

# IQ/OQ/PQ in Electrophoresis

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■ serving scientists ■

## **IQ/OQ/PQ is important**

In quality and in-process control as well as research and development departments in biotechnological, diagnostic or other companies, it is becoming increasingly important to separate proteins and nucleic acids reproducibly using electrophoretic methods. This requires documented quality assurance both at installation (IQ) and operation of devices (OQ) as well as during ongoing processes (PQ).

## **Full service**

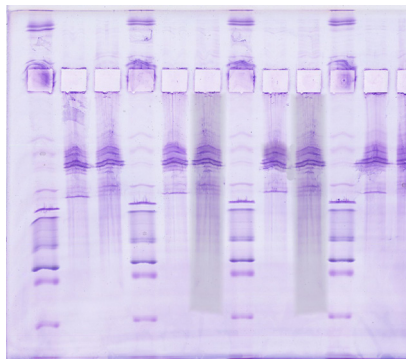
Prior to shipment of devices, e.g. HPE™ BlueHorizon™ flatbed system, we perform 3 independent electrophoresis experiments per application as the master of reference. A qualified SERVA specialist performs the installation (IQ) and the test run (OQ) using SERVA reagents and gels from the same batch. On an annual basis, a qualified specialist of SERVA checks the device, repeats the separation as qualification test, using reagents and gels which are traceable by lot number (PQ).

IQ/OQ/PQ of electrophoresis equipment and applied methods (IEF, SDS PAGE, 2D PAGE) may be of particular importance when applied to one of the following:

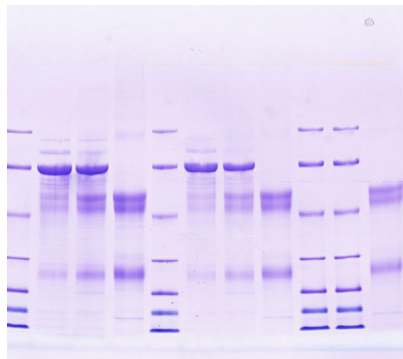
- Characterization/separation of recombinant antibodies
- Characterization/separation of therapeutic proteins
- HCP analysis and blotting

## **Training courses in electrophoresis**

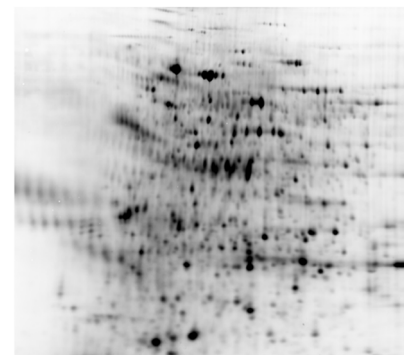
SERVA also offers training courses (webinar, theoretical course, practical hands-on workshops). The goal is to provide sound knowledge and practice in versatile electrophoresis techniques like isoelectric focusing (IEF), SDS PAGE and 2D gel electrophoresis. Please, inquire for specific programs; IQ/OQ/PQ does not include any theoretical or practical training.



Antibody Analysis by IEF



Antibody Analysis by SDS PAGE



HCP Analysis by 2D PAGE  
(kindly provided by BioGenes GmbH/Berlin)

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### **Installation Quality**

- Check packing list
- Full Installation
- Check Installation
- Operator briefing
- Documentation
- DIN EN ISO/IEC 17025

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### **Operational Quality**

- 3 Reference runs
- Test run
- Documentation
- DIN EN ISO/IEC 17025

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### **Performance Quality**

- Service Contract
- Cleaning
- Maintenance
- Repair
- Re-Qualification
- DIN EN ISO/IEC 17025

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## Methods in electrophoresis covered by SERVA:

### Vertical electrophoresis (10 cm x 10 cm)

- SDS PAGE
- IEF (isoelectric focusing)
- Native PAGE
- 2D gel electrophoresis
- Western blot of vertical gels

### Horizontal electrophoresis (up to 26 cm x 20.5 cm)

- SDS PAGE
- SDS TA PAGE
- IEF (isoelectric focusing)
- Native PAGE
- 2D gel electrophoresis
- DNA/RNA electrophoresis
- Western blot of thin, film-backed gels

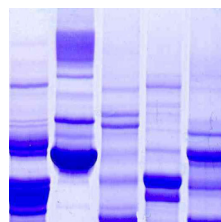
### Special applications:

- EPO differentiation
- Antibody separation
- IEF of serum and cerebrospinal fluid (CSF)
- IEF & SDS PAGE in Phast™ gel format
- IEF in IPG strips (1<sup>st</sup> dimension in 2D)

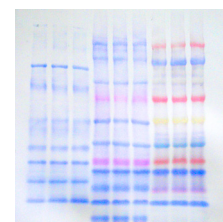
## Application-based IQ/OQ/PQ

At SERVA, we believe that application based IQ/OQ/PQ is the best way to qualify an electrophoresis workflow (including device and separation method). Measuring electro-physical properties would not provide ultimate answers about the performance of an electrophoresis system; human factors (e.g., user and knowledge), material factors (e.g., reagents and gels) and environmental factors (e.g. climate and laboratory condition) have also a significant but not measurable impact on performance. There is nothing better than proving performance by a standardized application! At SERVA, we developed a protocol using standard marker proteins and batch-to-batch consistent precast gels and reagents. Marker proteins are separated applying preset conditions, the rf value (relative-to-front) are recorded. They serve as reference and are applied to each qualification that is performed. We offer this service only in conjunction with the SERVA BlueLine devices.

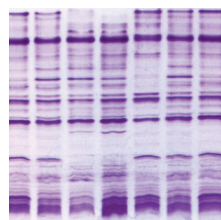
- Capturing systems (scanner or CCD camera based) may need to be certified for conformity to CRF Part 11 regulations as delivered by SERVA.



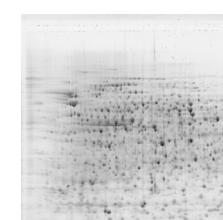
SDS PAGE



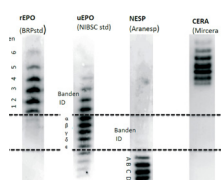
Western blot



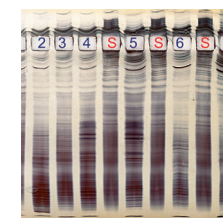
IEF (isoelectric focusing)



2D gel electrophoresis



EPO differentiation



CSF separation



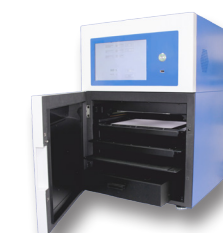
BlueVertical™ PRIME™



HPE™ BlueHorizon™



Bio-5000 Plus VIS Gel Scanner



SERVA Musketeer

## For more information:

If you would like to learn more about SERVA IQ/OQ/PQ or workshops, products and services please contact SERVA at [info@serva.de](mailto:info@serva.de). We are happy to start a dialogue with you how we can support you the best in your existing workflow and how you could benefit from SERVA's expertise in electrophoresis technology.