Quality assessment service of the Institute for Quality Assurance Lübeck

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DAkkS
Deutsche
Akkreditierungsstelle
D-EP-13423-01-00

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the provider of proficiency testing schemes

EUROIMMUN Medizinische Labordiagnostika AG
Institut für Qualitätssicherung Lübeck

at the locations

Seekamp 31, 23560 Lübeck, Germany
Werkstraße 2, 23942 Dassow, Germany

is competent for the relevant sections under the terms of DIN EN ISO/IEC 17043:2010 to carry out proficiency testing/interlaboratory comparisons in the following fields:

Qualitative antibody diagnostics using serum and plasma specimens

The accreditation certificate shall only apply in connection with the notice of accreditation of 06.08.2015 with the accreditation number DEP-13423-01 and is valid until 06.04.2019. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 2 pages.

Registration number of the certificate: **D-EP-13423-01-00**

Frankfurt / Main, 06.08.2015

p.p. Uwe Zimmermann
Head of Division

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

Institute for Quality Assurance Lübeck

ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-EP-13423-01-00

The Institute for Quality Assurance Lübeck was founded as an affiliated institution of EUROIMMUN Medizinische Labordiagnostika AG (hereinafter called EUROIMMUN AG) in 2005. It belongs 100 % to EUROIMMUN AG, Lübeck (umbrella organisation). The Institute for Quality Assurance Lübeck is responsible for the organisation, management and evaluation of quality assessment schemes and the provision of professional support to participants. In December 2008 the Institute for Quality Assurance Lübeck received accreditation. The quality assessment service is designed to evaluate the capabilities of participating laboratories, based on performed analyses in comparison to reference values and results from other participating laboratories. It aims to provide an objective aid for assessing and determining the reliability of data obtained, for evaluating results and recognising problems. Great value is placed on the use of clinically and serologically well characterised samples. The reference values are determined by independent external reference laboratories, which use reagents from different manufacturers for analysis and share their test results. Our quality assessment schemes are not restricted to specific test systems. Based on the results, participating laboratories should introduce corrective measures, if necessary, to improve the quality of their services. The Institute for Quality Assurance Lübeck supports participants with competent scientific advice. Quality assessment schemes are held regularly in order to give the participating laboratories the chance to monitor their performance capabilities continuously.

Further information can be found at **www.ifq-portal.de**

IfQ staff Lübeck. Back row: Mareen Zimmermann-Ahmari, Dr. Monika Probst, Michaela Pfeiffer; front row: Jessica Nehlsen, Juliane Eggert, Anne Kahl

QA coordination

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Quality assessment parameters

Autoimmunity

- Thyroid gland
- Neuronal antigenes
- ANCA
- Kidney
- Liver
- Structural proteins of the skin
- CCP
- Cell nuclei (ANA I: ANA, ENA, dsDNA)
- Autoimmune myopathies (ANA II)
- Phospholipids
- Coeliac disease

Infectious serology

- Borrelia
- Hepatitis E virus
- Herpes simplex virus
- Parvovirus B19
- Epstein-Barr virus
- Arboviruses (Zika virus, dengue virus, chikungunya virus)

Allergology

- Total IgE, specific IgE

Timetable on pages 34 and 35!

Registration possible until:

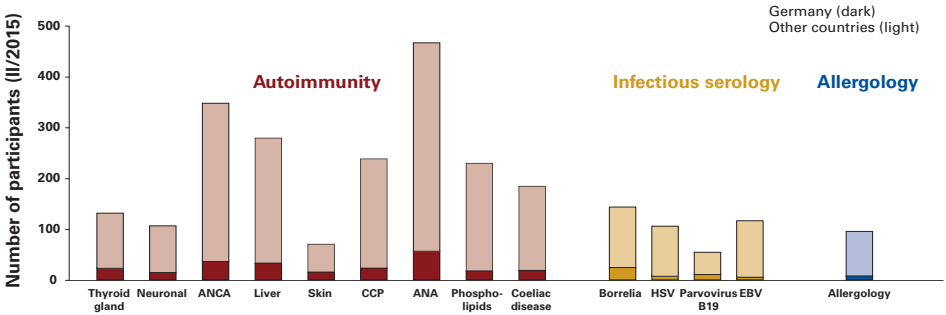
30 June 2017
for schemes during the second half-year

30 November 2017
for schemes during the first half-year

Characteristics of the IfQ-Lübeck quality assessment

- Online registration, entry of results and evaluation
- No restriction to specific test systems
- Target values established by external reference laboratories
- Clinically characterised sera
- Two quality assessment schemes per year for each parameter
- Evaluation contains images (IFA, Westernblot) and results from reference labs
- Certificates at successful completion
- High number of participants from over 40 countries

Numbers of participants II/2015



Procedure:

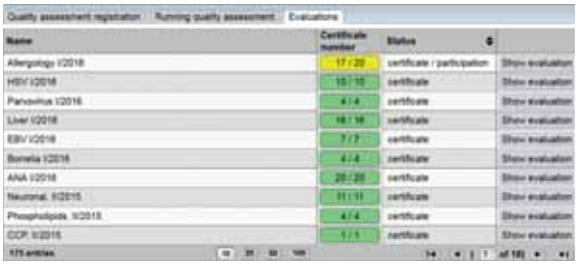
General registration at
www.ifq-portal.de

Registration for the individual schemes

Shipment of samples as indicated

Data entry

Evaluation available on the internet



Certificates sent by postal mail

Example of an evaluation report

Dear Ms./Mr. ...,

we thank you for your participation in the interlaboratory test. A total of 440 laboratories participated. The rate of correct results was 98 %.

Characterisation of samples

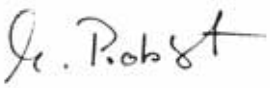
	Clinical expression	Target value (cANCA)	Target value (anti-PR3)	Target value (pANCA)	Target value (anti-MPO)
Sample 1	Wegener's granulomatosis	pos	pos	neg	neg
Sample 2	Healthy blood donor	neg	neg	neg	neg
Sample 3	Wegener's granulomatosis	pos	pos	neg	neg

Rate of correct results per test method (IgG)

Test methods	Frequency of use	Correct single results
IIFT	404	98 %
ELISA (PR3 and MPO)	261	99 %
Lineblot (PR3 and MPO)	123	98 %
Westernblot (PR3 and MPO)	2	100 %
Other (PR3 and MPO)	78	100 %

The reference values from reference laboratories, immunofluorescence images of the interlaboratory samples and details about the performance and evaluation of EUROIMMUN interlaboratory test schemes are available through our quality assessment portal. The next interlaboratory test for the investigation of "Autoantibodies against granulocytes" will take place in October 2016. We hope you will participate again!

Sincerely yours



Dr. rer.nat. Monika Probst
Quality Assessment Service Coordinator

Individual evaluation

Participant:	Represented by:

Test system used in your lab (class IgG): EUROIMMUN Anti-PR3-hn-hr ELISA					All users of this test system			
	Parameter	Intended result	Your result		Median [U/ml]	Interval of 68 % of results	n	Correct [%]
Sample 1	anti-PR3	positive	positive	428.0 U/ml	282.9	200.0 - 546.0	75	98.7
Sample 2	anti-PR3	negative	negative	2.0 U/ml	2,0	1,7 - 4,2	75	98.7
Sample 3	anti-PR3	positive	positive	1009.0 U/ml	318.5	200.0 - 916.0	75	98.7

Certificate:	yes	October 2015:	yes	May 2015:	yes	November 2014:	yes	May 2014:	yes

Rate of correct results of the different test systems

2. Anti-PR3				Correct results		
Test system	Manufacturer	Test method	Number of partici-pants	Sample 1 target: anti-PR3 pos	Sample 2 target: anti-PR3 neg	Sample 3 target: anti-PR3 pos
Aeskulisa PR3 sensitive	Aesku.Diagnostics	ELISA	5	100 %	100 %	100 %
Anti-PR3-ELISA	Biorad	ELISA	2	100 %	100 %	100 %
Anti-PR3-ELISA	Diesse	ELISA	2	100 %	100 %	100 %
Anti-PR3-ELISA	Eurodiagnostica	ELISA	4	100 %	100 %	100 %
Anti-PR3-hn-hr ELISA	EUROIMMUN	ELISA	104	99 %	98 %	98 %
ANCA-Profile ELISA	EUROIMMUN	ELISA	25	96 %	96 %	92 %
Quanta Lite PR3	Inova Diagnostics	ELISA	8	100 %	88 %	88 %
⋮	⋮	⋮	⋮	⋮	⋮	⋮
Anti-proteinase 3	Other	Other	1	100 %	100 %	100 %
Antibodies against MPO and PR3	Other	Other	2	100 %	100 %	100 %
All anti-PR3 test systems			371	99 %	97 %	98 %

Results of reference laboratories

Anti-PR3		Units	Cut-off	Sample		
External ref. laboratory	Test system (manufacturer)			1	2	3
Laboratory 1	Anti-PR3-hn-hr ELISA (EUROIMMUN)	U/ml	20	769	<2	1,302
Laboratory 2	Anti-PR3-hn-hr ELISA (EUROIMMUN)	U/ml	20	594	1	1,054
Laboratory 5	PR3 ANCA capture ELISA (Eurodiagnostica)	IU/ml	7	pos	neg	pos
Laboratory 5	PR3 ANCA direct ELISA (Phadia)	IU/ml	3	63	<2	599
Laboratory 7	Anti-PR3-hn-hr ELISA (EUROIMMUN)	U/ml	20	457	2	1,100
Target value				pos	neg	pos

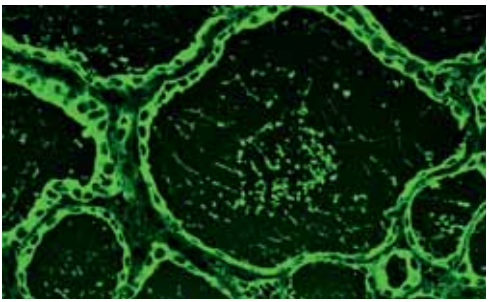
Autoantibodies against thyroid gland

Shipment:	April and October
Number of samples:	3
Evaluated parameters:	TPO, TG, TRAb
Sample volume:	300 µl (double set available)
Quality assessment no:	QV 1010
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

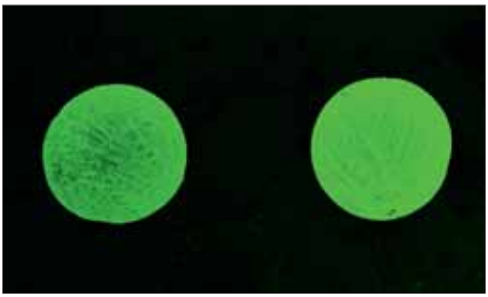
Test substrate: Thyroid gland (monkey)

anti-TPO pos/
anti-TG pos/ TRAb neg



Dilution 1:10

Test substrate: Thyroglobulin BIOCHIP

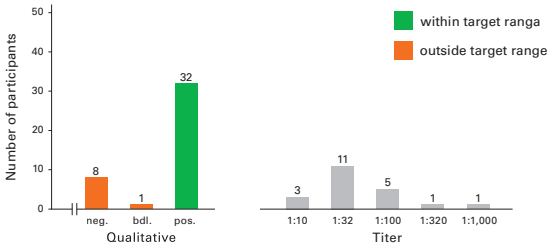


Dilution 1:10

Autoantibodies against neuronal antigens

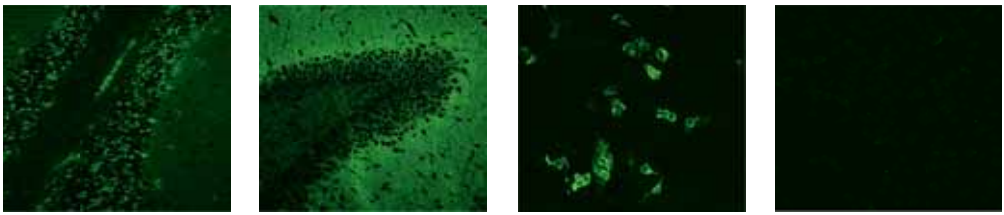
Shipment:	April and October
Number of samples:	3
Evaluated parameters:	Hu, Yo, Ri, amphiphysin, NMDA receptor, CASPR2, LGI1, Ma/Ta, CV2, GAD, aquaporin 4
Sample volume:	200 µl (double set available)
Quality assessment no:	QV 1111
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)



positive: anti-NMDAR

Cerebellum (monkey)	Hippocampus (rat)	Transfected cells	Control-transfected cells



Dilution 1:10

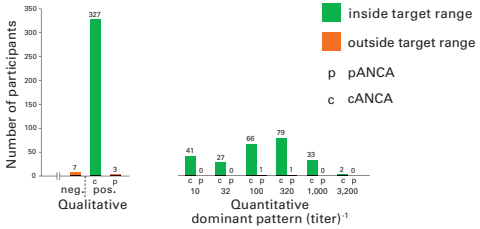
QV 1111-151013 Sample 2
Test method: PNS Profile 12 Ag EUROLINE (EUROIMMUN)

positive: anti-Hu

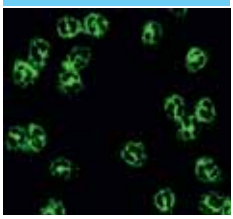
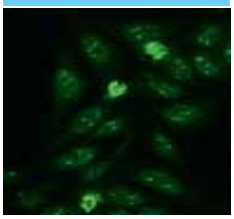
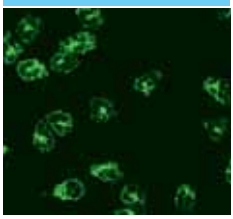
Autoantibodies against granulocytes

Shipment:	April and October
Number of samples:	3
Evaluated parameters:	pANCA, cANCA, PR3, MPO
Sample volume:	200 µl (double set available)
Quality assessment no:	QV 1200
Evaluation:	If immunofluorescence is used, only borderline and positive samples in the immunofluorescence must be confirmed by monospecific test systems to obtain a certificate.

Further available figures to complement the QA report (examples)



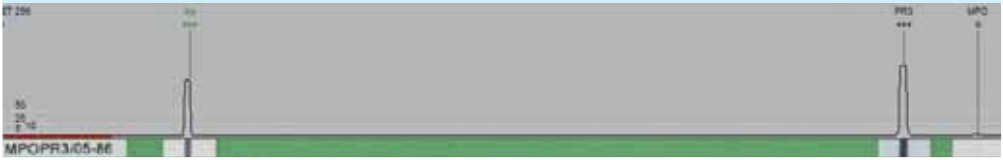
positive: cANCA

Test substrate: Ethanol-fixed granulocytes	Test substrate: HEp-2/ethanol-fixed granulocytes	Test substrate: Formalin-fixed granulocytes	Test substrate: PR3 BIOCHIP
			

Dilution 1:10

QV 1200-160419 Sample 1
Test method: ANCA Profile EUROLINE (EUROIMMUN)

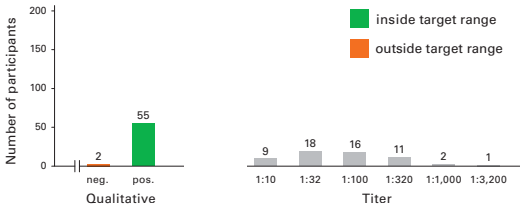
positive: anti-PR3



Antibodies in autoimmune kidney diseases

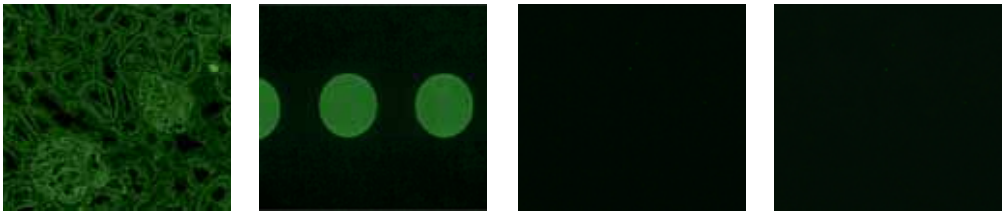
Shipment:	April und October
Number of samples:	3
Evaluated parameters:	GBM, PLA2R, THSD7A
Sample volume:	200 µl (double set available)
Quality assessment no:	QV 1250
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)



positive: anti-GBM

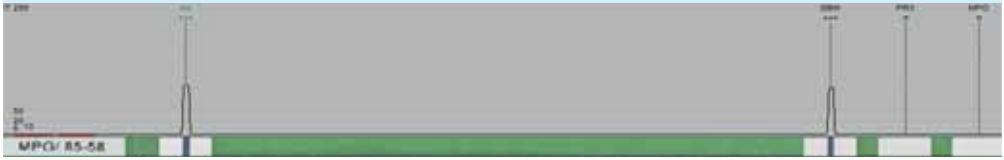
Kidney	Antigenspots GBM	PLA2R-transfected cells	THSD7A-transfected cells



Dilution 1:10

QV 1250-161011 Sample 1
Test method: ANCA/-GBM Profile EUROLINE (EUROIMMUN)

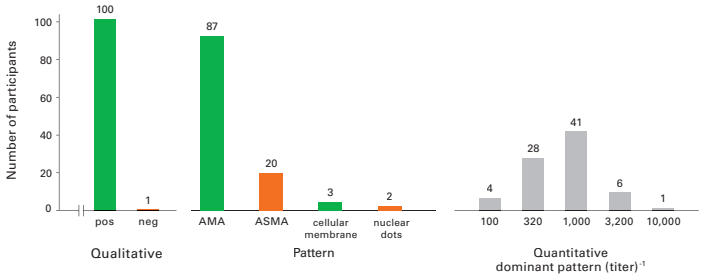
positive: anti-GBM



Antibodies in autoimmune liver diseases

Shipment:	March and September
Numbers of samples:	3
Evaluated parameters:	AMA, ASMA, nuclear dots, nuclear membrane, F-actin, SLA/LP, LC-1, LKM-1, M2, Sp100, gp210 (IgG, IgAGM)
Sample volume:	200 µl (double set available)
Quality assessment no:	QV 1300
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

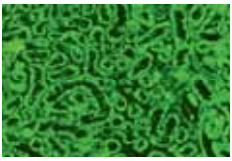
Further available figures to complement the QA report (examples)



positive: AMA

HEp-2 cells	Liver	Kidney	Antigen spots pos: Anti-M2

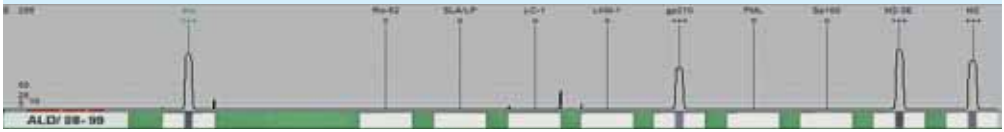





Dilution 1:100

QV 1300-140325 Sample 1
Test method: Liver Profile EUROLINE (EUROIMMUN)

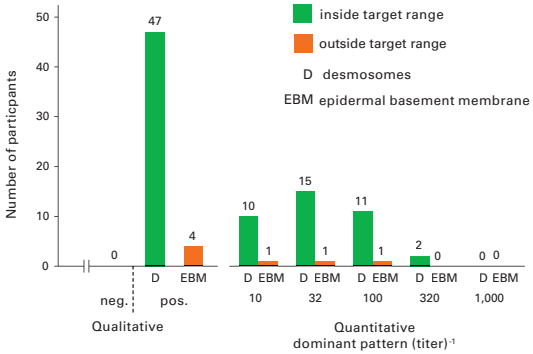
positive: anti-gp210, anti-M2-3E, anti-M2



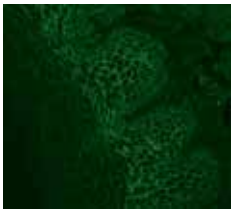
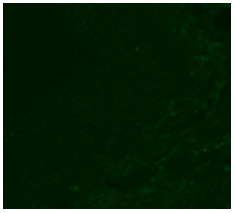
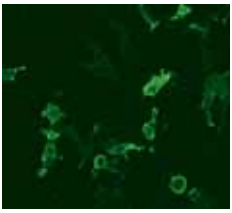
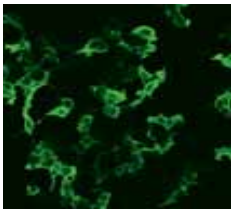
Autoantibodies against structural proteins of the skin

Shipment:	April and October
Numbers of samples:	3
Evaluated parameters:	Prickle cell desmosomes, epidermal basement membrane, desmoglein 1, desmoglein 3, BP180, BP230
Sample volume:	200 µl (double set available)
Quality assessment no:	QV1501
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)



positive: anti-desmosomes, anti-Dsg 1, anti-Dsg 3

Oesophagus		Anti-Dsg 1	Anti-Dsg 3
			
Dilution 1:10	**Dilution 1:100**	**Dilution 1:10**	**Dilution 1:10**

Antibodies against CCP

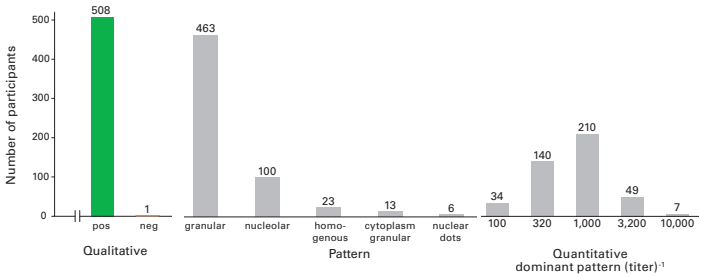
Shipment:	April and October
Number of samples:	3
Evaluated parameter:	CCP
Sample volume:	200 µl (double set available)
Quality assessment no:	QV1505
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples. Only test systems that detect antibodies against CCP will be accepted.

QA report without further figures

Autoantibodies against cell nuclei (ANA I)

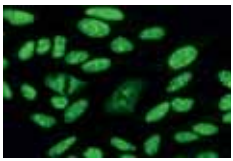
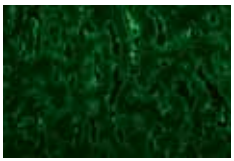
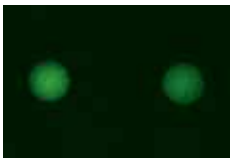
Shipment:	March and September
Number of samples:	3
Evaluated parameters:	Cell nuclei, dsDNA, nucleosomes, RNP, RNP/Sm, SS-A, SS-B, Scl-70, centromeres, CENP A, CENP B
Sample volume:	400 µl
Quality assessment no:	QV1510
Evaluation:	If immunofluorescence is used, only borderline and positive samples in the immunofluorescence must be confirmed by monospecific test systems to obtain a certificate.

Further available figures to complement the QA report (examples)



positive: ANA (pattern: granular / nucleolar)

HEp-2 cells	Liver	Antigen spots pos: SS-A; neg: nRNP/Sm, Sm	Antigen spots pos: SS-B; neg: Scl-70, Jo-1


Dilution 1:100

QV 1510-130319 Sample 1
Test method: ANA Profile 5 EUROLINE (EUROIMMUN)

positive: anti-SS-B, anti-SS-A, anti-Ro-52

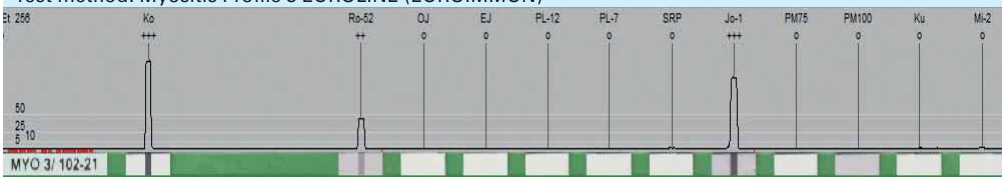
Antibodies in autoimmune myopathies (ANA II)

Shipment:	March and September
Number of samples:	3
Evaluated parameters:	cN-1A, Jo-1, Ku, Mi-2, Mi-2α, Mi-2β, EJ, OJ, PL-7, PL-12, SRP
Sample volume:	200 µl (double set available)
Quality assessment no:	QV1530
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

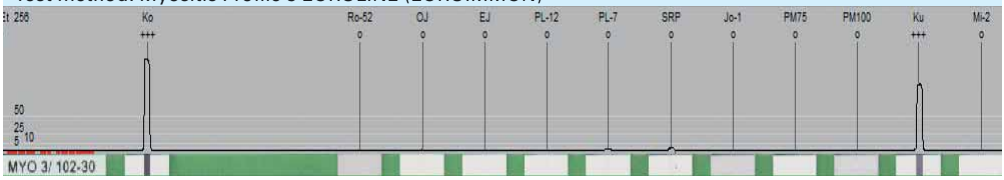
QV 1530-170319 Sample 1
Test method: Myositis Profile 3 EUROLINE (EUROIMMUN)

positive: anti-Jo-1, anti-Ro-52



QV 1530-170319 Sample 2
Test method: Myositis Profile 3 EUROLINE (EUROIMMUN)

positive: anti-Ku



Autoantibodies against phospholipids

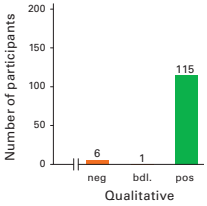
Shipment:	April and October
Number of samples:	3
Evaluated parameters:	Cardiolipin, β2-glycoprotein (IgG, IgM, IgAGM)
Sample volume:	150 µl (double set available)
Quality assessment no:	QV1632
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

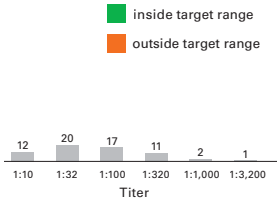
QA report without further figures

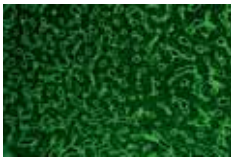
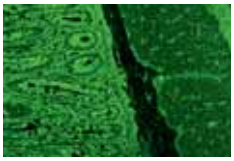
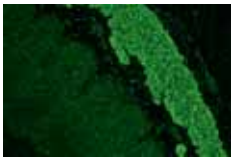
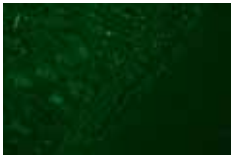
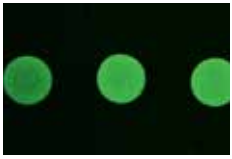
Antibodies against tissue transglutaminase (tTG), endomysium and gliadin

Shipment:	April and October
Number of samples:	3
Evaluated parameters:	Tissue transglutaminase (tTG), endomysium, deamidated gliadin (IgA, IgG)
Sample volume:	200 µl (double set available)
Quality assessment no:	QV1913
Evaluation:	Certificates will only be awarded to participants who use a test system that determines antibodies against tTG (IgA) or EMA (IgA) in combination with a coeliac-disease-specific IgG test system. The latter may be for the analysis of transglutaminase (IgG) or EMA (IgG), or an IgG test system based on deamidated gliadin. Test systems using native gliadin will not be certified.

Further available figures to complement the QA report (examples)





	Test substrate: Liver	Test substrate: Intestine	Test substrate: Oesophagus	Test substrate: Gliadin (deamidated)
IgA				
	positive			positive
IgG				
	negative			positive

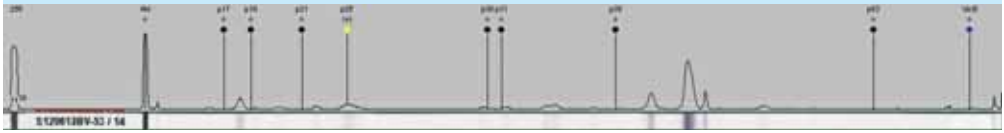
Dilution 1:10

Antibodies against Borrelia burgdorferi sensu lato

Shipment:	March and September
Number of samples:	3
Evaluated parameters:	Borrelia (IgM, IgG), overall serological diagnosis
Sample volume:	250 µl (double set available)
Quality assessment no:	QV2132
Evaluation:	If a screening assay is used only borderline or positive samples have to be confirmed in a confirmation assay to obtain a certificate.

Further available figures to complement the QA report (examples)

QV 2132-130319 Sample 2 Test method: EUROLINE-WB (IgG) negative



QV 2132-130319 Sample 2 Test method: EUROLINE-WB (IgM) positive

QV 2132-130319 Sample 2 Test method: EUROLINE-RN-AT (IgG) negative

QV 2132-130319 Sample 2 Test method: EUROLINE-RN-AT (IgM) positive

Antibodies against hepatitis E virus

Shipment	March and September
Number of samples:	3
Evaluated parameter:	Hepatitis E virus (IgM, IgG, IgAGM)
Sample volume:	200 µl (double set available)
QA number:	QV 2525
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

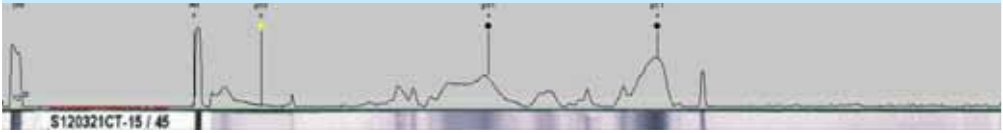
QA report without further figures

Antibodies against herpes simplex virus

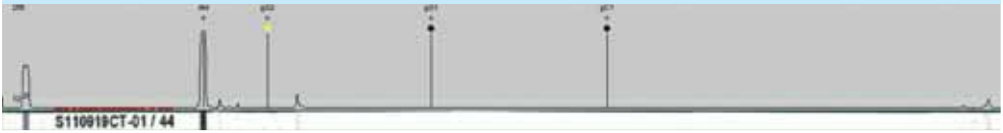
Shipment:	March and September
Number of samples:	3
Evaluated parameters:	HSV-1, HSV-2, HSV1/2 (IgM, IgG)
Sample volume:	200 µl (double set available)
Quality assessment no:	QV2531
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

QV 2531-130319 Sample 2 Test method: EUROLINE-WB (IgG) positive: anti-HSV-1



QV 2531-130319 Sample 2 Test method: EUROLINE-WB (IgM) negative

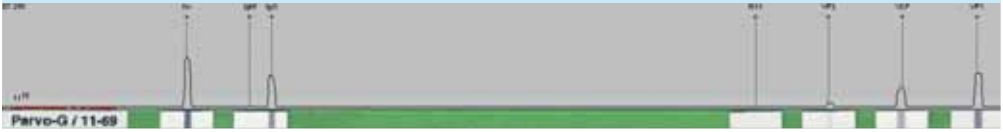


Antibodies against parvovirus B19

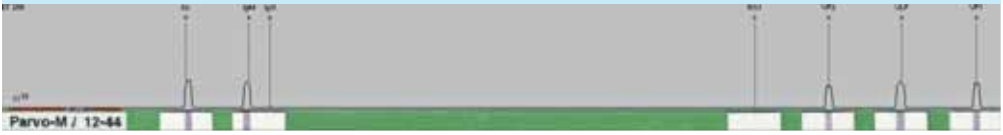
Shipment:	March and September
Number of samples:	3
Evaluated parameter:	Parvovirus (IgM, IgG)
Sample volume:	200 µl (double set available)
QA number:	QV2580
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

QV 2580-130319 Sample 2 Test method: EUROLINE (IgG) positive



QV 2580-130319 Sample 2 Test method: EUROLINE (IgM) positive

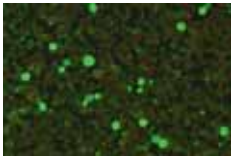
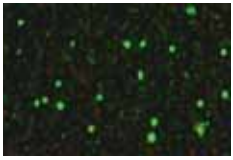
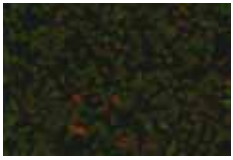
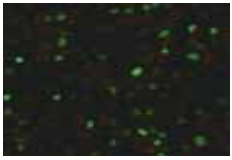


Antibodies against Epstein-Barr virus

Shipment:	March and September
Number of samples:	3
Evaluated parameters:	EBV-CA (IgM, IgG), EBNA-1(IgG), avidity
Sample volume:	200 µl (double set available)
QA number:	QV2790
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

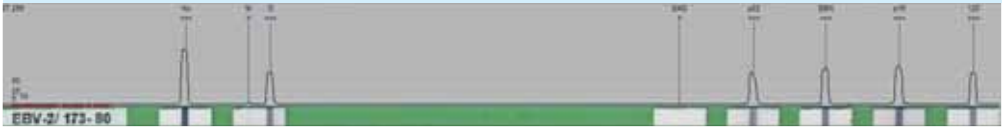
positive: anti-EBV-CA (IgG), anti-EBNA (IgG); high avidity

EBV-CA (IgG)	EBV-CA (IgG) treated with urea	EBV-CA (IgM)	EBNA (IgG)
			

Dilution 1:10

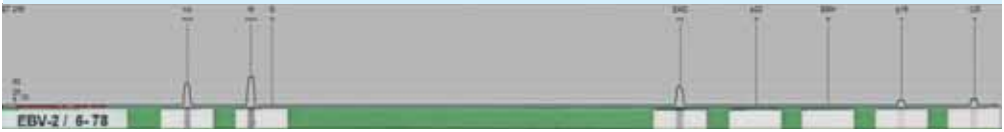
QV 2580-130319 Sample 2
Test method: EUROLINE Profile 2 EBV (IgG)

positive: anti-EBV-CA, anti-EBNA-1



QV 2580-130319 Sample 2
Test method: EUROLINE Profile 2 EBV (IgM)

positive: anti-EBV-EA, anti-EBV-CA

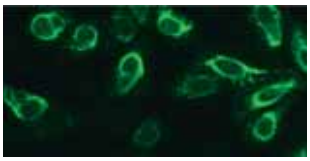
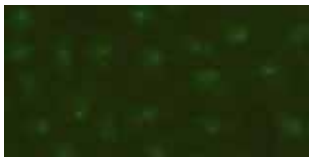
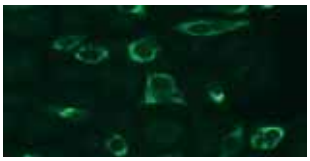
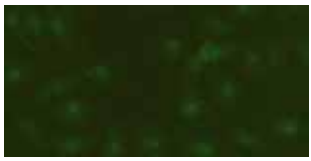
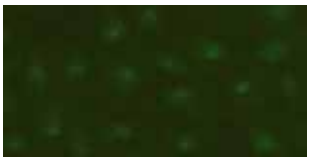


Antibodies against arboviruses

Shipment:	March and September
Number of samples:	3
Evaluated parameters:	Zika virus, dengue virus, chikungunya virus, flavivirus (IgM, IgG) Detection of dengue virus NS1 antigen
Sample volume:	300 µl (double set available)
QA number:	QV 2668
Evaluation:	The test systems are evaluated individually. A certificate is only awarded upon correct analysis of all three samples.

Further available figures to complement the QA report (examples)

positive: anti-Zika virus (IgG, IgM)

	Zika virus	Dengue virus	Chikungunya virus
IgG			
IgM			

Dilution 1:10

Allergology

Shipment:	March and September
Number of samples:	3
Evaluated parameters:	Total IgE, specific IgE
Sample volume:	Total IgE 1 x 500 µl Total IgE/specific IgE 2 x 1000 µl
QA number:	QV 3000
Evaluation:	The test systems are evaluated individually. One certificate is be awarded for the correct analysis of total IgE and one for the correct analysis of specific IgE in each case.

Further available figures to complement the QA report (examples)

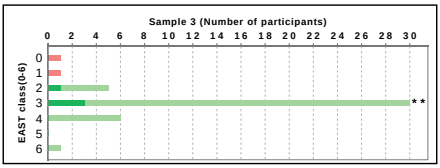
Quality Assessment Report QV 3000-150922, II/2015
"Allergology": Evaluation of your results

Participants: **Represented by:**

Test systems employed at your lab (class IgE):
EUROIMMUN
Allercoat 6 system (EAST class [0-6])
ELISA

	Parameter	Intended result (EAST class [0-6])	Your Result		
Sample 2	w1 (common ragweed)	0-1	0	kU/l:	<0,35
Sample 3	w1 (common ragweed)	2-6	3	kU/l:	6,11

Certificate:	yes	April 2015	-

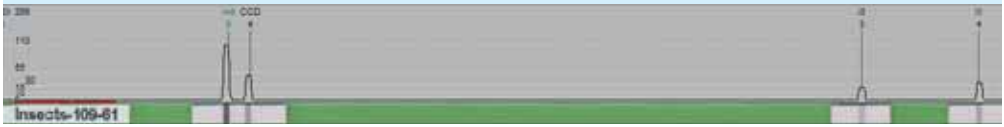


Legend
** Your Result result accepted: All assay Your assay result not accepted: All assay Your assay

Test method: EUROLINE Profile Inhalation

Test method: EUROLINE Profile Food

Test method: EUROLINE Profile Insect Venoms



Information about the quality assessment schemes

General information

Quality assessment schemes take place twice a year, each time with three samples. The dates can be found in the calendar on the quality assessment portal. Registration, entering of results and issuing of reports take place online via the quality assessment portal.

Quality assessment samples

"Real" clinically characterised samples are used preferably. These are obtained in collaboration with doctors or sample donors. The origin of each sample is known. All samples are tested for HBsAg and antibodies against HCV, HIV-1 and HIV-2 and must be negative in these tests. The samples can be serum or plasma. Methods used by the participants must therefore be validated for both serum and plasma.

Determination of expected results

Expected results for quality assessment samples are determined before delivery of the samples in cooperation with competent external laboratories. A list of the reference laboratories is available on the quality assessment portal. For each scheme at least one reference laboratory is commissioned, which is accredited for performing the respective tests according to the appropriate laboratory standards (e.g. ISO 15189 or ISO/IEC 17025, ISO 15195) or whose competence has been verified by an on-site audit. The samples are measured and assessed by the appropriate reference laboratories. The qualitative result of the reference laboratories is taken as the expected result.

Stability

Usually samples are conserved with sodium azide (< 1%); other preservatives may be used occasionally. Every quality assurance sample undergoes a stability check. In this check, transport and storage of the samples are simulated in stress tests. The stability check establishes that the sample is stable at the given storage temperature for the duration of the quality assessment round (generally 4 weeks).

Homogeneity

Quality assurance samples are fluid and are mixed before and during filling to ensure homogeneity. The homogeneity of the samples is determined during process validation of the filling process.

Evaluation, quality assurance report and issuing of certificates

The Institute for Quality Assurance Lübeck evaluates the data promptly and publishes the evaluation online on the quality assessment portal. This includes the results of every participant (only available for the corresponding participant), a statistical total evaluation with anonymous and summarised results of all participating laboratories, and further helpful information (e.g. images from immunofluorescence tests, blot strips). Participants receive a message when the evaluation is available.

Qualitative evaluation is crucial for the granting of a certificate. If the qualitative result of the participant for all samples is in agreement with the expected value, the quality assessment scheme has been passed and a certificate will be issued.

If in normal practice a confirmatory test is performed because of results obtained in a screening test then this must also be performed. If it is not performed, then even if the correct result is obtained for the screening test no certificate will be issued. If a quality assurance scheme is not passed the participant receives a confirmation of participation rather than a certificate. Certificates and confirmation of participation are sent to participants by post. In the results

evaluation for each participant, the following statistical information is given alongside the participant's results and the expected results. These values are based on all participants who used the same test system.

- Median of results*
- 68% result range*
- Number of participants
- Percentage of correct results (pass rate)

*with positive samples, if at least 6 participants gave a quantitative result.

The *median* is the middle value of all measurement values when sorted by size, so that half of the values lie under the median and half over. If the number of measurement values is even, the arithmetic mean of the two middle values is taken as the median. The median rather than the arithmetic mean is used as a statistical parameter to reduce the influence of extreme values. Outlier tests are not performed. The *68% result range* gives the distribution range of quantitative results, within which the measurement values of 68% of the participants lie. In the total evaluation the following information is given for each test that was used by participants in the quality assessment scheme:

- Number of participants
- Percentage of correct results (pass rate)

Conditions of participation

The Institute for Quality Assurance Lübeck at EUROIMMUN Medizinische Labordiagnostika AG (henceforth called EUROIMMUN AG) organises quality assessment schemes for laboratory external quality assurance. Participation is only permitted under the conditions given here.

Purpose of the quality assessment service

The quality assessment service is designed to evaluate the capabilities of participating laboratories, based on performed laboratory tests in comparison to target values and results from other participating laboratories. It provides an objective aid for assessing and determining the reliability of data obtained and for recognising problems.

Based on the results, participating laboratories should introduce corrective measures, if necessary, to improve the quality of their services. Quality assessment schemes are held regularly in order to give the participating laboratories the chance to monitor their performance capabilities continuously. Participation in the quality assessment schemes should establish additional confidence for customers of participating laboratories. Quality assessment schemes are not aimed at evaluating the products (test systems) used and should not be drawn on to assess the performance of the products.

Costs

Costs for participation in the quality assessment service should be taken from the current valid price list. Participants bear the costs for reagents, time expenditure, etc.

Safety warnings

No antibodies against HCV, HIV-1 or HIV-2 are detected in quality assessment samples using CE-registered or FDA-approved test systems. Nevertheless, samples should be handled as carefully as infectious material. Quality assessment samples contain perservatives, usually sodium azide. Avoid skin contact. Occasionally preservatives can interfere with certain test methods. To exclude the influence of preservatives, consult the instructions of the test system used.

Participant registration

Any laboratory that routinely carries out the respective laboratory analyses can take part in the quality assessment, including those

who are not customers of EUROIMMUN. Participants are required to register on the internet under *www-ifq-portal.de*. The Quality Assessment Portal allows participants to register for the different quality assessment schemes and later enter their results online. The e-mail address given by the participant is used to provide effective communication between the Institute for Quality Assurance Lübeck and the participant. Participants are required to notify the Institute for Quality Assurance Lübeck of any changes in their personal details (e.g. e-mail address or shipping address) and to keep their details up to date. If the address given is incorrect, participants are not entitled to a new delivery.

Registration for quality assessment and performance

The dates for each quality assessment scheme are given on the portal. Participants can register for the scheme during the registration period. Despite careful planning it may happen that the sample contingent is used up before the end of the registration phase. There is no entitlement to the number of samples being extended. Early registration ensures participation.

After the end of the registration period quality assessment samples are sent by the Institute for Quality Assurance Lübeck at the date given in the portal. If samples are lost or damaged and the Institute for Quality Assurance Lübeck is informed straightaway, replacements will be sent if possible. However, participants are not entitled to replacements. If a new delivery results in lateness or delayed service, there is no entitlement to the participant's results being taken into account in the evaluation of the quality assessment round.

Quality assessment samples must be handled, stored, and measured in the own laboratory in the same way as routine samples. Participants must state their method(s) used (routine method) together with the results.

Results obtained under routine conditions must be entered online in the portal by the respective deadline. No additional determinations or further methods that are not used for routine samples may be used to obtain results. Averaging of test results from different methods is not permitted.

If a test procedure consists of a screening test followed by a confirmatory test, results for the two methods must be given separately. If the confirmatory test is performed by an external laboratory this shall be indicated.

The certificate is only valid for tests performed by the participating laboratory; externally performed tests are therefore not recognised in the certificate. Falsification and secret communication between participating laboratories contradicts the goal of external quality assurance and is therefore not permitted.

It is recommended that participants double-check that their results are entered correctly in the portal. Participants should also file a print-out of their entry with their documentation. Errors in data entry can be corrected up until the deadline for results. After the deadline no changes may be made to the entered results. In cases of necessity, for example faulty internet connection, results can be submitted to the Institute for Quality Assurance Lübeck in writing (e.g. email, fax). These will be entered into the portal by the quality assurance team, as long as the deadline is met.

Evaluation, quality assurance report and issuing of certificates

The Institute for Quality Assurance Lübeck evaluates the data promptly and places the

evaluation online in the quality assessment portal. Participants receive a message when the evaluation is available. The certificate for a parameter is issued if the results for all quality assessment samples match the expected results.

If in normal practice a confirmatory test is performed because of results obtained in a screening test then this must also be performed. If it is not performed, then even if the correct result is obtained for the screening test no certificate will be issued.

Complaints
Complaints about the quality assessment carried out by the Institute for Quality Assurance Lübeck should be sent in written form to the institute within 4 weeks of receiving the quality assessment report. After this deadline complaints can no longer be considered.

If it becomes evident that a quality assessment scheme result is invalid due to a mistake made by the Institute for Quality Assurance Lübeck, an additional scheme will be offered free of charge (with the same conditions for participation). Further claims on the Institute for Quality Assurance Lübeck are excluded.

Declaration of confidentiality
The Institute for Quality Assurance Lübeck treats all participant data as confidential. Only anonymous results from each quality assessment scheme are made available to all participants on the portal.

Other
Further information about the quality assessment service can be found in the quality assurance portal. The Institute for Quality Assurance Lübeck reserves the right to exclude a laboratory if it repeatedly does not return results or if a participant has falsified data or has made secret consultations or has tried to. This also applies to attempts to influence employees of the Institute for Quality Assurance Lübeck.

The Institute for Quality Assurance Lübeck reserves the right to change individual quality assessment schemes with regard to their scope or to discontinue them completely. For further issues the general terms and conditions of EUROIMMUN AG apply.

Please address any questions about the individual quality assessment schemes or the quality assessment service to the Institute for Quality Assurance Lübeck at

E-mail: ifq@euroimmun.de
Tel: +49 451 29288 233

Time schedule 2017

Autoimmunity

Scheme	Format		Dates QAS 2017/II	Dates QAS 2018/I
Autoantibodies against cell nuclei Cell nuclei, dsDNA, nucleosomes, RNP, RNP/Sm, SS-A, SS-B, Scl-70, centromeres, CENP A, CENP B	1 set of specimen	3x400µl	**Registration until:** June 30, 2017 **Shipment:** September 19, 2017 **Deadline:** October 17, 2017	**Registration until:** November 30, 2017 **Shipment:** March 21, 2018 **Deadline:** April 18, 2018
Antibodies in autoimmune myopathies (ANA II) cN-1A, Jo-1, Ku, Mi-2, Mi-2α, Mi-2β, EJ, OJ, PL-7, PL-12, SRP	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Antibodies in autoimmune liver diseases AMA, ASMA, nuclear dots, nuclear membrane, F-actin, SLA/LP, LC-1, LKM-1, M2, Sp100, gp210	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Autoantibodies against thyroid gland TPO, TG, TRAb	1 set of specimen 2 sets of specimen	3x300µl 3x600µl	**Registration until:** June 30, 2017 **Shipment:** October 17, 2017 **Deadline:** November 14, 2017	**Registration until:** November 30, 2017 **Shipment:** May 5, 2018 **Deadline:** May 30, 2018
Autoantibodies against neuronal antigens Hu, Yo, Ri, amphiphysin, NMDA receptor, CASPR2, LGI1, Ma/Ta, CV2, GAD, aquaporin 4	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Autoantibodies against granulocytes ANCA, MPO, PR3	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Autoantibodies against structural proteins of the skin desmoglein 1 and 3, BP180, BP230, desmosomes, epidermal basement membrane	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Antibodies against CCP	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Autoantibodies against phospholipids Cardiolipin (IgG, IgM, IgAGM); β2-glycoprotein (IgG, IgM, IgAGM)	1 set of specimen 2 sets of specimen	3x150µl 3x300µl		
Antibodies against tissue transglutaminase (endomysium), deaminated gliadin (IgA, IgG)	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		
Antibodies in autoimmune kidney diseases GBM, PLA2R, THSD7A	1 set of specimen 2 sets of specimen	3x200µl 3x400µl		

Infectious serology

Scheme	Format	Dates QAS 2017/II	Dates QAS 2018/I
Antibodies against Borrelia burgdorferi sensu lato (IgG, IgM)	1 set of specimen 3x250µl 2 sets of specimen 3x500µl	**Registration until:** June 30, 2017 **Shipment:** September 19, 2017 **Deadline:** October 17, 2017	**Registration until:** November 30, 2017 **Shipment:** March 21, 2018 **Deadline:** April 18, 2018
Antibodies against herpes simplex virus HSV-1, HSV-2, HSV-1/2 (IgG, IgM)	1 set of specimen 3x200µl 2 sets of specimen 3x400µl		
Antibodies against parvovirus B19 (IgG, IgM)	1 set of specimen 3x200µl 2 sets of specimen 3x400µl		
Antibodies against Epstein-Barr virus EBV-CA (IgG, IgM), EBNA-1 (IgG), avidity	1 set of specimen 3x200µl 2 sets of specimen 3x400µl		
Antibodies against hepatitis E virus (IgG, IgM, IgAGM)	1 set of specimen 3x200µl 2 sets of specimen 3x400µl		
Antibodies against arboviruses Zika virus, dengue virus, chikungunya virus (IgG, IgM)	1 set of specimen 3x300µl 2 sets of specimen 3x600µl		

Allergology

Scheme	Format	Dates QAS 2017/II	Dates QAS 2018/I
Allergology **Total IgE, specific IgE**	1 set of specimen consisting of **Total IgE** 1x500µl **Total IgE/ specific IgE** 2x1000µl	**Registration until:** June 30, 2017 **Shipment:** September 19, 2017 **Deadline:** October 17, 2017	**Registration until:** November 30, 2017 **Shipment:** March 21, 2018 **Deadline:** April 18, 2018

Please ask your local distributor for prices.

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YV_0000_I_UK_B08, 04/2017