

Paul-Ehrlich-Institut: Scope of Services

Last update: 2021/03/15

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. Test 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.

Field of testing – Chemical and physical analytics of medicinal products and active pharmaceutical ingredients

1 Photometry **

Internal document key / test assay code	Title of test-assay	Sample	Year of accreditation	Year of MJA attestation
1/2-A-020	Assay for poly-ribosyl-ribitolphosphate: assay for ribose (orcinol test)	Haemophilus influenzae Type B Vaccines	2007	
1/2-S-026	Particle counters	Polycaccharide vaccines and ad-sorbed vaccines	2016	2016

Internal document key / test assay code	Title of test-assay	Sample	Year of accreditation	Year of MJA attestation
1/2-S-052	Resorcinol Assay	Pneumococcal conjugate vaccine (monovalent bulks)	2010	
1/2-S-058	Nephelometry for measuring antigen content	Multivalent pneumococcal polysaccharide conjugate vaccine	2016	2016
3/1-A-004	Protein determination using the optical method at 280 nm	Immunoglobulins	2001	2012, 2016
3/1-A-007	Colorimetric determination of the Formaldehyde content	Allergens, Immunglobulins and Vaccines	2008	
3/1-A-008	Colorimetric determination of the phenol content	Allergens, Antitoxins, Immunoserum, Vaccines	2002	
3/1-A-162	Total protein by BCA	Vaccines	2010	
5/1-A-001	Protein Determination I according to Bradford; Range: 25 µg/ml- 300 µg/ml	Test- and Therapy-Allergens	2007	2012, 2016
5/1-A-002	Protein Determination II according to Bradford; Range: 200 µg/ml - 1,000 µg/ml	Test- and Therapy-Allergens	2007	2012, 2016
5/1-A-034	Protein Determination I according to Kjeldahl; Range: 2,5 - 40 µg/ml	Test- and Therapy-Allergens	2012	2012, 2016
5/1-A-035	Protein Determination II according to Kjeldahl; Range: 30 - 1000 µg/ml	Test- and Therapy-Allergens	2012	2012, 2016

Internal document key / test assay code	Title of test-assay	Sample	Year of accreditation	Year of MJA attestation
5/1-A-039	Determination of refraction index in Test and Therapy-Allergens containing glycerin	Test- and Therapy-Allergens	2019	
5/1-A-040	Hyaluronidase-Activity test	Test- and Therapy-Allergens (bee and wasp venom preparations)	2014	2016
5/1-A-041	Particle-size analysis by laser light diffraction	Therapy-Allergens	2019	
7/3-A-003	Factor XIII- potency determination	Factor XIII concentrates, Fibrin Sealants	2006	2016
7/3-A-014	Determination of Fibrinogen as clottable protein by Biuret-reaction	Plasmaprotein concentrates	2012	2012, 2016
7/3-A-063	Determination of Ristocetin-Cofactor-Activity of von-Willebrand-Factor using the coagulation analyzer BCS-XP	Factor XIII concentrates	2019	
7/3-A-064	Protein determination according to biuret in microplate reader and in coagulation analyzer BCS-XP	Albumines	2008	

2 High Performance Liquid Chromatography (HPLC) **

Internal document key / test assay code	Title of test-assay	Sample	Year of accreditation	Year of MJA attestation
3/1-A-032	Molecular size distribution	Immunoglobulins Monoclonal Antibodies	2001	2012, 2016 (Immunoglobulins)
7/3-A-033	HPLC: Gel-filtration chromatography for albumins	Albumins	2017	

3 Potentiometry **

Internal document key / test assay code	Title of test-assay	Sample	Year of accreditation	Year of MJA attestation
3/1-A-025 and 3/1-A-180	pH - determination	Albumin, immunoglobulin containing products, immunosera, monoclonal antibodies, plasma products, vaccines ad. us. hum and ad. us. vet.	2001	2016 (immunoglobulin containing products, immunosera)
3/1-A-114	Potentiometric determination of the chloride content	Immunoglobulins, Sera	2004	2016

4 Gas Chromatography (GC) **

Internal document key / test assay code	Title of test assay	Sample	Year of accreditation	Year of MJA attestation
3/1-A-121	Determination of Tri-n-butyl phosphate by gas-chromatography	Immunoglobulins	2010	

5 Agar diffusion test **

Internal document key / test assay code	Title of test assay	Sample	Year of accreditation	Year of MJA attestation
2/1-A-007	Influenza SRD test	Inactivated influenza vaccines	2002	

6 Electrophoresis **

Internal document key / test assay code	Title of test assay	Sample	Year of accreditation	Year of MJA attestation
1/2-S-063	Identity: Rocket-Immuno-electrophoresis	Diphtheria- and Tetanus Vaccines Acellular Pertussis-Vaccines (Antigens: PT, FHA, Pertactin) Acellular Pertussis Vaccines (Antigens: Fim 2/3)	2003, 2004, 2007	

Internal document key / test assay code	Title of test assay	Sample	Year of accreditation	Year of MJA attestation
3/1-A-096	SDS Electrophoresis	Immunoglobulins, monoclonal Antibodies	2004	
3/1-A-144	Protein composition by capillary zone electrophoresis of serum proteins and immunoglobulins	Immunosera und Immunoglobuline	2010	2012, 2016
3/1-A-150	2-Phenoxy ethanol determination by Micro-Emulsion-Electrokinetic-Chromatography	Vaccines	2010	
3/1-A-194	Purity: Protein composition by zone electrophoresis	Immunoglobulins (human)	2003	
5/1-A-030	Identification of allergen extracts by SDS PAGE	Test- und Therapy-Allergens	2004	2012, 2016
5/1-A-033	Isoelectric Focusing (IEF) of proteins in modified allergens extracts	Therapy-Allergens	2004	2012, 2016

7 Osmometry **

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

8 Rheology **

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
4/3-S-061	Rotating viscosimeter method	Vaccines ad.us.vet.	2010	

9 Other individual test methods

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
1/2-S-032	Appearance testing	Polycaccharide vaccines and ad-sorbed vaccines	2016	2016

Field of testing – Biological analytics of medicinal products, active pharmaceutical ingredients and excipients

10 Microbiological potency determination**

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
1/2-S-041	Sandwich ELISA (free poly-ribitol-ribosylphosphate)	Haemophilus influenzae Typ B Vaccines	2007	

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
1/2-S-054	Sandwich ELISA: Assay for free pneumococcal polysaccharide	Pneumococcal conjugate vaccine (monovalent bulks)	2010	
1/2-S-066	Multiplex-Immunoassay by MSD U-PLEX®	Toxoid and combined vaccines: diphtheria, tetanus and pertussis	2020	
2/1-A-002	IPV ELISA Method B	IPV Vaccines	2019	
2/1-A-003	HAV ELISA Method B	Hepatitis A Vaccine	2005	
2/1-A-004	HAV ELISA Method A	Hepatitis A Vaccines	2017	
2/1-A-023	Hepatitis B ELISA Method A	Hepatitis B Vaccines	2007	
2/1-A-026	HPV-16 und HPV-18 ELISA Method A	Human Papillomavirus Vaccines (HPV): Type 16 und 18	2015	
2/1-A-038	Vaccinia Live Virus Vaccines - Titration on embryonated hen's eggs	Vaccinia Live Virus Vaccines	2003	
2/1-A-061	Indirect immunofluorescence technique for titration of human Rotavirus in Live Vaccines	Rotavirus Live Vaccines	2016	
2/1-A-062	HPV IVRP-ELISA Method B	Human Papillomavirus Vaccines, Type 6, 11, 16 und 18	2021	
3/1-A-412	Anti-Tetanus ELISA	Anti-Tetanus Immunglobuline and Immunsera	2003	
3/1-A-438	Anti-HBV ELISA	Anti-HbsAg Immunglobuline	2006	

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
3/1-A-439	Anti-CMV ELISA	Anti-CMV Immunglobuline	2005	2016
3/1-A-440	Anti-VZV ELISA	Anti-VZV Immunglobuline	2017	
4/3-S-018	RFFIT (rapid fluorescent focus inhibition test)	Anti Rabies Immunglobulins	2002	
4/3-S-040	CCID ₅₀ determination: Cell titration for measuring antigen in Live Vaccines ad. us. vet	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	Hemagglutination inhibition test (HI)	Determination of antibodies against equine influenza strains	2012	2012, 2016
4/3-S-044	Challenge test	Inactivated Rabies Vaccines for human use	2007	
4/3-S-048	Serum neutralisation test to determine the potency of rabies vaccines for animal use	Inactivated Rabies Vaccines for animal use	2008	

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
4/3-S-057	Indirect ELISA to determine anti-erysipelas antibodies	Inactivated Erysipelas vaccines	2002	
4/3-S-076	Live bacteria count: Spatula method	Mycoplasma gallisepticum Live Vaccine Bacterial live vaccines (Salmonella)	2003 2012 2004	2012, 2016 (Mycoplasma gallisepticum Impfstoff)
4/3-S-083	Titration on embryonated SPF-hen's eggs	Newcastle-disease (ND) Live Vaccines Infectious Bursitis (IBD) Live Vaccines Infectious Bronchitis (IB) Live Vaccines	2002, 2004	2012, 2016
4/3-S-085	ND-Antigen-ELISA	Inactivated ND Vaccines ad. us. vet	2006	2012, 2016
4/3-S-086	Haemagglutination Inhibition-Test (HI)	Determination of ND antibodies in chicken sera	2007	2012, 2016 (NDV)
4/3-S-087	AE-Antigen-ELISA (Indirect Sandwich ELISA)	Avian Encephalomyelitis Live Vaccines (AE Vaccines) ad. us. vet.	2014	
4/3-S-088	CCID ₅₀ determination: Titration on primary chicken embryo fibroblasts	IBD and MD Live Vaccines rCP Influenza rCP FeLV rCP Rabies	2002, 2003 2003 2003 2016	

11 Serological determination of potency / content**

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
3/1-A-401	Flow Cytometry (FACS)	Anti-D-Immunoglobulins	2002	
3/1-A-426	Anti-D-Purity, Haemagglutination	Normal human Immunoglobulins	2007	
3/1-A-432	Test for anti-A and Anti-B Haemagglutinins, Haemagglutination	Normal human Immunoglobulins	2014	2016
5/1-A-003	Western Blot	Test- und Therapy-Allergens	2008	2012, 2016
5/1-A-023	Determination of the allergenic activity of test allergens using FEIA inhibition	Testallergens	2005	2012, 2016
5/1-A-038	Determination of the allergenic activity of therapy allergens using FEIA inhibition	Therapy Allergens	2012	2016

12 Determination of Bacterial Endotoxins **

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

1/3-S-010	Monocyte-Activation-Test (MAT), Method B	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2016
1/3-S-011	Dicytokine-(IL-1 β ;IL-6)-ELISA within the scope of MAT	Albumin and immunoglobulin containing products, Vaccines, Coagulation factors Solutions and media	2016	2016
1/3-S-012	Bacterial endotoxins – kinetic-turbidimetric Method	Vaccines ad us. hum. and vet. Solutions and media	2019	

13 Purity **

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
4/3-S-060	Purity testing of bacterial life vaccines	Bacterial Life Vaccines	2007	

14 Chromogenic Tests *

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
7/3-A-002	Activity of prekallikrein activator	Human Albumin	2005	2012, 2016

7/3-A-006	Antithrombin-chromogenic test	Plasma, Plasmaproteinconcentrates	2004	2012, 2016
7/3-A-010	Protein C activity – chromogenic test	Protein-C-Concentrates	2007	2016
7/3-A-024	C1-Inhibitor - chromogenic test	C1-Inhibitor Concentrates	2006	2016
7/3-A-069	Alpha 1-Proteinase-Inhibitor chromogener Elastase-Inhibitor-Test	Alpha1-Proteinase-Inhibitor Concentrates, Plasma	2014	2016
7/3-A-072	Factor VIII – Chromogenic Test	Factor VIII Concentrates, Plasma	2005	2012, 2016 MJA-Attestation valid for Factor VIII concentrates
7/3-A-073	Factor X – Chromogenic Test	Factor X products	2019	

15 Coagulation tests *

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
7/3-A-007	Factor IX potency determination	Factor IX concentrates, plasma protein concentrates	2006	2016
7/3-A-012	Thrombin potency determination	Fibrin Sealants	2005	2012, 2016
7/3-A-022	Factor V potency determination	Plasma	2005	2012, 2016
7/3-A-028	Factor XI-clotting assay	Plasma	2010	2016

16 Amplification techniques *

Internal document key / test assay code	Title of test assays	Sample	Year of accreditation	Year of MJA attestation
4/3-S-075	Identity und quantification of equine Influenza strains by qPCR	rCP Influenza vaccines	2020	
4/3-S-079	Detection of Virus contaminations by PCR	Poultry Vaccines (CAV and MDV contaminations) Live Vaccines ad. us. vet. Bovine Live Vaccines (BVDV contaminations)	2010 2007	2016 (Poultry Vaccines)