

Paul-Ehrlich-Institut: Scope of Services

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This scope of services reflects the PEI's inhouse test methods that are continuously updated within 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. 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	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-A-020-13	Assay for poly-ribosyl-ribitolphosphate: assay for ribose (orcinol test)	Photometer	Haemophilus influenzae Type B Vaccines	2007	
1/2-S-052-06	Resorcinol Assay	UV Spektrometer	Pneumococcal conjugate vaccine (monovalent bulks)	2010	

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-058-04	Nephelometry for measuring antigen content	Nephelometer	Multivalent pneumococcal polysaccharide conjugate vaccine- from 10 different polysaccharides of different serotypes of S. pneumoniae	2016	2016
3/1-A-004-24	Protein determination using the optical method at 280 nm	Photometer	Immunoglobulins	2001	2016
3/1-A-007-18	Colorimetric determination of the Formaldehyde content	Photometer	Test- and Therapy-Allergens, Immunglobulins and Vaccines	2008	
3/1-A-008-22	Colorimetric determination of the phenol content	Photometer	Test- and Therapy-Allergens, Antitoxins, Immunoserum, Vaccines	2002	
3/1-A-162-11	Total protein by BCA	Photometer	Vaccines	2010	
5/1-A-001-19	Protein Determination I according to Bradford; Range: 25 µg/ml- 300 µg/ml	Photometer	Test- and Therapy-Allergens	2007	2016
5/1-A-002-19	Protein Determination II according to Bradford; Range: 200 µg/ml - 1,000 µg/ml	Photometer	Test- and Therapy-Allergens	2007	2016
5/1-A-034-13	Protein Determination I according to Kjeldahl; Range: 2,5 - 40 µg/ml	Photometer (Auto-Analyzer)	Test- and Therapy-Allergens	2012	2016

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
5/1-A-035-13	Protein Determination II according to Kjeldahl; Range: 30 - 1000 µg/ml	Photometer (Auto-Analyzer)	Test- and Therapy-Allergens	2012	2016
5/1-A-040-12	Hyaluronidase-Activity test	Photometer	Test- and Therapy-Allergens (bee and wasp venom preparations)	2014	2016
7/3-A-003-07	Factor XIII- potency determination	Automatic coagulator	Factor XIII concentrates, Fibrin Sealants	2006	2016
7/3-A-014-02	Determination of Fibrinogen as clottable protein by Biuret-reaction	Photometer	Fibrin Sealants	2012	2016
7/3-A-038-03	Determination of Fibrinogen quantity in sealing matrices	Photometer	Fibrin Sealants	2021	
7/3-A-063-02	Determination of Ristocetin-Cofactor-Activity of von-Willebrand-Factor using the coagulation analyzer BCS-XP	Automatic coagulator	Factor XIII concentrates, vWF concentrates	2019	
7/3-A-064-04	Protein determination according to biuret in microplate reader and in coagulation analyzer BCS-XP	Photometer	Albumines, Plasma	2008	

2 High Performance Liquid Chromatography (HPLC) **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-032-17	Molecular size distribution	HPLC	Immunoglobulins Monoclonal Antibodies	2001	2016 (Immunglobuline)
7/3-A-033-06	HPLC: Gel-filtration chromatography for albumins	HPLC	Albumins	2017	

3 Potentiometry **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-025-13 und 3/1-A-180-05	pH - determination	pH meter	Albumin, immunoglobulin containing products, immunosera, monoclonal antibodies, plasma products, vaccines ad. us. hum and ad. us. vet.	2001	2016 (for preparations containing albumin and immunoglobulin)
3/1-A-114-20	Potentiometric determination of the chloride content	Automatic Titrator	Immunoglobulins, Sera	2004	2016

4 Gas Chromatography (GC) **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-121-22	Determination of Tri-n-butyl phosphate by gas chromatography	Gas chromatography	Immunglobulins	2010	

5 Agar diffusion test **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
2/1-A-007-16	Influenza SRD test	Transmitted light scanner	Inactivated influenza vaccines	2002	

6 Electrophoresis **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-063-02	Identity: Rocket-Immuno-electrophoresis	Elektrophoresis unit	Antigens in Diphtheria- and Tetanus Vaccines Acellular Pertussis-Vaccines	2003, 2004, 2007	

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
			(Antigens: PT, FHA, Pertactin) Acellular Pertussis Vaccines (Antigens: Fim 2/3)		
3/1-A-096-11	SDS Electrophoresis	Elektrophoresis unit	Immunoglobulins, monoclonal Antibodies	2004	
3/1-A-144-21	Protein composition by capillary zone electrophoresis of serum proteins and immunoglobulins	Capillary electrophoresis	Immunosera und Immunoglobulins	2010	2016
3/1-A-150-14	2-Phenoxy ethanol determination by Micro-Emulsion-Electrokinetic-Chromatography	Capillary electrophoresis	Vaccines	2010	
3/1-A-194-06	Purity: Protein composition by zone electrophoresis	Elektrophoresis unit	Immunoglobulins (human)	2003	
5/1-A-030-12	Identification of allergen extracts by SDS PAGE	Elektrophoresis unit & imager	Test- and Therapy-Allergens	2004	2016
5/1-A-033-08	Isoelectric Focusing (IEF) of proteins in modified allergens extracts	Elektrophoresis unit & Imager	Therapy-Allergens	2004	2016

7 Osmometry **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-006-24	Cryoscopic determination of osmolality	Osmomat	Albumin and immunoglobulin containing products, sera, immunosera, vaccines ad.us.hum and ad. us.vet.	2001	2016

8 Rheology **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
4/3-S-061-03	Rotating viscosimeter method	Viscosimeter	Vaccines ad.us.vet.	2010	

9 Emmissionspectrometry with inductive linked plasma **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-202-06	Determination of aluminium with ICP-OES	ICP-OES	Allergens and vaccines	2021	

10 Visual inspections **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-032-05	Appearance testing of vaccines	Apparatus for visible particles	Polycaccharide vaccines and adsorbed vaccines	2016	2016
1/3-S-015-01	Appearance testing of Vaxchora-samples	Petri dish, white and black background	Cholera vaccines	2021	
5/1-A-041-05	Particle-size analysis by laser light diffraction	Laser diffractometer	Therapy-Allergens	2019	

11 Refractive index **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
5/1-A-039-08	Determination of refractive index of glycerine-containing Test- and Therapy-Allergens	Refractometer	Test- and Therapy-Allergens	2019	

Testing field – Pharmaceutical-technological analysis of medicinal products, active pharmaceutical ingredients and excipients

12 Particle contamination - invisible particles **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-026-05	Particle counters	Laser diffractometer	Polycaccharide vaccines and adsorbed vaccines	2016	2016

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

13 Microbiological potency determination **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-041-09	Sandwich ELISA (free poly-ribitol-ribosylphosphate)	ELISA Reader	Haemophilus influenzae Typ B Vaccines	2007	
1/2-S-054-08	Sandwich ELISA: Assay for free pneumococcal polysaccharide	ELISA Reader	Pneumococcal conjugate vaccine (monovalent bulks)	2010	

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/2-S-066-04	Multiplex-Immunoassay by MSD U-PLEX®	MESO™ QuickPlex SQ 120	Toxoid and combined vaccines: diphtheria, tetanus and pertussis	2020	
1/3-S-013-01	Live bacteria count	Colony count (visual)	Cholera Vaccine	2021	
2/1-A-002-04	IPV ELISA Method B	ELISA Reader	IPV Vaccines	2019	
2/1-A-003-09	HAV ELISA Method B	ELISA Reader	Hepatitis A Vaccine	2005	
2/1-A-004-05	HAV ELISA Method A	ELISA Reader	Hepatitis A Vaccines	2017	
2/1-A-023-11	Hepatitis B ELISA Method A	ELISA Reader	Hepatitis B Vaccines	2007	
2/1-A-026-02	HPV-16 und HPV-18 ELISA Method A	ELISA Reader	Human Papillomavirus Vaccines (HPV): Type 16 und 18	2015	
2/1-A-038-06	Vaccinia Live Virus Vaccines - Titration on embryonated hen's eggs	Visual identification of plaques	Vaccinia Live Virus Vaccines	2003	
2/1-A-061-02	Indirect immunofluorescence technique for titration of human Rotavirus in Live Vaccines	Microscope (Fluorescence microscope)	Rotavirus Live Vaccines	2016	
2/1-A-062-03	HPV IVRP-ELISA Method B	ELISA Reader	Human Papillomavirus Vaccines, Type 6, 11, 16 und 18	2021	
3/1-A-412-02	Anti-Tetanus ELISA	ELISA Reader	Anti-Tetanus Immunoglobulins and Immunoserum	2003	

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-438-02	Anti-HBV ELISA	ELISA Reader	Anti-HbsAg Immunoglobulins	2006	
3/1-A-439-02	Anti-CMV ELISA	ELISA Reader	Anti-CMV Immunoglobulins	2005	2016
3/1-A-440-02	Anti-VZV ELISA	ELISA Reader	Anti-VZV Immunoglobulins	2017	
4/3-S-018-12	RFFIT (rapid fluorescent focus inhibition test)	Fluorescence microscope	Anti-Rabies Immunoglobulins	2002	
4/3-S-040-11	CCID ₅₀ determination: Cell titration for measuring antigen in Live Vaccines ad. us. vet	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	
4/3-S-041-09	Hemagglutination inhibition test (HI)	Visual assessment	Determination of antibodies against equine influenza strains	2012	2016

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
4/3-S-044-15	Challenge test	Visual assessment	Inactivated Rabies Vaccines for human use	2007	
4/3-S-048-10	Serum neutralisation test to determine the potency of rabies vaccines for animal use	Fluorescence microscope	Inactivated Rabies Vaccines for animal use	2008	
4/3-S-057-05	Indirect ELISA to determine anti-erysipelas antibodies	ELISA-Reader	Inactivated Erysipelas vaccines	2002	
4/3-S-076-04	Live bacteria count: Spatula method	Visual assessment	Mycoplasma gallisepticum Live Vaccine Bacterial live vaccines (Salmonella)	2003; 2012; 2004	2016 (Mycoplasma gallisepticum Vaccine)
4/3-S-083-04	Titration on embryonated SPF-hen's eggs	Visual assessment	Newcastle-disease (ND) Live Vaccines Infectious Bursitis (IBD) Live Vaccines Infectious Bronchitis (IB) Live Vaccines	2002, 2004	2016
4/3-S-085-03	ND-Antigen-ELISA	ELISA-Reader	Inactivated ND Vaccines ad. us. vet	2006	2016
4/3-S-086-02	Haemagglutination Inhibition-Test (HI)	Visual assessment	Determination of ND antibodies in chicken sera	2007	2016

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
4/3-S-087-04	AE-Antigen-ELISA (Indirect Sandwich ELISA)	ELISA-Reader	Avian Encephalomyelitis Live Vaccines (AE Vaccines) ad. us. vet.	2014	
4/3-S-088-05	CCID ₅₀ determination: Titration on primary chicken embryo fibroblasts	Microscope (Light microscope, Fluorescence microscope)	IBD and MD Live Vaccines rCP Influenza rCP FeLV rCP Rabies	2002, 2003 2003 2003 2016	

14 Serological determination of potency / content **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
3/1-A-401-02	Flow Cytometry (FACS)	Flow cytometer	Anti-D-Immunoglobulins	2002	
3/1-A-426-03	Anti-D-Purity, Haemagglutination	Visual assessment	Normal human Immunoglobulins	2007	
3/1-A-432-03	Test for anti-A and Anti-B Haemagglutinins, Haemagglutination	Visual assessment	Normal human Immunoglobulins	2014	2016

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
5/1-A-003-17	Western Blot	Electrophoresis unit, Western Blot chamber & Imager	Test- und Therapy-Allergens	2008	2016
5/1-A-023-21	Determination of the allergenic activity of test allergens using FEIA inhibition	ImmunoCAP device	Testallergens	2005	2016
5/1-A-038-13	Determination of the allergenic activity of therapy allergens using FEIA inhibition	ImmunoCAP device	Therapy Allergens	2012	2016

15 Determination of Bacterial Endotoxins **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/3-S-008-08	Bacterial endotoxin test (BET) Routine test (Method A + B) & testing for disturbing factors (gel clot)	Visual assessment	Vaccines ad us. hum. and vet. Solutions and media	2001	
1/3-S-012-01	Bacterial endotoxins – kinetic-turbidimetric Method	Photometer	Vaccines ad us. hum. and vet. Solutions and media	2019	

16 Monocyte activation test **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/3-S-010-05	Monocyte-Activation-Test (MAT), Method B	ELISA-Reader	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2016
1/3-S-011-05	Dicytokine-(IL-1 β ;IL-6)-ELISA within the scope of MAT	ELISA-Reader	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2016

17 Purity **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/3-S-014-02	Serological identity check	Visual assessment	Cholera vaccines	2021	
4/3-S-060-03	Purity testing of bacterial life vaccines	Visual assessment	Bacterial Life Vaccines	2007	

18 Chromogenic Tests **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
7/3-A-002-10	Activity of prekallikrein activator- chromogenic test	Photometer	Human Albumin	2005	2016
7/3-A-006-05	Antithrombin-chromogenic test	Photometer	Plasma, Plasmaproteinconcentrates	2004	2016
7/3-A-010-04	Protein C activity – chromogenic test	Photometer	Protein-C-Concentrates	2007	2016
7/3-A-024-05	C1-Inhibitor - chromogenic test	Photometer	C1-Inhibitor Concentrates	2006	2016
7/3-A-069-05	Alpha 1-Proteinase-Inhibitor chromogenicElastase-Inhibitor-Test	Photometer	Alpha1-Proteinase-Inhibitor Concentrates, Plasma	2014	2016
7/3-A-072-02	Factor VIII – Chromogenic Test	Automatic coagulator	Factor VIII Concentrates, Plasma	2005	2016 (Faktor VIII Produkts)
7/3-A-073-03	Factor X – Chromogenic Test	Automatic coagulator	Factor X products	2019	

19 Coagulation tests **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
7/3-A-007-05	Factor IX potency determination	Automatic coagulator	Factor IX concentrates, Prothrombincomplex-Concentrates, plasma protein concentrates	2006	2016
7/3-A-012-05	Thrombin potency determination	Automatic coagulator	Fibrin Sealants	2005	2016
7/3-A-018-04	Factor II potency determination	Automatic coagulator	Prothrombincomplex-Concentrates	2021	
7/3-A-022-04	Factor V potency determination	Automatic coagulator	Plasma	2005	2012, 2016
7/3-A-028-03	Factor XI-clotting assay	Automatic coagulator	Plasma	2010	2016
7/3-A-039-03	Determination of Thrombin in sealing matrices	Automatic coagulator	Fibrin Sealants	2021	

20 Amplification techniques **

Internal document	Title of test-assay	Equipment	Sample	Year of accreditation	Current Year of MJA attestation
1/3-S-016-01	Proof of deletion of toxin component by PCR	PCR-Cycler	Cholera vaccines	2021	
4/3-S-075-04	Identity und quantification of equine Influenza strains by qPCR	qPCR-Cycler	rCP Influenza vaccines	2020	
4/3-S-079-03	Detection of Virus contaminations by PCR	PCR-Cycler	Poultry Vaccines (CAV and MDV contaminations) Bovine Live Vaccines (BVDV contaminations)	2010 2007	2016