2022

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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_R2	Factor IX potency determination	7/3-A-007	Automatic coagulator	Factor IX concentrates, Prothrombincomplex-Concentrates, plasma protein concentrates	2006	2022
QM-00237_R2	Thrombin potency determination	7/3-A-012	Automatic coagulator	Fibrin Sealants	2005	2022
QM-00239_R2	Factor II potency determination	7/3-A-018	Automatic coagulator	Prothrombincomplex-Concentrates	2021	2022
QM-00242_R2	Factor V potency determination	7/3-A-022	Automatic coagulator	Plasma	2005	2022
QM-00246_R2	Factor XI-clotting assay	7/3-A-028	Automatic coagulator	Plasma	2010	2022
QM-00250_R2	Determination of Thrombin in sealing matrices	7/3-A-039	Automatic coagulator	Fibrin Sealants	2021	2022

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_R3	Proof of deletion of toxin component by PCR	1/3-S-016	PCR-Cycler	Cholera vaccines	2021	---

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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-00148_R3	Identity und quantification of equine Influenza strains by qPCR	4/3-S-075	qPCR-Cycler	rCP Influenza vaccines	2020	2022
QM-00150_R2	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