

## Provantage® Services

# K-Prime® 40 Chromatography Systems qualification protocol and services

## Ensuring optimum chromatography performance and reliability

Ensuring optimum separation and purification of proteins is critical throughout your biochromatography steps. Our Provantage® services will help ensure your K-Prime® 40 systems continue to deliver consistent, reliable and efficient chromatographic performance, run after run. The mission of our Provantage® team is to provide you with the highest levels of support to help you achieve the operational results you need.



### Comprehensive range of value-added services

All of our Provantage® services include a team of experienced engineers who are personally committed to ensuring your processing success and will partner with you to overcome any challenge.

#### Site Acceptance Test, Installation and Operational Qualification, Protocols and On-Site Execution

This service includes one on-site visit by a qualified field service engineer to perform Site Acceptance Testing, Installation and Operational Qualification Protocols. The protocols have been designed according to cGMP guidelines. This provides you with results that satisfy your regulatory requirements. Customers may also elect to execute the qualification independently utilizing our published protocol.

#### Preventive Maintenance Support

Using preventive maintenance protocols designed according to cGMP guidelines, your qualified field service engineer will replace worn components and verify your K-Prime® 40 system to ensure trouble-free operation.

#### Corrective Maintenance Support

For quick resolution of any performance issues that may arise, our qualified field service engineers are available to ensure that your K-Prime® 40 systems are up and running at optimum performance with minimum delay.

---

### Benefits

- Reliable and consistent system performance
- Meets your regulatory requirements
- Our broad range of experience enables us to easily adapt to any challenge for ease of qualification

## Ordering Information

Description	Catalogue No.
K Prime® 40 SAT Protocol (Documentation only)	DOC ICQK P
K Prime® 40 SAT Protocol & Execution (Includes Labor and travel expenses)	SSV SAT KPR
K Prime® 40 SAT & IQ/OQ Protocol (Documentation only)	DOC IQOQ KP
K Prime® 40 SAT and IQ/OQ Protocol & Execution (Includes Labor and travel expenses)	SSV IOQ KPR
K Prime® 40-I, 40-II, 40-III On-site Preventive Maintenance (Includes Labor, Travel, and Protocol)	SSV OPM KPR

## Spare Components

It is recommended that a customer stock a list of spare parts on site. Contact your local field service representative for a list of recommended spare parts.

## Custom Service Agreements

We offer a range of qualification and preventative maintenance services to meet your unique manufacturing requirements, resulting in peace of mind and maximum operational flexibility.

## References

1. FDA Guidance for Industry Process Validation: General Principles and Practices - January 2011
2. Annex 15 to the EU Guide to Good Manufacturing Practice Qualification and Validation - July 2001

## To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 069 86798021

Italy: 848 845 645

Spain: 901 516 645 Option 1

Switzerland: 0848 645 645

United Kingdom: 0870 900 4645

For other countries across Europe,  
please call: +44 (0) 115 943 0840

Or visit: [www.merckmillipore.com/offices](http://www.merckmillipore.com/offices)

For Technical Service visit:

[www.merckmillipore.com/techservice](http://www.merckmillipore.com/techservice)



[www.merckmillipore.com/offices](http://www.merckmillipore.com/offices)