

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

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1 BACKGROUND

1.1 ICLAS Monitoring and Reference Centres Program (MRCP)

Since its creation, one of ICLAS's core objectives has been to promote international harmonization in the quality of animals used in research. From 1983 until 2006, ICLAS's main scientific initiative in this area was the 'ICLAS Monitoring and Reference Centers Program' (MRCP).

This program was set up in 1983 to promote the breeding and maintenance of microbiologically and genetically standardized laboratory animals and to standardize and harmonize research and testing procedures. The goal was to establish several laboratories around the world to assist countries in standardizing animals in accordance with ICLAS guidelines for international standardization.

Under the MRCP, laboratories could apply for formal recognition by ICLAS to serve as either a Monitoring or Reference Centre or both. As a Monitoring centre, the lab was required to provide animal microbiological and/or genetic testing for organizations either free or on a fee-for-service basis. As a Reference Centre, the lab maintained reference reagents and provided reagents, information and support to Monitoring Centres.

Written applications were made to the ICLAS GB detailing the lab's staff, their achievements over the previous 3-5 years, a description of their genetic and or microbiological monitoring techniques and their R&D program relating to testing procedures. If the application was approved, the lab was given ICLAS recognition for 12 months and to maintain designation, the lab was required to send an annual report of activities to the Governing Board for approval.

While attempts were made to revitalize the program, by 2004, a number of shortcomings had become apparent. Firstly, the program was not really international in scope. Applications were restricted to certain laboratories, only one laboratory had been designated as a Monitoring centre and no more than 6 Reference Centers were regularly sending in annual reports. Secondly, without inspections, which would have been prohibitively expensive, it was impossible for the ICLAS GB to verify the content of applications or reports.

1.2 ICLAS Network for Promotion of Animal Quality in Research

In 2004, Patri Vergara (then ICLAS Secretary General) and Cecilia Carbone (then ICLAS Treasurer) began discussions with internationally recognized scientists in the field of health monitoring with the aim of finding a replacement for the MRCP. The goal was to create a new initiative which would be more international in scope and able to serve as a truly international reference in the field of high-quality laboratory animal models.

These discussions led to the creation, in 2006, of the ICLAS Network for Promotion of Animal Quality in Research (LAQ Network) which was set up to develop programs to help achieve ICLAS's objective of improving the quality of animals used in research.

The Network's founding members were: Patri Vergara & Cecilia Carbone (ICLAS GB); Bill Shek (RADs, Charles River, USA); Lela Riley (RADIL, University of Missouri); Werner Niclas (German Cancer Research Center); Esther Schoondermark (Radboud University, the Netherlands); Marge Strobel (The Jackson Laboratory, USA).

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The focus was in two areas: animal health and genetic monitoring. For its first initiative, the Network focused on health monitoring, and in 2007, established the ICLAS Performance Evaluation Program (PEP). The aim of the program was to improve health monitoring by providing diagnostic laboratories with a tool to monitor the sensitivity of their diagnostic techniques.

1.3 Overview of PEP

Under PEP, Network member laboratories would prepare standardized sera and microbiological specimens and send them by World Courier for analysis to any diagnostic laboratory (participating laboratory) wishing to participate.

A comparison of the participant lab's results with the actual biological contents of the specimens as detailed in a report (Expected Results) sent later by the Network laboratory could be used to indicate the accuracy/sensitivity of the lab's assay performance.

1.4 PEP's key features

PEP would be developed in line with the following principles.

1. Self- assessment. Diagnostic performance would be self-assessed. Participating laboratories would not be required to submit any reports of their results to ICLAS or any other agency. One reason for self-assessment was because the alternative - external assessment would have been prohibitively expensive. Secondly, the aim of the program was to improve animal health monitoring not through external accreditation or assessment as with the MRCP but by providing a practical diagnostic tool to enable laboratories to measure the sensitivity of their own diagnostic techniques.
2. No specific eligibility requirements. The aim was to develop a truly international initiative which would be open to any diagnostic laboratory worldwide.
3. Self-financing. While ICLAS agreed to make \$3,000 available to help set up the program, PEP would have to be self-financing in that it could not depend on subsidies from ICLAS funds for development. Accordingly, participating laboratories would be required to pay a participation fee to cover the costs of producing and shipping the specimens and administering the program. In the end, the \$3,000 pledged by ICLAS was not required as the cost of the production and shipment of the first batch of specimens was paid for by Charles River and RADIL, USA.
4. Despite the fact that the majority of Network scientists and labs were not ICLAS members, PEP would be developed as an ICLAS project. This was important for ICLAS because for the first time it would enable the organization to be actively involved in an international scientific LA quality program. It was also important for the Network because ICLAS was the only organization with sufficient international reach and prestige that could successfully develop an international LAQ program.
5. Self-management: As PEP would not be financed from ICLAS member fees or reserves and as the Network had direct representation from the ICLAS Governing Board, all matters relating to PEP strategy, management and finance would be made the LAQ Network. Another important consideration was the fact that Network

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scientists were all working on a voluntary basis and in order to maintain their motivation and interest, it was felt important to establish a management structure which would give them democratic control over the programs they were developing. The original proposal for the management of the LAQ Network and its programs is contained in Appendix 13.

1.5 Program implementation

PEP would be developed in two stages: a development phase with only two designated specimen production laboratories - Charles River (RADs), USA and RADIL, (University of Missouri) and up to six diagnostic laboratories from the Network.

This would be followed by an operational phase, when the project would be open for applications from laboratories worldwide, in accordance with the capacity of the network to supply specimens.

Following a successful development stage in 2007, PEP became fully operational in 2008 with 9 participating labs offering the following programs: a Serology only program for a fee of \$1,500; a Microbiology only program for a fee of \$ 1,500; and a Combination program comprising both serology and microbiology specimens for a fee of \$3,000.

13% of the participation fee was used to cover administrative costs and the remainder to cover the costs of producing and shipping specimens.

1.6 PEP Distribution Centre

For the first two years of the program, shipments were made from the two specimen production laboratories to participating labs three times a year with each shipment comprising 4 specimens per program. However, by the end of 2008, it had become apparent that a number of changes needed to be made to the program.

Firstly, more Network labs needed to be involved in specimen production. So far, specimen supply had been dependent on the generosity and enthusiasm of two individuals: Lela Riley (RADIL) and Bill Shek (Charles River). However, production had proved both time consuming and costly and the only way to ensure future consistency in supply would be for other Network labs to become involved.

Secondly, specimen production needed to be made simpler and less time consuming. To this end, specimens would be shipped only once a year and the Network agreed to look for funding to establish a PEP distribution centre (DC). A centralized DC would make the production task easier and less costly as producer labs would only need to focus on producing samples and sending them in bulk to the DC and not be involved in time consuming logistic work liaising with World Courier and participating labs.

In March 2009, with the agreement of the Network, Patri Vergara applied to the Spanish Ministry of Science (SMS) under their Internationalization of Science program for a grant to set up a specimen DC for PEP at the Universitat Autònoma de Barcelona (UAB). In order to satisfy SMS's grant requirements, the application was made in the name of Patri Vergara as principle investigator on behalf of the UAB with three other individuals: Lela Riley, Bill Shek and Werner Nicklas, together with letters of support from participating labs and the ICLAS Secretary General.

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The application was successful and the UAB was awarded €65,000 over three years to cover the cost of a -80°C storage freezer as well as the costs of administration and a part-time technician (8 hours per week). The grant was paid directly to the UAB and as principal investigator, Patri Vergra would be responsible for approving the use of the money and, as with all grants paid to the UAB, the university would be responsible for providing annual audits in accordance with Spanish financial legislation.

1.7 LAQ Network Management

In November 2010, the ICLAS Governing Board approved a Network proposal to formalize the management of the PEP program (see Appendix 14). Under this agreement, the LAQ Network was constituted as an autonomous decision-making body empowered to take all management, financial and operational decisions relating to PEP. The Network would be managed by a Network Management Group comprising two representatives from the ICLAS Governing Board, one representative from the PEP Distribution Centre (DC) and one representative from each Network laboratory. The current Network Management group comprises: -

LAQ Network Members (as from June 2019)	
Representative	Institution
Patri Vergara, (Network Coordinator)	SIAL (DC), Universitat Autònoma de Barcelona, Spain
Cynthia Pekow, USA (ICLAS President)	University of Washington, USA
William Shek	Charles River Laboratories (RADS),USA
Atsushi Yoshiki	RIKEN BioResource Center, Japan
Martin Toft	QM Diagnostics, Radboud University, Netherlands
Cynthia Besch-Williford	IDEXX RADIL, Missouri, USA
Ana Perez	Humodigen, USA
Greg Ballard	The Jackson Laboratory, USA
Nobuhito Hayashimoto (ICLAS Governing Board member)	Central Institute for Experimental Animals, Japan
Bob Stevenson	Cerberus Sciences, Australia
Katja Smitdt	Deutsches Krebsforschungszentrum (DKFZ), Germany

Since 2012, Network members have met every 18 months in conjunction with AALAS and FELASA meetings. In addition, when necessary, teleconferences have been organised.

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2 PEP SPECIMEN PRODUCTION

The new DC began trials in November 2009 and became fully operational in 2010. By 2011, five Network labs were producing specimens and in 2014, they were joined by Cerberus Sciences, Australia. As at July 2020, there are 6 specimen production laboratories, as follows: -

2.1 PEP Network Laboratories (as at July 2020)

PEP Network Laboratories (as at July 2020)	
Institution	Representatives
Central Institute for Experimental Animals, Japan	Nobuhito Hayashimoto
Charles River Laboratoires (RADS), USA	William Shek (PEP Scientific Director)
QM Diagnostics, Radboud University, Netherlands	Arletta van Lent-Bol
IDEXX RADIL, Missouri, USA	Cynthia Besch-Williford
Cerberus Sciences, Australia	Bob Stevenson
Deutsches Krebsforschungszentrum (DKFZ), Germany	Katja Smitdt
LAQ Specimen Distribution Center	
SIAL Laboratory, Universitat Autònoma de Barcelona)	Patri Vergara (Network Coordinator)

2.2 Stages of specimen production

- I. Network labs produce standardised serology and/or microbiology specimens.
- II. Specimen samples are exchanged between Network labs for confirmation, i.e., to confirm that target agent(s) can be detected. This is important because specimens must be standardized. If the target agent cannot be detected or if it proves positive for an unintended agent, the batch is rejected.
- III. Network labs analyse samples to confirm standardization.
- IV. When specimens have been confirmed, Network labs send specimens to the DC at the UAB.

2.3 Production and Characterization of PEP Specimens

- All specimens are generated under strict conditions and rigorously characterized.
- Infectious agents are obtained from known sources and sequenced to confirm identity.
- Experimental animals are then inoculated, and the serum and relevant tissues are collected and aliquoted for use as standardized specimens.
- Aliquoted specimens are evaluated by two laboratories to confirm quality

2.4 PEP Specimen Quality Control

- Acceptance Criteria: Pure and Potent
- Immune Serum
 - Seropositive to inoculated pathogen only
 - Moderate to strong reaction by standard assays
- Infectious Specimen
 - Free of extraneous pathogens

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–Easily detected concentration of pathogen

2.5 Overview of PEP specimens sent to participants 2007-2019

Overview of PEP simples sent to participants 2007-2019			
animal species	pathogen	In PEP distributionlist (year in which samples have been received)	
mouse serum	Minute virus of Mice (MVM)	2007, 2010, 2011, 2015, 2017	
	Mouse Hepatitis Virus (MHV)	2010, 2014, 2016	
	Mouse Parvovirus (MPV)	2009, 2012, 2016, 2019	
	Parvo general (rNS1)	2009, 2010, 2011, 2012, 2015	
	Mouse rotavirus (EDIM)	2009, 2014, 2018, 2019	
	Pneumonia virus of Mice (PVM)	2009, 2012, 2018	
	Sendai Virus	2010, 2015, 2018	
	Theiler's murine encephalitis virus (TMEV)	2009, 2011	
	Ectromella virus (vaccinia?)	2014, 2018, 2019	
	Lymphocytic choriomeningitis virus (LCMV)	2008, 2010, 2011, 2014, 2019	
	Adenovirus FI (type 1)	2011, 2014, 2015	
	Adenovirus K87 (type 2)	2009	
	Mouse Cytomegalo virus (MCMV)	2009, 2015, 2018	
	Reovirus type 3	2009, 2012, 2017	
	Mycoplasma pulmonis	2007, 2012, 2016	
	Encephalomyocarditis virus (EMCV)		
	Clostridium piliforme		
	Hantavirus	2010, 2014	
	Mouse Thymic Virus		
	Murine Norovirus (MNV)	2009, 2010, 2011, 2015, 2016, 2018, 2019	
	Mouse polyomavirus	2012, 2017	
	CAR Bacillus	2017	
	Puumala	2019	
rat serum	Kilham rat virus (KRV)	2011, 2015, 2017	
	Pneumonia virus of Mice (PVM)	2009, 2014	
	Rat coronavirus (RCV / SDA)	2008, 2010, 2012, 2016, 2018	
	Rat parvovirus (rNS1)	2010, 2012, 2015, 2016	
	Sendai virus	2007, 2011, 2012, 2016	
	Toolan H-1 virus	2009, 2010, 2014	
	Theiler's murine encephalitis virus (TMEV)	2009, 2012, 2017, 2018	
	Rat minute virus (RMV) rNS1	2009, 2015, 2018	
	Rat Parvovirus (RPV)	2011, 2012, 2014, 2016, 2017, 2019	
	Adenovirus FI (type 1)	2017	
	Adenovirus K87 (type 2)		
	Reovirus type 3	2011, 2016	
	Mycoplasma pulmonis	2010, 2015, 2016, 2018, 2019	
	CAR Bacillus	2015, 2016, 2019	
	Lymphocytic choriomeningitis virus (LCMV)	2016	
	Clostridium piliforme	2011, 2014, 2017	
	Hantavirus		
	Encephalitozoon cuniculi	2009, 2010, 2017	
	Mouse Hepatitis virus	2019	
pathogen for PCR		In PEP distributionlist (year in which samples have been received)	
Minute virus of Mice (MVM)		2011, 2016, 2017	
Mouse Hepatitis Virus (MHV)		2008, 2011, 2014, 2016, 2018	
Mouse Parvovirus (MPV)		2007, 2009, 2011, 2017	
Mouse rotavirus (EDIM)		2014, 2019	
Pneumonia virus of Mice (PVM)		2011, 2015	
Sendai Virus		2008, 2017	
Theiler's murine encephalitis virus (TMEV)		2014, 2019	
Ectromella virus		2009, 2011, 2017	
Lymphocytic choriomeningitis virus (LCMV)		2008	
LDV		2019	
Adenovirus FI (type 1)		2012, 2016	
Adenovirus K87 (type 2)			
MAV		2017	
Muis Cytomegalo virus (MCMV)			
Reovirus type 3			
Mycoplasma pulmonis		2009, 2012, 2018	
Lactic Dehydrogenase Virus		2009	
K virus			
Mouse polyomavirus			
Kilham Rat Virus			
Murine Norovirus (MNV)		2012, 2019	
Rat coronavirus (RCV / SDA)		2015	
Toolan H-1 virus		2009, 2012	
Hantavirus			
Clostridium piliforme			
Corynebacterium bovis			
Helicobacter spp			
Helicobacter bills			
Helicobacter hepaticus		2007, 2008, 2010, 2016	
Helicobacter typhlonicus			
Helicobacter ganmani			
Helicobacter muridarum			
Helicobacter rodentium		2014	
Pasteurellaceae		2010	
Pasteurella pneumotropica		2014	
Actinobacillus muris		2017	
Pneumocystis murina		2012, 2015	
Pneumocystis carinii			
Pneumocystis spp		2018	
Trichomonas		2018	
Chilomastix spp		2019	
pathogen for bacteriology		In PEP distributionlist (year in which samples have been received)	
Aeromonas hydrophila		2010	
Bordetella bronchiseptica		2009, 2010, 2011, 2015, 2018	
Bordetella hinzii		2014, 2018	
Citrobacter freundii		2011, 2017	
Citrobacter rodentium		2010, 2012, 2016, 2019	
Corynebacterium spp		2009	
Corynebacterium bovis		2009, 2010, 2014, 2019	
Corynebacterium kutscheri		2009, 2011, 2016, 2018	
Corynebacterium mastiditis		2017, 2018	
Enterobacter cloacea		2015, 2016	
Escherichia coli			
Klebsiella oxytoca		2012, 2018	
Klebsiella pneumoniae		2009, 2015, 2019	
Pseudomonas aeruginosa		2019	
Salmonella spp.		2010, 2018	
S. choleraesuis		2017	
Serratia marcescens		2011, 2014	
Streptobacillus moniliformis		2015	
Streptococci (β-hemolytic)			
Streptococcus agalactiae		2012	
Streptococcus pneumoniae		2014	
Staphylococcus aureus		2007, 2011, 2014, 2015, 2019	
Staphylococcus xylosum		2012	
Staphylococcus sciuri		2012, 2016	
Stenotrophomonas maltophilia		2012, 2016	
Pasteurellaceae		2009	
Pasteurella dagmatis			
Pasteurella pneumotropica		2009, 2010, 2014	
Pasteurella multocida		2010, 2015	
Actinobacillus muris		2010	
Haemophilus influenza			
Proteus mirabilis		2015	
Pseudomonas aeruginosa		2009, 2014	
Yersinia enterocolitica		2016	
Yersinia pseudotuberculosis		2017	

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3 PEP PROGRAMS & PARTICIPANTS:

3.1 PEP Programs

PEP runs 3 programs, as follows:-

Programs	Shipments/Specimens	Annual Fee €
Serology only	1 annual shipment of 10 sera specimens	1,560
Microbiology only	1 annual shipment of 10 microbiology specimens	1,350
Combination	1 annual shipment of 10 sera & 10 microbiology specimens	2,150

3.2 Participants

By 2012, PEP had a truly international participation with labs from all five continents. With the program well established, it was felt appropriate to invite more labs to join the program. As the following table shows, since 2012, new labs have steadily joined the program with a maximum of 29 participants in 2016.

PEP Participating Laboratories: 2008-2019													
● Serology only	■ Microbiology only	■ Combination					◆ Not participating						
Participating Laboratories	08	09	10	11	12	13	14	15	16	17	18	19	
001 Biolytix AG, Switzerland	■	■	■	◆	◆	◆	■	■	◆	◆	◆	◆	
002 Harlan Laboratories UK					■	■	■	■	■	■	◆	◆	
003 QM Diagnostics, Netherlands	■	■	■	■	■	■	■	■	■	■	■	■	
004 Mic. Diagnostics, Germany	■	■	■	■	■	■	■	■	■	■	■	■	
005 MVMS, Australia	●	■	■	■	■	■	■	■	■	■	■	■	
006 Un.of Miami-Comp.Pat.Lab, USA	●	●	●	●	◆	◆	◆	◆	◆	◆	◆	◆	
007 The Jackson Lab, USA	■	■	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	
008 CIEA, Japan	■	■	■	■	■	■	■	■	■	■	■	■	
009 Cerberus Sciences, Australia	■	■	■	■	■	■	■	■	■	■	■	■	
010 Dynamimed S.L. Spain							●	●	●	●	◆	●	
011 Charles River Lab., France	●	■	■	■	■	■	■	■	■	■	■	■	
012 BioDoc, Hanover, Germany	●	●	●	●	●	●	●	●	●	●	●	●	
013 Taconic, Rockville, USA		■	■	◆	◆	■	■	■	■	■	◆	◆	
014 National An. Lab			●	■	■	■	■	■	◆	■	■	■	
015 Charles River Laboratories, Japan,			●	■	■	■	■	■	■	■	■	■	
016 IDEXX RADIL, Missouri, USA			■	■	■	■	■	■	■	■	■	■	
017 Charles River Laboratories, USA,			■	■	■	■	■	■	■	■	■	■	
019 Guangdong Lab An Mon.				■	◆	■	◆	◆	■	◆	◆	◆	
018 CEMIB, Brazil					■	■	■	■	■	■	■	■	

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020 Harlan Laboratories SRL, Italy					■	■	■	■	■	■	■	■
021 AnLab Ltd, Czech Republic					■	●	●	●	■	●	●	●
022 National An. Lab Center, Tainan,					■	●	◆	■	◆	◆	◆	◆
023 XpressBio, Maryland, USA					●	●	●	●	■	■	●	●
024 GIM Gesellschaft.,Mikroökologie					□	□	□	□	□	◆	◆	◆
025 Division of Laboratory Animal						□	■	■	■	■	□	□
026 GVG Diagnostics GmbH, Germany					■	◆	◆	■	◆	◆	◆	◆
027 NLAC, Mahidol University,						■	■	■	■	□	□	□
028 Model An. Res Center, China						■	◆	◆	■	◆	◆	◆
029 Laboratory Animal Monitoring						■	◆	◆	◆	■	◆	◆
030 IDEXX Bioresearch, Germany							■	■	■	■	■	■
031 Belki-Biotechnologies, Russia								□	◆	◆	◆	◆
032 Micro. Monitoring Lab., Korea									●	■	●	●
033 Vebio Laboratory, France									■	◆	◆	◆
034 Universiteit Utrecht, Netherlands									□	□	◆	◆
035 Biosait Europe SLU, Spain,									□	◆	◆	◆
036 Daegu-Gyeongbuk Med, Korea									■	■	■	■
037 Taiwan University, Lab. Taiwan									●	◆	◆	◆
038 Suzhou Xishan Biotech Inc. China										●	◆	◆
039 The Francis Crick Institute BRF., UK											■	■
040 VRL Maryland, LLC, USA											■	■
041 GemPharmatech CO.,Ltd. Nanjing,												■
Total Serology only	4	2	4	2	2	4	4	4	4	4	4	5
Total Microbiology only	0	0	0	0	1	2	2	3	5	4	3	3
Total Combination	6	9	1	1	16	18	1	1	20	18	15	16
Total Participants	10	11	14	13	19	24	23	25	29	26	22	24

Most of the labs who have left the program have done so for financial reasons or because the lab has closed

3.3 Terms and Conditions of participation in the ICLAS PRP Program

Participation in the ICLAS PEP program is in accordance with the following terms and conditions:

Eligibility: Any diagnostic laboratory worldwide can participate in the program. There are no specific eligibility requirements.

Programs and fees: Participating laboratories may choose to participate in any of the following programs. Fees must be paid in advance:-

Serology program: €1,560.1 shipment per year of 10 serology specimens

Microbiology program: €1,350 1 shipment per year of 10 microbiology specimens

Combination program: € 2,150 for 1 shipment of 10 serology specimens and 10 microbiology specimens

Shipment of Specimens: Specimens are shipped from the Network's distribution centre by World Courier normally in January. Participants may be required to apply for an import license and carry out other related administrative tasks as requested by World Courier

Reporting of results: PEP is a self-assessment program and participating laboratories are under no obligation to submit any reports of their results to ICLAS or any other agency.

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Assistance to Network specimen producer laboratories: While evaluation is self-assessed, participating laboratories are encouraged to report any differences between their analysis and expected results to help specimen production labs monitor their performance in the production of standardised samples. .

Certificate of Participation: Participating laboratories will be issued with a certificate of participation for a twelve month period running from 1st July to 30th June the following year.

ICLAS logo: Participating laboratories are not authorised to use the ICLAS logo on any of their own electronic or paper documents.

4 PEP INCOME & COSTS

4.1 Income

The only source of income for PEP is from fees paid by PEP participants, which are paid into an ICLAS bank account with the Caixa Bank on the UAB campus. This account was set up in April 2011 for the exclusive use of the LAQ Network to run the PEP program.

Around 90% of shipping costs are related to the weight and volume of dry ice required to maintain specimens at -18° C. As the volume and weight of specimens is relatively small compared to the volume and weight of the dry ice, the quantity of dry ice required for 20 specimens is not that much greater than the quantity required for 10 specimens. As a result, the cost of the combination program is only 30% more than the serology only program.

In order to cover the real costs of specimen production, shipment costs and administration, the following increases in PEP fees were agreed at the 2016 Network meeting in Brussels.

Program	Participation fee: 2008-2016	Fee: 2017- present
Microbiology only program	€1,260	Increased by 5% to €1,350
Serology only program:	€1,360	increase by 15% to €1,560
Combination program	€1,950	increase by 10% to €2,150

4.2 Costs

Income from fees are used to cover the costs of specimen production, confirmation and shipping to the DC, shipping specimens from the DC to PEP participants and program administration, as follows:-

4.2.1 Specimen production costs

In order to cover real costs of specimen production costs, the following changes to the amounts paid to network labs for specimen production were agreed at the 2016 Network meeting in Brussels. The costs of specimen production incurred by each producer lab is deducted from their participation fee so that no money is paid direct to producer labs.

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

Specimen type	Payments to producer labs per aliquot, 2008-2016	Payments to producer labs per aliquot 2017- present
Sera specimens	€17.50	€40
Microbiology specimens	€7.50	€4

4.2.2 Specimen confirmation analysis costs

These are costs of analysing specimens to ensure standardization and are currently met by the Network labs at an estimated cost of €100 per Network lab = € 500 for five labs. These costs are shared between participating labs.

4.2.3 Specimen confirmation shipping costs

These costs are for shipping specimens between Network labs for confirmation. Specimens are shipped by World Courier and payments are made direct to World Courier by the DC.

4.2.4 Specimen shipping costs from Network labs to DC

When specimens have been confirmed, they are shipped by World Courier to the DC at the UAB. Payments are made direct to World Courier by the DC.

4.2.5 Distribution shipping costs from DC to PEP participants.

Specimens are shipped by World Courier from the DC to individual participants. Payments are made direct to World Courier by the DC.

4.2.6 Distribution Centre costs

The Network is currently using space for its fridge and a work area for handling specimens from the SIAL laboratory at the UAB, Barcelona. Costs include:

- I. Equipment depreciation: Cost of fridge € 9,000 over 10 years = € 900 per year
- II. Equipment maintenance: Estimated annual premium
- III. Personnel costs: Lab technician: Full time employee of UAB. Estimated time allocated to
- IV. PEP = 40 hours per year @ €30/hour = €1,200
- V. Personnel costs: Shipping Administrator: Full time employee of UAB. Estimated time
- VI. allocated to PEP = 20 hours per year @ €30/hour = € 600
- VII. Program administration: Costs estimated at 2 hours per PEP participant at a gross cost of €33 hour as originally agreed by ICLAS Governing Board, to cover the following tasks:
 - Sending out application forms to participants.
 - Receiving applications and transferring data to shipping list.
 - Creating and sending invoices to participants.
 - Sending acknowledgements and participation certificates to participants.
 - Sending expected results to participants
 - Maintaining records of receipt of fees and payments to World Courier
 - Providing copies of all financial transactions to auditor.
 - Writing annual reports

From 2017, it was agreed that the DC could claim €100 per PEP participant per year to partially cover these expenses.

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

4.2.7 LAQ Network annual income & expenditure on ICLAS bank account.

There are two forms of financial reporting for LAQ Network programs: annual accounts covering the financial year January to December and indicative income and costs to estimate the cost of each individual program.

The following table shows all income and expenditure on the LAQ Network bank account from January to December for the years 2017 and 2018:

	2017	2018
Income	EURO	EURO
Balance at 31st Dec brought forward from previous year	47,025.17	50,650.35
PEP Participant fees	43,054.00	29,877.00
GENRef Participant fees	5,975.00	4,080.00
Total Income	96,054.17	84,607.35
Expenditure		
PEP Bank Charges	183.00	278.37
PEP Specimen production costs: Shipping costs of specimens to DC	8,450.07	3,169.45
GENRef Specimen production costs: Shipping costs of DNA specimens to DC	5,952.39	
PEP Specimen distribution costs from DC to participants	27,918.37	34,167.85
Meetings		
DC Admin Costs	2,899.99	
Total Expenditure	45,403.82	37,615.67
+ Balance at 31st December	50,650.35	46,991.68

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

4.2.8 Indicative income & expenditure for each PEP Program

The problem with annual accounts is that they don't present a real picture of the financial state of PEP because the income and expenditure of each program runs over two and sometimes 3 financial years. The following figures show indicative income and expenditure for the 2017 and 2018 PEP programs. As can be seen, for both 2017 and 2018, the programs generated a small surplus.

PEP Indicative Income & Expenditure for 2017 and 2018 programs		
	2017	2018
Number of Participants	26	22
	EURO	EURO
Income		
Participant fees	50,340.00	42,540.00
Total Income	50,340.00	42,540.00
Expenditure		
Bank Charges	141.00	152.20
Admin Costs	2,900.00	2,900.00
Meetings /Presentations		
Specimen production costs discounted from fees	8,600.00	4,720.00
Specimen production costs: shipping to DC	1,787.07	3,165.45
Specimen distribution costs: DC to participants	35,479.70	30,020.00
Total Expenditure	48,907.77	40,957.65
Balance	+1,432.23	+1,582.35

5 PEP REPORTS

The LAQ Network provides two types of Reports, as follows:

5.1 LAQ Network Annual Report

As shown in Appendix 12, this report details:

- Changes in Network Members and Network laboratories .
- Changes in PEP and GENRef fees and specimen production costs .
- The number of PEP and GENRef participants and program types for the previous year.
- PEP & GENRef income & expenditure on ICLAS bank account for the previous two years.
- Indicative income & expenditure for the previous year's PEP and GENRef programs.
- Objectives for the following year.

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

5.2 PEP Program Report for Participants

As shown in Appendix 13, this report details:

- The Network Laboratories Performing Sample Preparation and QC.
- Number of shipments made for each program.
- Contents of the specimens shipped.
- Remarks from Participating Labs on quality and labelling of specimens and discrepancies between their test results and expected results.
- Comments from the Distribution Center regarding quality and labelling of specimens and confirmation of expected results.

6 MANAGEMENT OF PEP PROGRAM

PEP programs run over two calendar years with tasks as follows:

6.1 Task 1: Send out PEP application forms

From May -July (year 1), send renewal PEP application form to all of the previous year's participants (see Appendix 1). Application forms for new PEP applicants (Appendix 2) can be downloaded from the ICLAS webpage:

<http://iclas.org/animal-quality-network/application>

6.2 Task 2: Receive PEP application forms

Check applications are correctly completed and signed and dated

6.3 Task 3: Update PEP Shipping List

Update shipping list with information, as in Appendix 3.

6.4 Task 4: Send PEP Invoices

Create and send invoices to participants acknowledging receipt of their application. For the majority of participants, the invoice will be for the cost of the program they have applied for (Appendix 4). However, in the case of the Network labs who have produced samples, the invoice may include a discount (Appendix 5) or may be in the form of a credit note (Appendix 6)

6.5 Task 5: Check LAQN bank account

Check LAQN bank account (Appendix 7) to see which participants have paid their fee.

6.6 Task 6: Transfer bank data to Excel sheet

Transfer bank data to Excel sheet showing movements on LAQN Account number 2100 0424 31 02 00242020 Jan - Dec 2017 (Appendix 8)

6.7 Task 7: Send acknowledgement of fee and Participation Certificate

June -December Year 1

To those participants who have paid their fee, send acknowledgement of receipt of fee (Appendix 9) and Participation Certificate (Appendix 10)

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

6.8 Task 8: Specimens are shipped to Participants

In July each year, a call is made to all Network laboratories for new samples, which must be confirmed and then sent to the DC (see section 2.2 above).

By December (year 1), the total number of participants is known and the DC coordinator (Patri Vergara) together with the PEP Scientific Director (currently W. Shek), discuss which samples from the stock can be used for the current year, with the aim of ensuring that no sample is repeated for two years.

Once all the samples have arrived in the DC, the agreed specimens are prepared for each participant together with the documentation for each shipment in collaboration with World Courier, the participating laboratory and the export authorities at Barcelona airport.

Once the import of specimens has been approved by the customs/health authorities of country in which the participating lab is located, (a task that may take months in the case of some countries), PEP samples are shipped by World Courier.

6.9 Task 9: Send Expected Results and Feedback Form

From January of year 2 onwards, PEP participants request expected results (Appendix 11), which are sent together with a feedback form (Appendix 12) to provide the project with information to include in the PEP Program Report for Participants (see section 5.1 above). The results provided by participants are completely anonymous and given on an entirely voluntary basis.

6.10 Task 10: Write LAQ Network Annual Report

In May /June each year, an annual report is compiled to contain all information relating to PEP and GENRef, as detailed in the 8 sections in ICLAS Laboratory Animal Quality Network (LAQ Network) Report 2019, shown in Appendix 13: LAQ Network Annual Report. (See section 5.1 above)

6.11 Task 11: DC Coordinator writes PEP Program Report for Participants

When most of the Expected Results have been sent, the DC coordinator writes and sends a PEP Program Report for Participants (see Appendix 14 and section 5.2 above)

6.12 Task 12: Prepare PEP invoices and bank statements for ICLAS Auditor

June, Year2: Make PDF copies of all PEP invoices and all related bank statements for the previous calendar year (Jan-Dec) . PEP bank statements can be downloaded from the CaixaBank LAQ Network current account, as shown in Appendix 7. Combine all documents in a single PDF binder and send to DC


7 APPENDICES

7.1 Appendix 1: Renewal PEP Application Form

Appendix 1: Renewal PEP Application Form	
<p>INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE</p> <p>ICLAS ANIMAL QUALITY NETWORK</p> <p>Application to participate in the 2020 ICLAS Performance Evaluation Program</p> <p>Please check that the following contact data we have for your lab is correct and indicate which program you wish to apply for. Please make any additions or corrections in red, date your application and return to: laqnetwork@iclas.org</p>	
PEP Identification Reference:	PEP025DLA
Name of Lab:	Division of Laboratory Animal Monitoring, NIFDC, Beijing, China
Name and mailing address of person to receive sample shipment:	Hong Wang Division of Laboratory Animal Monitoring, National Institutes for Food and Drug Control, No.31 HUATUO ROAD DAXING DISTRICT Beijing 102629, CHINA
E-mail, tel. & fax. of person to receive sample shipment:	littstar@163.com Tel.: 86-10-53852659
Contact person and e-mail address for invoice (if different from lab contact person):	
Name and e-mail address of person to receive copy of invoice (if required):	
Your lab's web address for link from ICLAS PEP web page:	www.nifdc.org.cn
<p>2020 Programs</p> <p>Please put an x in the box for the program you wish to apply for:</p> <p><input type="checkbox"/> Serology only: fee = €1,560 for 1 shipment of 10 specimens</p> <p><input type="checkbox"/> Microbiology only: fee = €1,350 for 1 shipment of 10 specimens</p> <p><input type="checkbox"/> Combination (Serology + Microbiology): fee = € 2,150 for 1 shipment of 20 specimens</p> <p>Please note: if your shipment requires either a Health Certificate and/or Certificate of Origin, you will be charged an additional €100 for each certificate. Any subsequent amendments to these certificates will cost an additional €100 per amendment.</p>	
Date of Application:	
Name and title (Prof. Dr. Mr. Ms.) of person making application:	
Please make any suggestions to help us improve the program:	

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.2 Appendix 2: PEP Application Form for new PEP Applicants

INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE		
ICLAS ANIMAL QUALITY NETWORK		
<u>Application to participate in the ICLAS Performance Evaluation Program</u>		
Name of Lab:		
Please briefly describe activities of the laboratory:		
Name and mailing address of person to receive sample shipment:		
E-mail, tel. & fax. of person to receive sample shipment:		
Contact person and e-mail address for invoice (if different from lab contact person):		
Name and e-mail address of person to receive copy of invoice (if required):		
Your lab's web address for link from ICLAS PEP web page:		
<u>Cost of Programs</u> Please put an x in the box for the program you wish to apply for: <input type="checkbox"/> Serology only: fee = €1,560 for 1 shipment of 10 specimens <input type="checkbox"/> Microbiology only: fee = €1,350 for 1 shipment of 10 specimens <input type="checkbox"/> Combination (Serology + Microbiology): fee = € 2,150 for 1 shipment of 20 specimens Please note: if your shipment requires either a Health Certificate and/or Certificate of Origin, you will be charged an additional €100 for each certificate. Any subsequent amendments to these certificates will cost an additional €100 per amendment.		
Date of Application:		
Name and title (Prof. Dr. Mr. Ms.) of person making application:		
Terms and Conditions of participation in the ICLAS Performance Evaluation Program for Diagnostic Laboratories (PEP) Eligibility: Any diagnostic laboratory worldwide can participate in the program. There are no specific eligibility requirements. Programs and fees: Participating laboratories may choose to participate in any of the following programs detailed above. Fees must be paid in advance. Shipment of Specimens: Specimens are shipped from the Network's distribution centre by World Courier normally in January. Participants may be required to apply for an import license and carry out other related administrative tasks as requested by World Courier Reporting of results: PEP is a self assessment program and participating laboratories are under no obligation to submit any reports of their results to ICLAS or any other agency.		

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

Assistance to Network specimen producer laboratories: While evaluation is self-assessed, participating laboratories are encouraged to report any differences between their analysis and expected results to help specimen production labs monitor their performance in the production of standardised samples. .

Certificate of Participation: Participating laboratories will be issued with a certificate of participation for a twelve month period running from 1st July to 30th June the following year.


ICLAS logo: Participating laboratories are not authorised to use the ICLAS logo on any of their own electronic or paper documents.

7.3 Appendix 3: PEP Shipping List

20



ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.4 Appendix 4: Standard PEP Invoice

Appendix 4: Standard PEP Invoice	
<div><div>INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE <i>ICLAS Network for the Promotion of Animal Quality in Research</i></div><div></div></div>	
NETWORK MEMBERS	
Central Institute for Experimental Animals, Japan	Carmen Calabresi Envigo RMS srl Via Vincenzo Monti 78 20832 Desio (MB) Italy C/A Laboratorio
Charles River Laboratories (RADS), USA,	
Cerberus Sciences, Australia	13 July 2020
German Cancer Research Center, Germany	PEP reference number: PEP020HIT
Institute for Experimental Animals, Hamamatsu University School of Medicine, Japan	Your PO number 657298
International Council For Laboratory Animal Science	Ref: ICLAS 2020 Performance Evaluation Program invoice.
QM Diagnostics, Radboud University Medical Centre, Netherlands	Dear Ms. Calabresi,
IDEXX RADIL, Missouri, USA	Further to your application to participate in the ICLAS 2020 Performance Evaluation Program, could you please remit a fee of EUR 2,150 to cover the participation of Envigo RMS srl , MI, Italy in the Serology and Microbiology programs.
SIAL Laboratory, Universitat Autonoma de Barcelona, Spain	This fee is in respect of 1 shipment per year containing 10 sera specimens and 10 microbiological specimens.
Taconic Health Diagnostic Laboratory, USA	Please pay in EURO € by bank transfer to the following account:
The Jackson Laboratory, USA	ACCOUNT NAME: International Council for Laboratory Animal Science
	BANK: Caja de Ahorros y Pensiones de Barcelona,
	ACCOUNT NUMBER: 2100 0424 31 0200242020
	IBAN: ES27 2100 0424 3102 0024 2020
	SWIFT: CAIX ES BB
	IMPORTANT: Please state your PEP reference number to facilitate payment identification. If you have any queries about this invoice please contact me at laqnetwork@iclas.org
	Yours sincerely,
	
	Andrew Hudson ICLAS LAQ Network Administrator
<div>ICLAS LAQ Network Room V0-141, Veterinary Faculty, Edifici V, Universitat Autònoma de Barcelona, 08193 Bellaterra, Spain http://www.ICLAS.org E-mail: LAQNetwork@ICLAS.org</div>	



ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.5 Appendix 5: PEP Invoice to Network Lab with discount for sample production

Appendix 5: PEP Invoice to Network Lab with discount for sample production							
<div style="text-align: center;"> INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE  </div> <p style="text-align: center;"><i>ICLAS Network for the Promotion of Animal Quality in Research</i></p>							
NETWORK MEMBERS Central Institute for Experimental Animals, Japan Charles River Laboratories (RADIS), USA, Cancer Sciences, Australia, German Cancer Research Center, Germany Institute for Experimental Animals, Hamamatsu University School of Medicine, Japan International Council For Laboratory Animal Science QM Diagnostics, Radboud University Medical Centre, Netherlands IDEXX RADIL, Missouri, USA SIAL Laboratory, Universitat Autònoma de Barcelona, Spain Taconic Health Diagnostic Laboratory, USA The Jackson Laboratory, USA	<p>Arletta van Lent QM Diagnostics Transistorweg 5 6534 AT Nijmegen The Netherlands</p> <p>18 July 2019</p> <p>PEP reference number: PEP003QMD</p> <p>Ref: ICLAS 2019 Performance Evaluation Program fee.</p> <p>Dear Ms van Lent ,</p> <p>Further to your application to participate in the ICLAS 2019 Performance Evaluation Program, could you please remit a fee of EUR 1,850 to cover the participation of QM Diagnostics, Nijmegen, the Netherlands in the Serology and Microbiology programs.</p> <table border="0"> <tr> <td> This fee is made up as follows: 2019 PEP combination fee: Less credit from 2019 Specimen production costs 40 QMG Mouse DNA extract, Chilomastix sp. Total to pay: </td> <td style="text-align: right; vertical-align: bottom;"> <table border="0"> <tr><td>EUR</td></tr> <tr><td>2,150</td></tr> <tr><td>300</td></tr> <tr><td style="border-top: 1px solid black;">1,850</td></tr> </table> </td> </tr> </table> <p>Please pay in EURO € by bank transfer to the following account:</p> <p>ACCOUNT NAME: International Council for Laboratory Animal Science</p> <p>BANK: Caja de Ahorros y Pensiones de Barcelona,</p> <p>ACCOUNT NUMBER: 2100 0424 31 020024 2020</p> <p>IBAN: ES27 2100 0424 3102 0024 2020</p> <p>SWIFT: CAIX ES BB</p> <p>If you would prefer to pay by cheque, please make it payable to ICLAS and send to:-</p> <p>ICLAS LAQ Network, Room V0-141, Veterinary Faculty, Edifici V, Universitat Autònoma de Barcelona, 08193 Bellaterra, Spain.</p> <p>IMPORTANT: For either payment method, please state your PEP reference number to facilitate payment identification. If you have any queries about this invoice please contact me at laqnetwork@iclas.org</p> <p>Yours sincerely,</p> <div style="text-align: center;">  Andrew Hudson ICLAS LAQ Network Administrator </div>	This fee is made up as follows: 2019 PEP combination fee: Less credit from 2019 Specimen production costs 40 QMG Mouse DNA extract, Chilomastix sp. Total to pay:	<table border="0"> <tr><td>EUR</td></tr> <tr><td>2,150</td></tr> <tr><td>300</td></tr> <tr><td style="border-top: 1px solid black;">1,850</td></tr> </table>	EUR	2,150	300	1,850
This fee is made up as follows: 2019 PEP combination fee: Less credit from 2019 Specimen production costs 40 QMG Mouse DNA extract, Chilomastix sp. Total to pay:	<table border="0"> <tr><td>EUR</td></tr> <tr><td>2,150</td></tr> <tr><td>300</td></tr> <tr><td style="border-top: 1px solid black;">1,850</td></tr> </table>	EUR	2,150	300	1,850		
EUR							
2,150							
300							
1,850							


ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.6 Appendix 6: PEP Credit Note to Network Lab with invoice fee discounted

Appendix 6: PEP Credit Note to Network Lab with invoice fee discounted																									
<div style="display: flex; justify-content: space-between; align-items: center;"> <div> <p>INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE</p> <p><i>ICLAS Network for the Promotion of Animal Quality in Research</i></p> </div> <div>  </div> </div>																									
<p>NETWORK MEMBERS</p> <p>Central Institute for Experimental Animals, Japan</p> <p>Charles River Laboratories (RADS), USA,</p> <p>Cerberus Sciences, Australia</p> <p>German Cancer Research Center, Germany</p> <p>Institute for Experimental Animals, Hamamatsu University School of Medicine, Japan</p> <p>International Council For Laboratory Animal Science</p> <p>QM Diagnostics, Radboud University Medical Centre, Netherlands</p> <p>IDEXX RADIL, Missouri, USA</p> <p>SIAL Laboratory, Universitat Autònoma de Barcelona, Spain</p> <p>Taconic Health Diagnostic Laboratory, USA</p> <p>The Jackson Laboratory, USA</p>	<p>Steve Jennings Senior Manager Research Animal Diagnostic Services Charles River 251 Ballardvale Street Wilmington, MA 01887 USA</p> <p>29 July 2019</p> <p>PEP reference number: PEP017CRU</p> <p>Ref: Credit Note : ICLAS 2019 Performance Evaluation Program</p> <p>Dear Mr Jennings,</p> <p>Further to your application to participate in the ICLAS 2019 Performance Evaluation Program, please be advised that your account is in credit to the sum of EUR 2,230.</p> <p>This credit has been calculated as follows:</p> <table style="width: 100%;"> <thead> <tr> <th></th> <th style="text-align: right;">EUR</th> </tr> </thead> <tbody> <tr> <td>2019 PEP combination fee:</td> <td style="text-align: right;">-2,150</td> </tr> <tr> <td>Amount of credit from 2018 invoice</td> <td style="text-align: right;">+1,300</td> </tr> <tr> <td>Credit for 2019 Specimen production</td> <td></td> </tr> <tr> <td>60 aliquot sera 0.1 ml Mouse a-Ectromelia 30 x €8 per aliquot</td> <td style="text-align: right;">+480</td> </tr> <tr> <td>60 aliquot sera 0.1 ml Mouse a-LCMV 30 x €8 per aliquot</td> <td style="text-align: right;">+480</td> </tr> <tr> <td>60 aliquot sera 0.1 ml Mouse a-MPV-I 30 x €8 per aliquot</td> <td style="text-align: right;">+480</td> </tr> <tr> <td>58 aliquot sera 0.25 ml Rat a-M pulmonis x €20 per aliquot</td> <td style="text-align: right;">+1,160</td> </tr> <tr> <td>60 aliquot Ectro specimen €4 per aliquot</td> <td style="text-align: right;">+240</td> </tr> <tr> <td>60 aliquot SDA V specimen €4 per aliquot</td> <td style="text-align: right;">+240</td> </tr> <tr> <td>Total Specimen prod credit</td> <td style="text-align: right;">+3,080</td> </tr> <tr> <td>Amount of credit to be deducted from your 2020 PEP fee:</td> <td style="text-align: right;">2,230</td> </tr> </tbody> </table> <p>Thank you for supporting ICLAS</p> <p>Kind regards,</p> <div style="text-align: center;">  </div> <p>Andrew Hudson ICLAS LAQ Network Administrator</p>		EUR	2019 PEP combination fee:	-2,150	Amount of credit from 2018 invoice	+1,300	Credit for 2019 Specimen production		60 aliquot sera 0.1 ml Mouse a-Ectromelia 30 x €8 per aliquot	+480	60 aliquot sera 0.1 ml Mouse a-LCMV 30 x €8 per aliquot	+480	60 aliquot sera 0.1 ml Mouse a-MPV-I 30 x €8 per aliquot	+480	58 aliquot sera 0.25 ml Rat a-M pulmonis x €20 per aliquot	+1,160	60 aliquot Ectro specimen €4 per aliquot	+240	60 aliquot SDA V specimen €4 per aliquot	+240	Total Specimen prod credit	+3,080	Amount of credit to be deducted from your 2020 PEP fee:	2,230
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<p>ICLAS LAQ Network Room V0-141, Veterinary Faculty, Edifici V, Universitat Autònoma de Barcelona, 08193 Bellaterra, Spain http://www.ICLAS.org E-mail: LAQNetwork@ICLAS.org</p>																									

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.7 Appendix 7: CaixaBank movements of LAQ Network current account



Appendix 7: CaixaBank movements of LAQ Network current account							
<div>  CaixaBank Now </div> <div> Liquid assets Cards Investments Financing Foreign trade Services Files Mobile </div>							
Position ^	Description	Date	Value date	More data	Amount	Balance	C
Of accounts	TRANSFERENC. DIV.	08/07/2020		KRIBB	+ 1.560,00	+ 33.712,95	T
Numerical global position	TRANSF.DIVISAS	03/07/2020		Wiebke Kohl	+ 1.560,00	+ 32.152,95	T
Graphic global position	TRANSF.DIVISAS	03/07/2020		CHARLES RIVER LABORATOIRE FRANCE	+ 1.350,00	+ 30.592,95	T
Most common transactions	DEP. MAINT. COMM.	01/07/2020			- 12,00	+ 29.242,95	
Balance and statement	TRANS. COMM. RCVED.	16/04/2020		WANG HONG	- 18,00	+ 29.254,95	
Favourite transactions	TRANSFERENC. DIV.	16/04/2020		WANG HONG	+ 1.285,00	+ 29.272,95	T
My certificates	TRANS. COMM. RCVED.	16/04/2020		NATIONAL APPLIED RESEARCH LABORA	- 18,00	+ 27.987,95	
Transfers	TRANSFERENC. DIV.	16/04/2020		NATIONAL APPLIED RESEARCH LABORA	+ 2.250,00	+ 28.005,95	T
Bring money from other entities v	DEP. MAINT. COMM.	01/04/2020			- 12,00	+ 25.755,95	
International v	ALIEN TRANS.FEE	06/03/2020			- 54,22	+ 25.767,95	
MailBox v	invoices 96400391	06/03/2020		world courier	- 13.554,44	+ 25.822,17	
Taxes, bills, enrolments and fines	TRANSFERENC. DIV.	11/02/2020		VRL SHARED SERVICES LLC	+ 2.150,00	+ 39.376,61	T
Drafts	ALIEN TRANS.FEE	07/02/2020			- 54,44	+ 37.226,61	
Bills	invoices 96400027	07/02/2020		world courier	- 13.610,73	+ 37.281,05	
Microdonations	TRANSF.DIVISAS	05/02/2020		The Francis Crick Institute Limi	+ 2.150,00	+ 50.891,78	T
Online direct debit bills invoicing	TRANSFERENC. DIV.	03/02/2020		EXPRESS BIOTECH INTERNATIONAL IN	+ 1.560,00	+ 48.741,78	T
<div> Solicitud moratoria hipotecaria y suspensión de cuotas de préstamos y tarjetas de crédito </div> <div> reply to annaula....docx ^ </div>							

7.8 Appendix 8: Excel sheet showing movements on LAQN bank account

Clipboard		Font		Alignment		Number			
K9	X	✓	<i>f_x</i>						
	A	B	C	D	E	F	G	H	I
1	Movements on LAQN Account number 2100 0424 31 02 00242020 Jan - Dec 2017								
2	Prog. Year	Prog.	Invoice year	Code	Description	Payment date	Description	Amount	Balance
3									
4									
5	2017	PEP	2017	2.2.1	PEP Participants Fees	13/12/2017	PEP0238XP XpressBio, Maryland, USA EXPRESS BIOTECH INTERNATIONAL IN	1,560.00	50,650.35
6		PEP	2017	4.2.2	Bank Charges	08/12/2017	PEP025DLA Division of Lab An Monitoring, NIFDC, China WANG HONG part of €3,635	-15.00	49,090.35
7	2017	PEP	2017	2.2.1	PEP Participants Fees	08/12/2017	PEP025DLA Division of Lab An Monitoring, NIFDC, China WANG HONG part of €3,635	2,335.00	49,105.35
8	2017	GENRef	2017	4.1	GENRef Part. fees	08/12/2017	GENRef-025DLA-11-2017 WANG HONG part of €3,635	1,300.00	46,770.35
9		PEP	2017	4.2.2	Bank Charges	30/11/2017	CHARLES RIVER LABORATORIES JAPAN	-15.00	45,470.35
10	2017	PEP	2017	2.2.1	PEP Participants Fees	30/11/2017	CHARLES RIVER LABORATORIES JAPAN	2,150.00	45,485.35
11			2017	4.2.2	Bank Charges	10/11/2017	PEP014NLA National Animal Lab Center, Taipei, Taiwan NATIONAL APPLIED RESEARCH	-15.00	43,335.35
12	2017	PEP	2017	2.2.1	PEP Participants Fees	10/11/2017	PEP014NLA National Animal Lab Center, Taipei, Taiwan NATIONAL APPLIED RESEARCH	2,264.00	43,350.35
13	2017		2016	3.6.4	DC Admin Charges	06/11/2017	UAB Invoice Admin charges	-2,899.99	41,086.35
14						06/11/2017	Cert Origin Bank charges 11062017	-7.15	43,986.34
15	2017	PEP	2017	3.6.1.3	Specimen production costs	06/11/2017	WC Invoice 0096390210 Charles River USA -> DC	-1,787.07	43,993.49
16	2017	PEP	2017	2.2.1	PEP Participants Fees	24/10/2017	PEP032MML PEP Microbiological Monitoring Lab., Korea 2000 0000-KRIBB	1,560.00	45,780.56
17						09/10/2017	Cert Origin Bank charges 10092017	-4.81	44,220.56
18	2017	PEP	2017	3.6.2	Specimen production costs	09/10/2017	WC Invoice 0096389967 DC -> PEP025DLA Division of Laboratory Animal Monitoring, NIFDC	-1,201.60	44,225.37
19	2017	PEP	2017	2.2.1	PEP Participants Fees	09/10/2017	PEP011CRL CHARLES RIVER LABORATOIRE FRANCE	1,350.00	45,426.97
20			2017	4.2.2	Bank Charges	06/10/2017	PEP005MVM ComPath SOUTH AUSTRAL HEALTH AND MEDICAL	-15.00	44,076.97
21	2017	PEP	2017	2.2.1	PEP Participants Fees	06/10/2017	PEP005MVM ComPath SOUTH AUSTRAL HEALTH AND MEDICAL	2,145.00	44,091.97
22	2017	PEP	2017	2.2.1	PEP Participants Fees	03/10/2017	PEP021ANL An Lab Ltd, Czech Republic	1,560.00	41,946.97
23			2017	4.2.2	Bank Charges	01/10/2017	PEP002HUK ENVIGO RMS (UK) LIMITED	-12.00	40,386.97
24	2017	PEP	2017	2.2.1	PEP Participants Fees	10/08/2017	PEP002HUK ENVIGO RMS (UK) LIMITED	2,150.00	40,398.97
25	2016	PEP	2017	4.2.2	Bank Charges	31/07/2017	CENTRAL INSTITUTE FOR EXPERIMENT	-15.00	38,248.97
26	2016	GENRef	2016	4.1	GENRef Part. fees	31/07/2017	GENRef-008CIE-11-2016 CENTRAL INSTITUTE FOR EXPERIMENT	490.00	38,263.97
27						28/07/2017	Cert Origin Bank charges 07282017	-5.33	37,773.97
28	2017	PEP	2017	3.6.2	Specimen distribution costs	28/07/2017	WC Invoice 009638935 DC -> PEP018 CEM Brazil	-1,331.25	37,779.30
29						26/07/2017	Cert Origin Bank charges 07262017	-3.95	39,110.55
30						26/07/2017	Cert of Origin F17002462	-45.00	39,114.50
31	2017	PEP	2017	2.2.1	PEP Participants Fees	20/07/2017	PEP030IBG Vet Med Labor GmbH	2,150.00	39,159.50
32	2017	PEP	2017	2.2.1	PEP Participants Fees	13/07/2017	PEP020HIT ENVIGO RMS SRL	2,150.00	37,009.50
33	2017	PEP	2017	2.2.1	PEP Participants Fees	07/07/2017	PEP027NMU NATIONAL LABORATORY ANIMAL CENTE	1,350.00	34,859.50
34	2017	GENRef	2017	4.1	GENRef Part. fees	07/07/2017	GENRef-027NMU-06-2017 NATIONAL LABORATORY ANIMAL CENTE	300.00	33,509.50
35	2016	PEP	2017	3.6.2	Specimen distribution costs	05/07/2017	Cert Origin Bank charges 07052017	-3.95	33,209.50
36	2016	PEP	2017	3.6.2	Specimen distribution costs	05/07/2017	Certificate of Origin F17002270	-45.00	33,213.45
37	2017	PEP	2017	4.2.2					

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.9 Appendix 9: Acknowledgment of receipt of PEP fee

Appendix 9: Acknowledgment of receipt of PEP fee	
<div style="text-align: center;">INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE </div> <p style="text-align: center;"><i>ICLAS Network for the Promotion of Animal Quality in Research</i></p>	
NETWORK MEMBERS	Carmen Calabresi Envigo RMS srl Z.I. Azzida, 57 33049 S. Pietro al Natisone, Udine, Italy
Central Institute for Experimental Animals, Japan	16 September 2019
Charles River Laboratories (RADS), USA,	PEP reference number: PEP020HIT
Cerberus Sciences, Australia	Ref: Acknowledgement ICLAS 2019 Performance Evaluation Program fee payment
German Cancer Research Center, Germany	Dear Ms. Calabresi,
Institute for Experimental Animals, Hamamatsu University School of Medicine, Japan	We acknowledge with thanks receipt of EUR 2.150 to cover the participation of Envigo RMS srl Bresso, Milano, Italy, in the 2019 ICLAS PEP Serology and Microbiology programs.
International Council For Laboratory Animal Science	Thank you for supporting ICLAS
QM Diagnostics, Radboud University Medical Centre, Netherlands	Yours sincerely,
IDEXX RADIL, Missouri, USA	
SIAL Laboratory, Universitat Autònoma de Barcelona, Spain	Andrew Hudson ICLAS LAQ Network Administrator
Taconic Health Diagnostic Laboratory, USA	
The Jackson Laboratory, USA	
<p>ICLAS LAQ Network Room V0-141, Veterinary Faculty, Edifici V, Universitat Autònoma de Barcelona, 08193 Bellaterra, Spain http://www.ICLAS.org E-mail: LAQNetwork@ICLAS.org</p>	

7.10 Appendix 10: PEP Participation Certificate

Appendix 10: PEP Participation Certificate



INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE

CONSEIL INTERNATIONAL DES SCIENCES DE L'ANIMAL DE LABORATOIRE

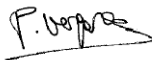
Established in 1956 under the auspices of UNESCO

*In official interaction with: OIE World Organization for Animal Health
World Health Organisation (WHO), International Council of Scientific Unions (ICSU)
Council for International Organisations of Medical Sciences (CIOMS)
World Veterinary Association (WVA)*

ICLAS LABORATORY ANIMAL QUALITY NETWORK

**Certificate of Participation in the ICLAS Performance Evaluation
Program for Diagnostic Laboratories**

*This is to certify that **Envigo RMS S.R.L., Bresso, Italy** is a participant
in the Serology and Microbiology ICLAS Performance Evaluation Programs for
diagnostic laboratories for the period 1 July 2019 – 30 June 2020.*





*Patri Vergara
Director, ICLAS Laboratory Animal Quality Network*

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.11 Appendix 11: PEP Expected Results

Appendix 11: PEP Expected Results

ICLAS Diagnostic Laboratory Performance Evaluation Program
Expected results for Distributed Specimens

Distribution # 50: PEP2019 Serology and Microbiology

Shipped To:
 QM Diagnostics, the Netherlands
 QM Diagnostics
 Transistorweg 5, 6534 AT Nijmegen, The Netherlands
 Attention: Arietta Bol
 Tel/Fax: +31 24 3615433 / +31 24 3616375
 Email: Arietta.bol@qmdiagnostics.org /
 qmdiagnostics@qmdiagnostics.org

Distributed By:
 Universitat Autònoma de Barcelona
 Unitat Fisiologia Facultat Veterinària
 08193 - Bellaterra (Barcelona), Spain
 Attention: Patxi Vargara
 Tel: +34 93 5811848
 Email: patxi.vargara@uab.es

Specimens				
ID #	Description	Quantity	Test For	Expected Positive Findings
50-1	Mouse serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	Adenovirus: FL Antibodies
50-2	Mouse serum diluted 5 fold in PBS	0.40 mL x1	Microbial Antibodies	CAR Bacillus: Antibodies
50-3	Rat serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	PVM Antibodies
50-4	Rat serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	Pneumocystis carinii (P. Jirovecii) + CARBAntibodies
50-5	Rat serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	Sendai virus: Antibodies
50-6	Rat serum diluted 5 fold in PBS	0.40 mL x1	Microbial Antibodies	Rat parvovirus (KRV) Antibodies
50-7	Mouse serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	Polyoma virus: Antibodies
50-8	Mouse serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	EMCV Antibodies
50-9	Rat serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	Reovirus: Antibodies
50-10	Mouse serum diluted 5 fold in PBS	0.50 mL x1	Microbial Antibodies	TMEV Antibodies
50-11	Rat spleen homogenate	0.50 mL x1	Virus	Toolan's HI
50-12	Bacterial culture	0.50 mL x1	Bacteria	Streptococcus agalactiae
50-13	Bacterial culture	0.50 mL x1	Bacteria	Serratia marcescens
50-14	Bacterial culture	0.50 mL x1	Bacteria	Rodentibacter heylti
50-15	Mouse faeces	0.50 mL x1	Bacteria	Helicobacter rodentium
50-16	Lung homogenate	0.50 mL x1	Virus	PVM
50-17	Bacterial culture	0.50 mL x1	Bacteria	Escherichia coli
50-18	Rat fluid diluted 10 fold	1.0 mL x1	Virus	SDAV
50-19	Bacterial culture	0.50 mL x1	Bacteria	Aeromonas hydrophila
50-20	DNA	0.1 mL x1	Bacteria	Streptococcus moniliformis

To be completed by Recipient

Received By: _____ Date: _____

Condition: _____

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.12 Appendix 12: PEP Expected Results Feedback Form

Appendix 12: PEP Expected Results Feedback Form

Dear PEP Participant,

To help us improve PEP and to provide us with information to include in our PEP annual report, we'd be very grateful if you would complete the column "Your Results and/or comments" in the table below.

Your results and any comments will be completely anonymous and although the information you provide is entirely voluntary, we would really appreciate your feedback.

Please return the completed form to me at: laqnetwork@iclas.org

Thanks for your cooperation.

Best regards,

Patri Vergara

Feedback Form: PEP 2019 Combination Program (Serology + Microbiology)					
ID #	Description	Quantity	Test For	Expected Positive Findings	Your Results and/or comments
50-1	Mouse serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	Adenovirus FL Antibodies	
50-2	Mouse serum diluted <u>5.fold</u> in PBS	0.40 mL x1	Microbial Antibodies	CAR Bacillus Antibodies	
50-3	Rat serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	PVM Antibodies	
50-4	Rat serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	Pneumocystis carinii (P. jirovecii) + CARBA Antibodies	
50-5	Rat serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	Sendai virus Antibodies	
50-6	Rat serum diluted <u>5.fold</u> in PBS	0.40 mL x1	Microbial Antibodies	Rat parvovirus (KRV) Antibodies	
50-7	Mouse serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	Polyoma virus Antibodies	
50-8	Mouse serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	EMCV Antibodies	
50-9	Rat serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	Reovirus Antibodies	
50-10	Mouse serum diluted <u>5.fold</u> in PBS	0.50 mL x1	Microbial Antibodies	TMEV Antibodies	

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

50-11	Rat spleen homogenate	0.50 mL x1	Virus	Toxigenic H1	
50-12	Bacterial culture	0.50 mL x1	Bacteria	Streptococcus agalactiae	
50-13	Bacterial culture	0.50 mL x1	Bacteria	Serratia marcescens	
50-14	Bacterial culture	0.50 mL x1	Bacteria	Bordetella pertussis	
50-15	Mouse feces	0.50 mL x1	Bacteria	Helicobacter rodentium	
50-16	Lung homogenate	0.50 mL x1	Virus	PVM	
50-17	Bacterial culture	0.50 mL x1	Bacteria	Escherichia coli	
50-18	Rat fluid diluted <u>10 fold</u>	1.0 mL x1	Virus	SDAV	
50-19	Bacterial culture	0.50 mL x1	Bacteria	Aeromonas hydrophila	
50-20	DNA	0.1 mL x1	Bacteria	Streptobacillus moniliformis	

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.13 Appendix 13: LAQ Network Annual Report

ICLAS Laboratory Animal Quality Network (LAQ Network) Report 2019

1. Network Members

Network Members	
Patri Vergara, (Network Coordinator)	Veterinary Faculty, Universitat Autònoma de Barcelona, Spain
Cynthia Pekow, USA (ICLAS President)	University of Washington, USA
William Shek	Charles River Laboratories (RADS),USA
Atsushi Yoshiki	RIKEN BioResource Center, Japan
Martin Toft	QM Diagnostics, Radboud University, Netherlands
Cynthia Besch-Williford	IDEXX RADIL, Missouri, USA
Ana Perez	Humodigen, USA
Greg Ballard	The Jackson Laboratory, USA
Nobuhito Hayashimoto (ICLAS Governing Board member)	Central Institute for Experimental Animals, Japan
Bob Stevenson	Cerberus Sciences, Australia

2. PEP Fees and Specimen production costs applied since 2017:

Microbiology only program: €1,350.00

Serology only program: €1,560

Combination program: €2,150.00.

Costs: payments to producer laboratories to cover specimen production costs:

Sera specimens: €40 per aliquot

Microbiology specimens: €4 per aliquot

3. PEP Participants

PEP Participating Laboratories: 2008-2019											
● Serology only	■ Microbiology only	■ Combination	◆ Not participating								
Participating Laboratories	08	09	10	11	12	13	14	15	16	17	18
001 Biolytix AG, Switzerland	■	■	■	◆	◆	◆	■	■	◆	◆	◆
002 Harlan Laboratories UK					■	■	■	■	■	■	◆
003 QM Diagnostics, Netherlands	■	■	■	■	■	■	■	■	■	■	■
004 Mic. Diagnostics, Germany	■	■	■	■	■	■	■	■	■	■	■
005 MVMS, Australia	●	■	■	■	■	■	■	■	■	■	■
006 Un.of Miami-Comp.Pat.Lab, USA	●	●	●	●	◆	◆	◆	◆	◆	◆	◆
007 The Jackson Lab, USA	■	■	◆	◆	◆	◆	◆	◆	◆	◆	◆
008 CIEA, Japan	■	■	■	■	■	■	■	■	■	■	■
009 Cerberus Sciences, Australia	■	■	■	■	■	■	■	■	■	■	■

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

010 Dynamimed S.L. Spain								●	●	●	●	◆
011 Charles River Lab., France	●	■	■	■	■	■	■	□	□	□	□	□
012 BioDoc, Hanover, Germany	●	●	●	●	●	●	●	●	●	●	●	●
013 Taconic, Rockville, USA		■	■	◆	◆	■	■	■	■	□	□	◆
014 National An. Lab Center, Taipei, Taiwan			●	■	■	■	■	■	■	◆	■	■
015 Charles River Laboratories, Japan,			●	■	■	■	■	■	■	■	■	■
016 IDEXX RADIL, Missouri, USA			■	■	■	■	■	■	■	■	■	■
017 Charles River Laboratories, USA,			■	■	■	■	■	■	■	■	■	■
019 Guangdong Lab An Mon. Institute, China				■	◆	■	◆	◆	■	◆	◆	◆
018 CEMIB, Brazil					■	■	■	■	■	■	■	■
020 Harlan Laboratories SRL, Italy					■	■	■	■	■	■	■	■
021 AnLab Ltd, Czech Republic					■	●	●	●	■	●	●	●
022 National An. Lab Center, Tainan, Taiwan					■	●	◆	■	◆	◆	◆	◆
023 XpressBio, Maryland, USA					●	●	●	●	■	■	●	●
024 GIM Gesellschaft, Mikroökologie mbH, Germany					□	□	□	□	□	◆	◆	◆
025 Division of Laboratory Animal Monitoring, China						□	■	■	■	■	■	□
026 GVG Diagnostics GmbH, Germany				■	◆	◆	■	◆	◆	◆	◆	◆
027 NLAC, Mahidol University, Thailand						■	■	■	■	□	□	□
028 Model An. Res Center, China niversity, China						■	◆	◆	■	◆	◆	◆
029 Laboratory Animal Monitoring Center, China						■	◆	◆	◆	■	◆	◆
030 IDEXX Bioresearch, Germany							■	■	■	■	■	■
031 Belki-Biotechnologies, Russia								□	◆	◆	◆	◆
032 Micro. Monitoring Lab., Korea									●	■	●	●
033 Vebio Laboratory, France									■	◆	◆	◆
034 Universiteit Utrecht, Netherlands									□	□	◆	◆
035 Biosait Europe SLU, Spain, Barcelona, Spain									□	◆	◆	◆
036 Daegu-Gyeongbuk Med, Korea									■	■	■	■
037 Taiwan University, Lab. Taiwan									●	◆	◆	◆
038 Suzhou Xishan Biotech Inc. China (VRL Asia)										●	◆	◆
039 The Francis Crick Institute BRF., UK											■	■
040 VRL Maryland, LLC, USA											■	■
Total Serology only	4	2	4	2	2	4	4	4	4	4	4	4
Total Microbiology only	0	0	0	0	1	2	2	3	5	4	3	3
Total Combination	6	9	1	1	16	18	1	1	2	1	15	15
Total Participants	10	1	1	1	19	24	2	2	2	2	22	22

4. PEP Network Laboratories:

Specimen production laboratories	Representatives
Central Institute for Experimental Animals, Japan	Nobuhito Hayashimoto
Charles River Laboratoires (RADSL), USA	William Shek (PEP Scientific Director)
QM Diagnostics, Radboud University, Netherlands	Arletta van Lent-Bol
IDEXX RADIL, Missouri, USA	Cynthia Besch-Williford
Cerberus Sciences, Australia	Bob Stevenson
LAQ Specimen Distribution Center	
SIAL Laboratory, Universitat Autònoma de Barcelona)	Patri Vergara (Network Chair)

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

5. PEP & GENRef income & Expenditure on ICLAS bank account Jan-Dec 2018

	2017	2018
Income	EURO	EURO
Balance at 31st Dec brought forward from previous year	47,025.17	50,650.35
PEP Participant fees	43,054.00	29,877.00
GENRef Participant fees	5,975.00	4,080.00
Total Income	96,054.17	84,607.35
Expenditure		
PEP Bank Charges	183.00	278.37
PEP Specimen production costs: Shipping costs of specimens to DC	8,450.07	3,169.45
GENRef Specimen production costs: Shipping costs of DNA specimens to DC	5,952.39	
PEP Specimen distribution costs from DC to participants	27,918.37	34,167.85
Meetings		
DC Admin Costs	2,899.99	
Total Expenditure	45,403.82	37,615.67
+ Balance at 31st December	50,650.35	46,991.68

6. PEP Indicative Income & Expenditure for 2018 PEP Program

The problem with yearly accounts is that they don't present a real picture of the financial state of PEP because the income and expenditure of each program runs over two and sometimes 3 financial years. The following figures show indicative income and expenditure for the 2018 program.

PEP Indicative Income & Expenditure for 2017 and 2018 programs		
	EURO	EURO
	2017	2018
Number of Participants	26	22
Income		
Participant fees	50,340.00	42,540.00
Total Income	50,340.00	42,540.00
Expenditure		
Bank Charges	141.00	152.20
Admin Costs	2,900.00	2,900.00
Meetings /Presentations		
Specimen production costs discounted from fees	8,600.00	4,720.00
Specimen production costs: shipping to DC	1,787.07	3,165.45
Specimen distribution costs: DC to participants	35,479.70	30,020.00
Total Expenditure	48,907.77	40,957.65
Balance	+1,432.23	+1,582.35

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7. Genetic Monitoring Reference Program (GENRef)

Launched at the end of 2016, the ICLAS GENRef program provides reference DNA from the 12 most common inbred strains/ sub-strains of laboratory mice, e.g. C57BL/6N, C57BL/6J, BALB/cJ, BALB/cN, C3He, 129S6, etc. As the program develops other mice strains and the most common rat strains will be incorporated.

4.1 GENRef Program Details

7.1 Samples:

Sample concentration: each sample = 250 nanograms/10 microliters

Sample quantity: maximum of 1 sample of each strain per applicant

7.2 Fees:

Sample cost: €100 per sample

7.3 Shipping costs:

For labs participating in the ICLAS PEP program, DNA samples are sent with PEP specimens for an additional shipping cost of €100 for 1-12 samples.

For labs not participating in the ICLAS PEP program or who want their DNA specimens sent separately, shipping costs are as follows:

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

Europe: €800 for 1-12 specimens

Rest of the world: €1,300 for 1-12 specimens

Rest of the world if health and origin certificates are required: €1,600 for 1-12 specimens.

On request DNA samples can be sent at room temperature to reduce shipping costs as stability has been proven although we recommend sending the samples with dry ice.

7.4 GENRef Participating Laboratories

GENRef Participating Laboratories 2016-2018				
♦ Not participating:				
Participating Laboratory:	2016 DNA strains ordered	2017 DNA strains ordered	2018 DNA strains ordered	
008 Central Institute for Experimental Animals, (CIEA), Japan	(1,2,5,6)	♦	♦	
018 CEMIB- Multidisciplinary Center, Brazil	(1-12)	(1-12)	(1-12)	
019 Guangdong Lab. Animal. Mon. Institute, Guangzhou, China	(1-12)	♦	♦	
025 Division of Lab. Animal Mon. Inst., (NIDF), China	(1-12)	(1-12)	♦	
027 National Laboratory Animal Center, Mahidol University, Thailand		(5,6)	1,2,3,5,6,7,9, 10,11	
028 Microbiological Detection Center, Nanjing University, China		(1,5,6,7,8)	♦	
Total Participants	4	4	2	
Total Strains	40	31	21	
DNA strains/sub-strains available:				
1. C57BL/6NTac	5. C57BL/6J (reg. #664)	9. DBA/2JcJcl		
2. BALB/cAnNTac	6. BALB/cJ (reg. #651)	10. C3H/HeJcJcl		
3. C3H/HeNTac	7. NOD/LtJ (reg. 1976)	11. DBA/2NJcJcl		
4. 129S6/SvEvTac	8. A/J (reg. #646)	12. FVB/NJcJcl		

8. Objectives for 2019

A meeting of all Network members took place on June 10th, 2019 in Prague, where both programs were thoroughly discussed.

Summary of decisions:

Performance Evaluation Program: main week points identified:

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

- 1) Serology program: there is a need for production of more sera samples and to diversify the list of microorganisms available. Although these problems are difficult to tackle, several solutions were discussed. As a starting point, a short list of organisms that should be added to PEP stock will be prepared.
- 2) Microbiology program: although the problem is not so acute, it was also discussed that instead of providing samples of isolated DNA it would be more relevant to provide a diluted sample where the microorganism could be isolated either by traditional microbiology methods or by molecular techniques. Some labs still do not do DNA testing.
- 3) In both programs, labs producing PEP samples must complete a common data sheet with details about the sample (origin, organ etc) to facilitate testing by participants.
- 4) SOPs for PEP sample preparation and retesting will be revised.
- 5) A new database will be created.
- 6) Feedback from participants will be encouraged and a form allowing them to report their results will be prepared. These data will be presented anonymously to all participants.

For the GENRef Program it was agreed that the program needed to be better advertised and for this the following actions were agreed:

- Ana Perez would give a presentation of the ICLAS GENRef program at the FELASA Congress Scientific Program to increase awareness.
- A publication on how the GENRef program works, how it can be applied at an institution was agreed as the next step. Some points to be included will be : What this program does to assist with quality assurance of lab animals (Inbred strains); Who needs it (labs versus individuals); How to use it; What equipment do labs need, what tests should be run, what samples to take from the in-house colony, how many animals to test. Example cases should be given on how labs have successfully used the program; strain information; markers to differentiate from other sub-strains, etc.
- Publication should be open access, so that we can provide links available on ICLAS and other web pages.

Patri Vergara,
LAQ Network Coordinador
June 2019

ICLAS Policies and Procedures: ICLAS Performance Evaluation Program (PEP)

7.14 Appendix 14: 2017 PEP Program Report for Participants

INTERNATIONAL COUNCIL FOR LABORATORY ANIMAL SCIENCE

ICLAS Animal Quality Network 2016 PEP Program Report Friday, 04 August 2017

Page 1 of 3

I. Network Laboratories Performing Sample Preparation and QC Laboratory	Preparation	QC
IDEXX, Columbia, MO	√	√
RADS, Wilmington MA	√	√
CIEA, Kawasaki, Japan	√	√
QM, Nijmegen, Netherlands	√	√
DKFZ, Heidelberg, Germany	√	√
Cerberus, Adelaide, Australia	√	√

I. Specimens Sample ID	Species	Matrix-Source	Target	Agent
41-1, 42-1	Mouse	Serum	Antibodies	Reovirus
41-2, 42-2	Mouse	Serum	Antibodies	Adenovirus FL
41-3, 42-3	Mouse	Serum	Antibodies	Polyoma virus
41-4, 42-4	Rat	Serum	Antibodies	<i>Encephalitozoon cuniculi</i>
41-5, 42-5	Rat	Serum	Antibodies	RTV
41-6, 42-6	Rat	Serum	Antibodies	KRV
41-7, 42-7	Mouse	Serum	Antibodies	CARB
41-8, 42-8	Rat	Serum	Antibodies	Tyzzer
41-9, 42-9	Rat	Serum	Antibodies	RPV
41-10, 42-10	Mouse	Serum	Antibodies	MVM
41-11, 43-1	Mouse	Spleen homogenate	DNA Viruses	Ectromelia

Page 2 of 3 Sample ID	Species	Matrix-Source	Target	Agent
41-12, 43-2	Mouse	Fluid	DNA Viruses	MPV-1
41-13, 43-3	NI	Culture	Microbe	<i>Actinobacillus muris</i>
41-14, 43-4	NI	Culture	Microbe	<i>Citrobacter freundii</i>
41-15, 43-5	NI	Culture/ from eye lesion	Microbe	<i>Corynebacterium mastiditis</i>
41-16, 43-6	Mouse	Lung homogenate	RNA viruses	<i>Sendai virus</i>
41-17, 43-7	Mouse	Liver	DNA viruses	MAdV-1
41-18, 43-8	Mouse	Fluid	Bacteria	<i>Salmonella choleraesuis</i>
41-19, 43-9	Mouse	Fecal sample	DNA viruses	MVM
41-20, 43-10	NI	Culture	Microbe	<i>Yersinia pseudotuberculosis</i>

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4. *Salmonella choleraesuis* Mouse fluid (Samples 41-8, 43-8)

Remarks: One lab reported additional microbe identification.

5. **MVM** Mouse fecal sample (Samples 41-19, 43-9)

Remarks: One lab reported that Mycoplasma DNA and not MVM had been identified.

V. Comments from the Distribution Center:

All specimens were analyzed by a different network lab before samples were sent to the distribution center. Only samples confirmed are used for PEP.

Once the PEP specimens had been determined, all aliquots were labeled as PEP samples at the same time to avoid any mixing or mislabeling of samples. In view of the discrepancies reported by some participants one of the Network labs was asked to confirm the expected results. This lab confirmed all the results.

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7.15 Appendix 15: Proposal for the management of the ICLAS Network

Proposal for the administration of the ICLAS Network for Promotion of Animal Quality in Research (Agreed November 2010)

BACKGROUND

ICLAS has always emphasized international harmonization in respect of the quality of laboratory animals and the ethics of animal experimentation with the overall aim of improving scientific and ethical standards.

Until recently, ICLAS was promoting the *Monitoring and Reference Center Program* (M&RCP) which contributed significantly to the establishment of genetic and microbiological monitoring and to important improvements in the quality of scientific research, especially in Asia.

This program, however, was limited in two main respects. Firstly, the program was not applicable to all laboratories around the world. Secondly, continuation of the program would have required implementation of a prohibitively expensive quality assurance program and the standardization of methods and procedures, neither of which were objectives of ICLAS.

For these reasons and also to accommodate the growing number of laboratories seeking ICLAS recognition, the ICLAS Governing Board (Argentina, 2004) decided to create a Laboratory Animal Quality sub-committee to evaluate the need and to make proposals for a new laboratory animal quality program.

ICLAS NETWORK FOR PROMOTION OF ANIMAL QUALITY IN RESEARCH

The ICLAS sub committee met with Monitoring and Reference Center representatives and experts from around the world in St Louis, 2005. Participants unanimously agreed on the necessity to replace the M&RCP with a new program that was more international in scope and which could serve as an international reference in the field of high quality laboratory animal models. The proposal was approved by the ICLAS Governing Board (Jeju, August 2006) (ICLAS GB meeting minutes 2006 Jeju, Korea) and it was agreed that:

1. ICLAS would provide funding for the development phase of the programs with the condition that the operational phase would be self-financing.
2. as one of ICLAS's key objectives was to promote scientific programs that improve the quality of laboratory animal health, the ICLAS Network for Promotion of Animal Quality in Research would be considered an ICLAS project.
3. there was need for a legal and financial framework for the management and administration of the LAQN, in particular for the PEP program.

PROPOSAL FOR THE ADMINISTRATION OF THE ICLAS NETWORK FOR PROMOTION OF ANIMAL QUALITY IN RESEARCH

Over the next year, the ICLAS LAQ Network completed the planning stage for the implementation of the ICLAS Performance Evaluation Program (PEP). Following successful trials in 2007, PEP became fully operational in 2008, starting with 4 founder labs and ending the year with a total of 9 PEP Participants and a total of 11

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participants for the 2009 PEP program.

With the PEP program established, in 2010, the Network submitted the following proposal to the ICLAS Governing Board for the creation of a management group to manage ICLAS LAQ programs, as follows:

Proposal for the administration of the ICLAS Network for Promotion of Animal Quality in Research

1. Name of the program:

ICLAS Network for Promotion of Animal Quality in Research (Short name: LAQ Network) hereinafter referred to as the Network.

2. Terms of reference of the Network

To manage and develop health and genetic monitoring programs that will fulfil ICLAS aims of improving the quality of animals used in research in compliance with international principles.

3. Composition of Network Management Group (NMG):

The Network to be composed of the following:

- i. two representatives from the ICLAS Governing Board
- ii. one representative from the PEP Distribution Centre (DC) , that should be the responsible of the DC
- iii. the expert representative from each LAQ Network member laboratory nominated by the laboratory/unit/department of the institution to which the laboratory belongs as their expert representatives to sit on the Network Management Group. They are network members and are to be selected among prestigious laboratories around the world by the representatives of the founder labs.
- iv. according to specific needs, the NMG can invite up to two representatives from the LAS community with expertise in Network programs as ad-hoc experts.

4. Network Meetings:

The Network shall meet every 18 months normally in conjunction with ICLAS scientific member meetings e.g., FELASA and AALAS to facilitate member participation without additional costs. Any decisions required between meetings will be made by telephone conference or by electronic ballot at the discretion of the Network scientific Director. Members of the Network will normally be responsible for paying their own travel costs and expenses incurred in attending Network meetings.

5. Network Executive.

- i. Members of the Network Executive elected by Network members.
- ii. The responsibility for implementing Network policy shall be vested in the Network Executive, consisting of the following members:
 - a. one of the ICLAS Governing Board representatives;
 - b. the DC representative;
 - c. two of the LAQ Network member laboratory representatives

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A Network Coordinator will be elected by the Network members among the Network executive members.

iii. Duties of the Network Coordinator will include:

- a. having executive responsibility for conducting the affairs of the Network;
- b. calling and chairing Network meetings, telephone conferences and electronic ballots;
- c. preparing and sending minutes of all types of Network meetings;
- d. co-ordinating the work of the Network Executive and other Network members;
- e. allocating Network administrative tasks together with the Network Executive.
- f. preparing and sending in collaboration with the NMG and the network executive Network budgets and annual reports detailing the Network's activities. The annual report of activities and the budget for the following year will be prepared no later than March 31st and presented by an ICLAS Governing Board representative to the ICLAS Governing Board during its annual meeting.
- g. ensuring that proper income and expenditure accounts are kept;
- h. acting as legal representative of the Network in its dealings with other organisations.
- i. making payments from ICLAS LAQ Network account

6. Quorum and Decision making

Seven members of the Network shall constitute a quorum. All decisions shall be made by simple majority of the votes of those present and taking part.

7. Outline of future management of the ICLAS Performance Evaluation Program (PEP).

7.1 PEP will be an ICLAS project managed and developed by the LAQ Network

7.2 Current and new PEP participant laboratories will be considered as **LAQ-PEP Participants**.

7.3 The Network will send an invoice to LAQ-PEP participants depending on whether they wish to participate in only one or both PEP programs. The annual fee should cover the cost of their participation in the program and may have to be changed periodically as the program grows and/or changes.

7.4. LAQ-PEP participants will pay in Euro their fees to the new ICLAS LAQ Network Account which will be set up at La Caixa, UAB, specifically to receive fees from participants in Network programs and donations specifically made to Network projects. The Network Scientific Director will be a signatory on this account and able to make direct payments from this account as agreed by the Network.

7.5 LAQ-PEP participant fees will accumulate in the ICLAS's LAQ Network account and the funds will be used to support the costs of specimen production, shipping, administration and all other costs incurred by the PEP project and any other expenditure as agreed appropriate by the Network.

7.6 The PEP distribution centre, already functioning under a grant received from the Spanish Ministry of Science, will continue to be based at the UAB for the duration of the grant i.e., until 2013. In the event that funding is not available from this grant after this date, then it will be necessary for other funding mechanisms to be identified and possibly to relocate the DC.

7.7 All legal agreements relating to PEP, i.e., in respect of specimen production, shipping, insurance and terms and conditions with PEP participant laboratories will be made between the DC (now at the UAB), ICLAS and the

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parties concerned with all terms and conditions decided by the Network.

8. Powers/ responsibilities of the NMG in respect of PEP.

The Network will be an autonomous decision-making body and empowered to take all management, financial and operational decisions relating to PEP including:

8.1 determining the terms of agreements or MOUs between the DC and producer labs;

8.2 determining the terms and conditions between the DC and participating labs (LAQ- PEP participants);

8.3 determining the terms of insurance cover required;

8.4 determining the administrative structure appropriate to the needs of PEP, including the administrative tasks required and the rates of pay for those tasks;

8.5 determining the disbursement of all funds from ICLAS LAQ Network account received by the Network in the form of participation fees, donations or grants, including decisions on how to spend the received money. It will continuously be accumulated and be available. If LAQN program comes to an end, the available money will be kept into ICLAS.

8.6 determining in collaboration with the ICLAS Governing Board the strategy for the future development of PEP;

8.7 determining in collaboration with the ICLAS Executive the content of all information relating to PEP appearing on the ICLAS.org web site.

8.8 determining the location of the PEP Distribution Centre;

8.9 responsibility for sending invoices to LAQ-PEP participants;

8.10 responsibility for paying all payments and costs incurred by the project through ICLAS LAQ Network account;

8.11 responsibility for ensuring that proper accounts are kept in respect of all PEP income and expenditure;

8.12 responsibility for compiling and sending annual reports to ICLAS, NMG members and to any donor organization, detailing the work of the Network and how donations have been spent.

9. Duties and responsibilities of ICLAS in respect of the PEP program. ICLAS will:

9.1 ICLAS will be supportive to the implementation and development of the LAQN program,

9.2 Set up a new ICLAS Euro account at la Caixa, UAB, to receive ICLAS LAQ-PEP participants fees and possibly LAQ-GENPEP participants fees and to nominate the Network Scientific Director as a signatory on these accounts;

9.3 set up a new e-mail account: LAQNetwork@ICLAS.org to be used for correspondence for all Network programs;

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9.4, continue to make space available on its website ICLAS.org for the Network to publish material relating to PEP, as determined by the Network.

9.5 Transfer all past PEP participant fees received since July 2007 (less bank charges, PEP administration fees, specimen production and shipment costs and any other costs related to the program already paid by ICLAS from these fees) to the new ICLAS LAQ Network account.

9.6 Authorise two members of the ICLAS Governing Board to serve on the Network.

10. Outline of future management and development of the ICLAS Genetic Quality Monitoring Program (GQMP).

10.1 The GQMP will be managed and developed as an ICLAS project.

10.2 The GQMP, as previously detailed in a report considered by the ICLAS Governing Board at their last meeting in May 2009, has five phases. Phases 1-4 are concerned with education and training and phase five is the establishment of a self- assessment genetic monitoring program (GENPEP) along similar lines to the current PEP program.

10.3 The Network will implement phases 1-4 and continue discussions on how and when to implement a GENPEP program which, as with PEP, may require a trial period. For the implementation of phase 5 the LAQ Network will present a proposal to the ICLAS G. Board following the terms established for the PEP management and administration. This means that Network will be empowered to take all management, financial and policy decisions in accordance with the PEP management structure.

11. Future Projects

Future projects may be initiated by either ICLAS or the Network only following an agreement with the ICLAS Governing Board.