

Want to know the basics to PCR? Read our e-book!

BioChek is known for its experience and expertise in the field of ELISA testing. We have more than 20 years of know-how and practice in that field. PCR is a much newer market to us. We embarked on the production and sales of PCR kits only three years ago: in 2015. Now, we have over 15 PCR kits in our growing portfolio!

So, we can imagine taking the steps into PCR can be overwhelming. That's why we created an e-book all about the basics of PCR. In the e-book we tell you how PCR works, how it differs from the ELISA-method and: how it can save you hours of your precious time.

In just ten pages we'll get you through all the basics. There's a segment on our BioChek Software and how it works together with our PCR kits. PCR can be virtually fully automated by the usage of the BioChek software. It helps with running PCR and sample setup. By combining the use of our PCR kits with our software, time will be saved, and errors prevented.

The decision to start performing PCR can have large consequences for your lab. BioChek has highly qualified experts that can help you with all these questions and steps. From lab setup to the needed equipment: BioChek will gladly share their knowledge and assist with the implementation of molecular diagnostics at your lab. In our e-book, we also take you through the steps of setting up a PCR lab and the logistics when running PCR assays every day.

For more info: www.biochek.com/ebook

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BioChek PCR in numbers

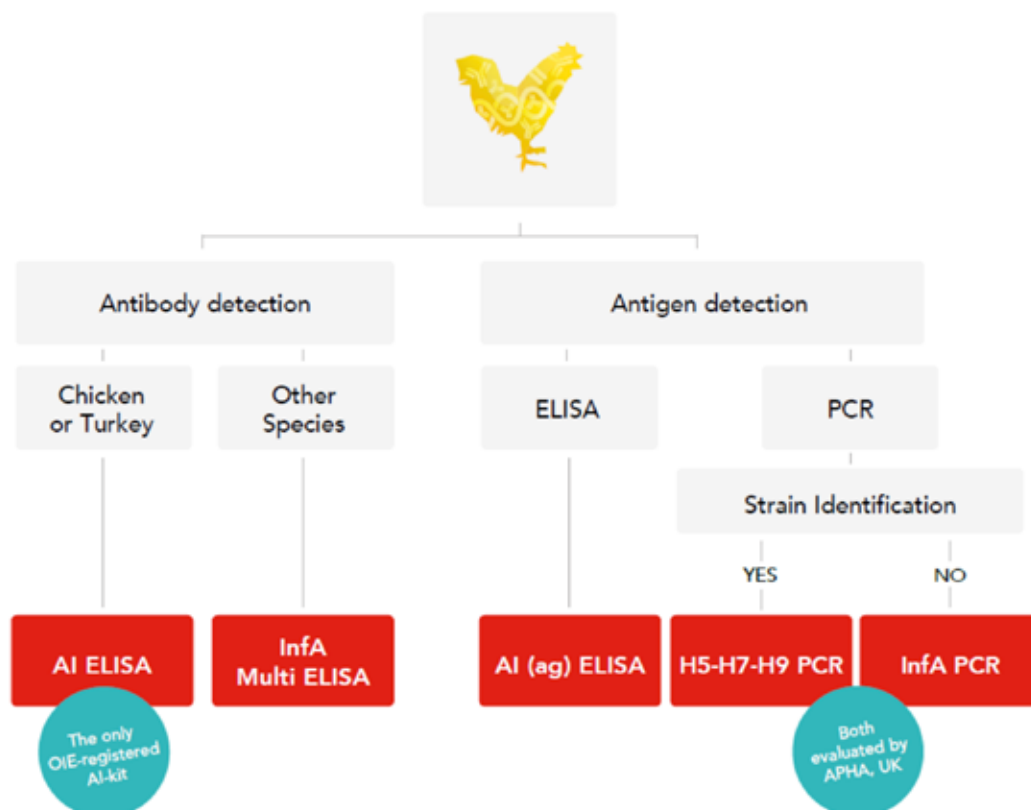
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Our Avian Influenza Portfolio

There are always ongoing risks of avian influenza around the globe. The benefits of active surveillance therefor ensure early detection of outbreaks in commercial poultry.

The OIE stresses the importance of active monitoring for Avian Influenza as the risk of new outbreaks remains and clinical signs are not always visible. BioChek is here to support you!

BE IN CONTROL of AVIAN INFLUENZA





BioChek's QC department: our eyes of quality

They're called 'eyes of quality': the Quality Control (QC) employees at the BioChek production facility in Ascot, UK. It's a driven team, led by Monika Piska. Everything is checked by these 'eyes': from raw materials, to volume of bottles, the kit performance, all the way to the packaging of an ELISA kit. Attention to detail is a very important part of the job.

Monika Piska has been the QC Manager for three years. She's got a passion for biology and chemistry ever since her Forensic Science degree at the University of South Wales. That passion got her where she is now. "After graduating, I started working at Thermo Fisher Scientific where I manufactured various diagnostic kits for human diagnostics. It led me to working within the development of ELISA tests, which spiked my interest. I worked at SciPac, part of the Abbott diagnostics division within an antibody characterisation role and then discovered BioChek. I started as QC/R&D technician, so I had a mix of quality control and research and development activities at work, I quickly was promoted to QC Supervisor. I loved what I was doing and so did management." She laughs. "Otherwise, they would never have made me the QC Manager a couple of years later."

Quality: first and last

As QC Manager, Piska is responsible for quality control of all swine and poultry kits produced in Ascot. "BioChek always puts quality first, it's what we stand for. Our job is to ensure that all products are of a very high quality and can also give

consistent reproducible results. We test each part of an ELISA kit, from plates to substrate reagent. Nothing is ever left to chance. Before, during and after production our motto is 'check, check, check!'."

Piska gives an example how her team works regarding the manufacture and approval of Reference controls. We manufacture specific Reference controls that are kit specific, or detect multiple diseases so can be used on a variety of kits, which we test extensively and create specification ranges. These controls can be purchased by our customers who can use these to ensure that their assay result is validated, this ensures that the kit to kit consistency is maintained at a high standard.

Another example is plate testing. After production, a specific number of plates are tested, tells Piska. "We look at the reproducibility and stability. With our test results, it's determined if we can approve the plates. Only plates that make it through our quality demands and registration specifications, will be approved. If a batch doesn't meet our standards, it's put in quarantine. Ultimately, that batch will be destroyed. It's a very strict and precise process with very high standards."

Traceability

BioChek documents all data and test results of all products sold. “One of the most important reasons for this is traceability,” tells Piska. “We supply a specific product to our customers, so we must be able to check if everything is, as it should be.”

The USDA checks all deliveries to the United States. “Our production information and data is essential in this. That way, the USDA can check if our products fit the required specifications. But the data is also important to us. If there’s ever a problem with our kits, we can trace everything. That way, we can find out what the possible cause is. And if we know the cause, we can work on a solution. So to document everything is very important to everybody involved.

Check, check double check

When all quality checks and tests before, during and after production are finished, a final check takes place during the assembling of the kits. “We assemble our ELISA kits by hand,” says Piska. “Obviously, there are very high demands to be met by all workers. Accuracy and attention to detail are of the utmost importance. Each kit is assembled with the highest care. Standard procedure at BioChek is that workers double check the work of their colleagues. When you have to pack 400 kits, it can’t hurt to have somebody from the outside give it a final check. That’s why the QC technicians

check five percent of all assembled and packaged kits. Kits from the beginning, middle and end of the production run are sampled. The labels, the contents and the packaging itself are checked. It’s the end of a very thorough and precise audit trail.”

Distribution

Finally, after production there’s the distribution. All of the distribution takes place at BioChek’s head office in the Netherlands, with exception of American customers. Piska explains why. “We are a USDA licenced facility. That’s why we ship our kits from Ascot to the States. Everything else goes to the Netherlands, where their logistics team makes sure the kits get distributed all over the world.”

At the moment, the QC team is working hard to optimise the quality control of distribution. “At the moment, we monitor the temperature during transport to the USA,” says Piska. “We also work with a tracking system and we always have contact with the customer when that system says the kits are delivered. Also, the distributors we work with have gone through a meticulous selection. As part of a team of Managers, we are working to develop a protocol for all of these aspects. That way, we’ll be assured of high quality from start to finish. At BioChek, we have the highest standards for our products and their production. We have to maintain those standards from the first step of production, right down to the delivery at our customers. We have set a high bar and can always set it higher.”



Meet our sales team

As you may know, there are some internal changes in the BioChek team:



- | | |
|---|--|
|  Luuk Stooker – Sales Director EMEA |  Haiqiang Ning – Sales Manager East Asia |
|  Tim Goode – Sales Director America's, Australia & New Zealand |  Ike Ng – Sales Manager South & West Asia |
|  Dmytro Yefimenko – Director for Eastern Europe and Asia |  Yongyut Sriyong – Sales Manager Thailand |
|  Jantina De Vylder – Business Unit Manager Poultry, Global |  Ilya Volkov – Eastern Europe swine program Manager |
|  Fernando Anuña – Distributor Manager Latinamerica |  Youssef Badr – Sales & Technical Manager Middle East |



CAL Labs' Neil Dominy: "We found a partner in BioChek"

Some of BioChek's customers have a small serology lab with one technician. Not Central Analytical Laboratories (CAL Labs) in South Africa. Not only do they have a dedicated Serology laboratory with six fulltime technicians, they have five BEARS fully operational, with a sixth currently on order. BioChek spoke with general manager Neil Dominy.

CAL Labs is one of the leading laboratories in Southern Africa. It's a division of Astral Operations Limited; the leading South African integrated poultry producer. Astral Operations has three main entities: a Feed Division an Agricultural Division and a Commercial Division. "We already offered a comprehensive service to the Feed Division," says Neil Dominy, who has been with CAL Labs for 17 years. "This experience and knowledge was leveraged to open our brand-new serology lab three years ago for the Agricultural Division."

Over thirty people work at CAL Labs, with six dedicated technicians in the serology laboratory. "We are a commercial laboratory with customers throughout the Southern African region, but Astral Operations is

our biggest client," says Dominy. "Astral Operations slaughters over five million chickens a week and has approximately 36 million chickens alive at any one time."

With that many ELISA tests to conduct, a partner in veterinary diagnostics was sought three years ago. "Our veterinarians wanted to work with a company with international ties, whose results could be interpreted or benchmarked against results available worldwide. As it was a new laboratory we needed to source both equipment and ELISA test kits," explains Dominy. We evaluated five different suppliers and spoke with two in the end, one of which was BioChek. Both our technicians and veterinarians chose BioChek as our preferred supplier."

The BioChek ELISA Assay Robot (BEAR) is a helpful tool for serology labs; it's a complete solution for running all BioChek ELISA test kits. The local BioChek representative introduced the BEAR to CAL Labs. There are now five BEARS working at their serology lab. Dominy tells why they wanted automation. "We looked for a machine that could provide a quality analysis - accuracy and repeatability. With the BEAR, you significantly reduce any errors or variations that humans make. Both our veterinarians and technicians are very satisfied with the BEARs." So satisfied, that a sixth BEAR will be on its way to South Africa soon.

Dominy is also satisfied with the technical support BioChek provides. "The BioChek Technical Support Manager came to CAL Labs to install the BEARs and explain how they worked. If we ever have an issue with a BEAR, BioChek is just a phone call away." And there's more room to work together with BioChek. CAL Labs is looking into the possibilities to work with the BioChek Monitoring Software, as well as potentially setting up a PCR lab in the future. "We've talked with

BioChek about the possibilities for testing with PCR, and I've read the e-book. We do have the space available to build a PCR lab. It's a long-term decision, we'll have to look into our customer needs and go from there."

As for working with the software, that might come a bit sooner. "We currently only use it together with our BEARs," says Dominy. Our technicians really like it. But our vets can't use it yet, as it does not interface with our LIMS system, however BioChek is working on a solution together with our software experts. It's great that BioChek listens to our needs. I've seen examples of what the software can do, and I hope we can use it soon."

Currently, CAL Labs uses fifteen BioChek ELISA test kits. "Working with BioChek is great. As soon as we signed the contract three years ago, I knew we had entered an equal partnership. BioChek isn't a competitor for our laboratory, it's a partner. I've never regretted the decision to pick BioChek."

In June 2017, South Africa was hit by an HPAI (H5N8) outbreak. The Department of Agriculture, Forestry and Fisheries immediately took full measures to contact and eliminate the disease as soon as possible. There were about 200 H5N8 detections between June 19th and July 18th, 2017.

Neil Dominy: During an HPAI outbreak a comprehensive analytical service including ELISA, HI and PCR is required. Currently the laboratory is actively involved in providing our customers with accelerated ELISA testing to enhance their BioSecurity controls.





BioChek COO Brahim Bozia: "our completeness makes us unique"

Practically noone at BioChek still works in the role he or she started in. The company active in veterinary diagnostics has been experiencing a positive flow for years and there seems to be no end in sight for growth for the time being. That offers a wealth of opportunity.

BioChek started offering diagnostic kits for the poultry sector 20 years ago. The company now enjoys a recognised worldwide reputation and is an active presence in every country. 'Simply mention our name and everyone knows what you're talking about,' says COO Brahim Bozia. BioChek produces over 30 different ELISA-kits: tests that trace antibodies or antigens against various diseases that frequently affect poultry and swine. These kits are produced in the United Kingdom. R&D, sales, marketing and logistics are coordinated from the head office in Reeuwijk.

BioChek, an established name in the poultry world

'The great thing about our reputation is that I don't have to convince potential customers of the quality of our products and the technical service we provide. We sell the complete portfolio in poultry diagnostics and have a number of unique characteristics: if you can convey those qualities, a customer is sure to buy 80% of our whole range. It's a slightly different story in the swine sector, as we have not been active all that long in that segment. But we're doing well. Compared to two years ago, the production facility in England has quadrupled. This has created more space to cope

with the current growth. It also means that we have to at least double our capacity here in Reeuwijk, both in terms of space and staffing levels. For that reason, we are moving to a new location at the end of next year.'

Year-on-year growth

'In the 11 years that I have worked at BioChek, I have not seen a single year that didn't achieve growth. In 2007 the turnover was 1.3 million euro's. That figure has gone up this year to the projected budget of 15 million and we think that can even be improved on. Some of that must be generated by the swine sector. Positioning our products in East Europe and Asia takes a lot of time and effort, as the sector is more fragmented and less organised than the poultry sector. Whereas in the poultry sector the tendency is to purchase the entire portfolio of products from a single supplier, the swine sector is used to dealing with multiple suppliers. In addition, the international swine industry often works with commercial labs and veterinarians. That dictates a different approach to the market.'

What is on the horizon for the company? What is your goal?

‘The ambition is to triple the turnover in five years. That is only feasible with the right products and the right people. With a share of 16%, we are the market leader in the poultry sector. And, for PCR and ELISA specifically, we account for a market share of 40%. If the branding and awareness of our products are successful in the swine sector, we expect to boost our market share of half a percent to 3% in 2023. We are aiming for growth from 5 to 15% for PCR and ELISA products. I’m fully aware just how ambitious that sounds, but it is achievable if you realise that until now we have noted growth of 15% annually.’

What makes BioChek so unique?

‘Our completeness is what makes us unique. The poultry portfolio is a total package with an extensive software tool that compares all data and identifies and reports trends. IT systems supplied by others do nothing more than read out results. We ensure reliable results and robust interpretation to enable customers to intervene and take the right course of action. That is valuable information for veterinarians! Especially as the data can be accessed anytime, from virtually anywhere, whereas others have to make do with a stand-alone in the lab.’

Developments are certainly not standing still. What other trends have you identified?

‘We used to monitor using just the ELISA technique, but nowadays more and more diagnostics are performed using PCR. In the past, you had to wait three to five weeks before you could identify a disease or vaccination, but PCR gives you the results within two days. Speed is becoming ever-more vital, as are easy-to-use kits. PCR used to be a relatively complicated process, but now we make it as easy as possible. What we’d really like to see is a result after just two or three steps. Another development are multiplex systems. No longer one test per disease, but one swab and six results in one assay. In addition, legislation is becoming more extensive and stricter: veterinary diagnostics are following the practice in human diagnostics. Reliability is priority number one!’

What do the R&D activities involve at BioChek?

‘We have a strong R&D team that comes up with a new product every two to three months. That level of creative flow makes it difficult to maintain a focus. For

that reason, we have decided to concentrate on PCR. Our new Business Unit Manager Swine will help define which products will be the main targets of our efforts.’

What kind of people can facilitate that growth?

‘Independent and flexible professionals who empathise with and reflect the growth ambitions of BioChek. Our work is driven by a certain strategy: if the market changes, the team has to change along with it. I value people who come up with ideas and tell me how things could work better. I’m adverse to people with a “but we’ve done it like that for years” mentality. Another of my pet peeves is a wait and see attitude. If you are the Marketing Manager and you can’t work with a certain agency, then find another one. Outdated product brochure? Tell me about it. I’m employing you for your expertise and drive, to show me the way, not follow my lead. If you are a Business Unit Manager and you think attending a certain trade event is vital, convince me and book your ticket. We have a robust organisational structure and healthy finances, so nothing is stopping us to try and test new ideas and concepts. We operate together, as a team, in an open and direct setting. If you’re ambitious, and you show it, the sky is the limit here.’

Is that how you reached the top?

‘More or less. After graduating with a degree in organic chemistry, I worked as an account manager in the human diagnostics field for four years. I then joined Thermo Fisher Scientific, a company that supplies technologies and equipment for laboratories. I started in the sales team for Europe, but my region was expanded, and I was given more responsibilities. When BioChek approached me, I said no at first, but after a year I accepted an international role which widened the scope of my activities to include not just Europe, but also the Middle East and Africa; an exciting challenge. Four years later I had progressed to Sales Manager Asia, then I became Sales Director and I have been COO since last year. Practically no one at BioChek still works in the role he or she started in. Everyone grows and progresses. It has to be something you want to do. It’s all part of the transition from entrepreneur to being a professional organisation. I am immensely proud that we have managed to achieve all this with just a small team. And there’s more to come. The plans and changes ahead in the coming five years offer a host of career opportunities.’

BioChek 2018

Ring Trial IBD (Gumboro)

In 2018, BioChek organised the BioChek IBD Ring Trial. The objective of this Ring Trial was to provide our customers with an opportunity to get an insight in their performance on BioChek ELISA and how their results compare to other laboratories. The performance was determined by accuracy (true titer) and precision (repeatability) of the Ring Trial Samples. Of course, all results must pass the criteria set for the positive, negative and reference controls.

For participants that have passed all criteria, a score was calculated based on both accuracy and precision. The closer the mean titer of all samples were to the results obtained by BioChek Quality Control, the more accurate the result is. The lower the coefficient of variance (%CV) was for similar samples with medium titer level, the more precise the result is. This resulted in a scoring and the top 5 laboratories with the highest score are presented below:

Rank	Participant	Country
1.	Jubilee Sky Sdn Bhd	Malaysia
2.	Yangji Hatchery	Republic of Korea
3.	Diagnósticos Clínicos Vetrinarios, S.A. de CV.	Mexico
4.	BÁBOLNA TETRA KFT:	Hungary
5.	Expert Laboratory LTD	Russia

Participants that have passed all criteria set for this ring trial, were certified with a **Certificate of Achievement**. All other labs were offered support and a retake of the Ring Trial, which allows BioChek to help improve the results of their customers.

With 104 participants BioChek sees a growing interest for Ring Trials. Next year we will invite our customers again to participate in a Ring Trial!

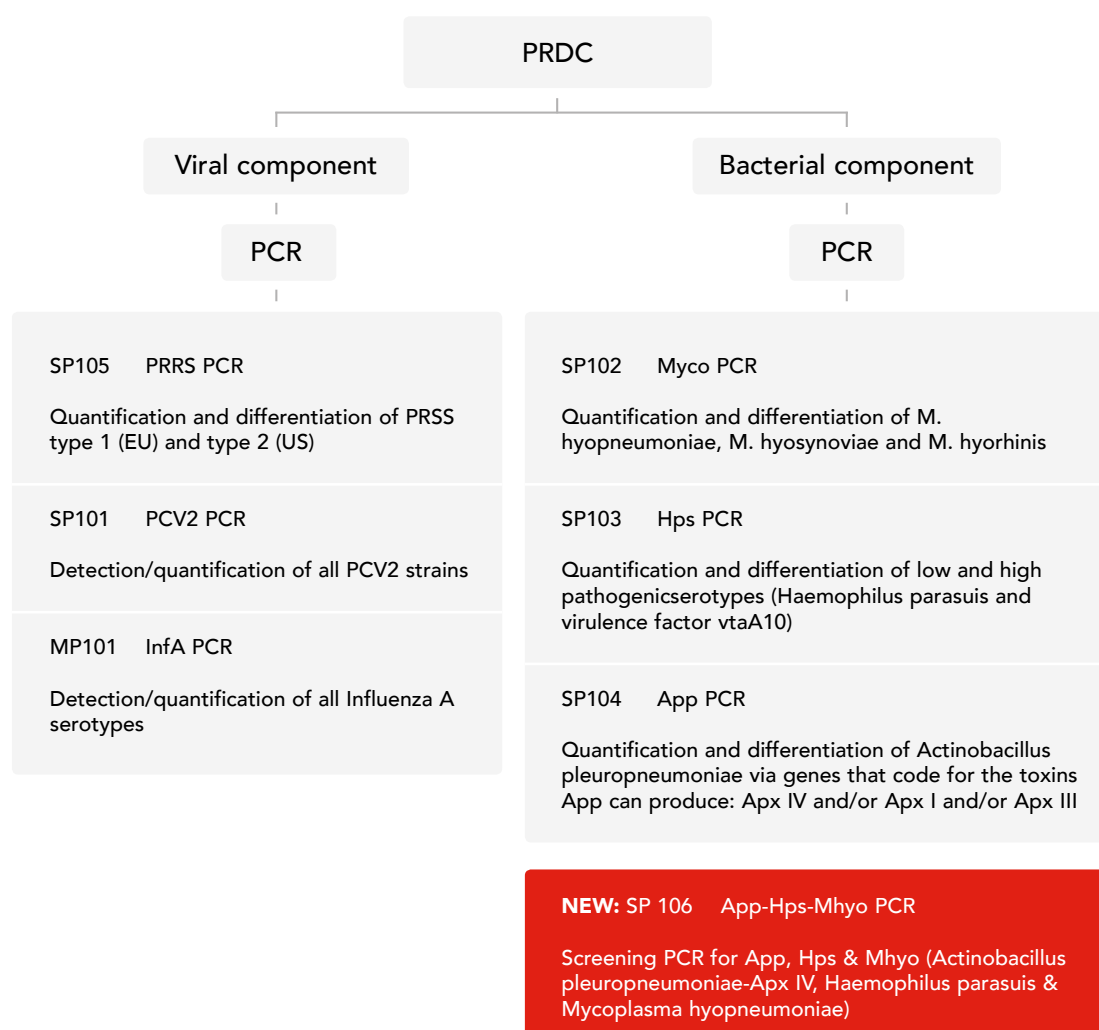


Swine PCR Respiratory Screening Kit

Porcine Respiratory Disease Complex (PRDC) is one of the major swine disease complexes and is economically important. Respiratory diseases attribute to high economic losses in swine. Since it is a complex of multiple pathogens, diagnosis of PRDC is not always easy. PCR's are a common tool in diagnostics, both for clinical diagnosis and monitoring program.

In PRDC you should test for all possible pathogens that can be involved. Since this can be an expensive exercise, multiplex PCR's can help determine the pathogens of interest in a cost effective way. If followed up by specific target PCR's in order to gain in depth information on pathogens of interest, it becomes a powerful diagnostic tool.

We offer a complete PCR Respiratory Screening panel.



BioChek Calender Winter / Spring 2019

We look forward meeting you at one of these following events.

IPPE

11 – 14 Feb 2019, Atlanta, USA

AASV

9 – 12 March 2019, Orlando, USA

VIV Asia

13 – 15 March 2019, Bangkok, Thailand

Aneca

2 – 6 April 2019, Puerto Vallarta, Mexico

BioChek Lab Training

April 2019, Reeuwijk, the Netherlands

ESPHM

22 – 24 May 2019, Utrecht, the Netherlands

Check our website or subscribe to our newsletter to stay up to date with BioChek and the events we'll attend.



More information on working together on animal health?

Don't hesitate to contact us. After all, reliable veterinary diagnostics start with BioChek! For more information, visit our website:

www.biochek.com

BioChek, SMART Veterinary Diagnostics



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