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Order Form

Pathology and Point of Care Testing, Associated Equipment, Instruments, Consumables, Accessories, and Managed Services Framework.

OJEU REF - 2019/S 212-519575

Contract number/reference/date: C96148/ 2nd August 2022

The Parties:

(1) Beckman Coulter United Kingdom Limited registered in England and Wales no. 00640961 and having its registered office at Oakley Court Kingsmead Business Park, London Road, High Wycombe, Buckinghamshire, HP11 1JU (the "Supplier"); and

(2) The Secretary of State for Health and Social Care as part of the Crown acting through the UK Health Security Agency, Nobel House, 17 Smith Square, London, SW10 3HX (the "**Authority**").

Whereas:

(A) The Parties hereto have entered into the Contract.

(B) This Schedule is entered into pursuant to the Contract.

It is agreed:

1 Contract

The Contract shall comprise the following terms in the following order of precedence:

1. This Order Form and its appendices;
2. The terms set out at the front end of this Contract;
3. The Call-off Terms and Conditions which are appended to the Framework Agreement as Appendix 3b;
4. The Specification; and
5. The Framework Agreement (including its Schedules).

Any purchase order issued by the Authority in respect of this Contract does not form part of this Contract.

2 The Services

2.1 The Supplier shall carry out preventative maintenance services **("PM")** on the following instruments **("the Instruments")** where specified, in the PM Month column in Table 1 below during the month stated in the same, if applicable, **("the Services"):**

Table 1

Pos.	Instrument and Note	Serial Number	Instance No	Contract Type	PM Month	Start Date	End Date
1	CytoFLEX S Base Instrument BRVI PORTON	AW48001	36085744	PT CytoFlex 4 Lasers with Plate Loader Service Contract	JULY 2022	01/07/2022	31/03/2023
2	Biomek NXP Multichannel COL NDALE	A318410492	1128766	PT OQ Biomek NXP MC Service Contract	MAR 2023	01/07/2022	31/03/2023
3	CytoFLEX S Base Instrument BRVI PORTON	AW48002	36085745	PT CytoFlex 4 Lasers with Plate Loader Service Contract	JULY 2022	01/07/2022	31/03/2023
4	Biomek NXP Multichannel COL NDALE	A318410414	1077250	PT OQ Biomek NXP MC Service Contract	MAR 2023	01/07/2022	31/03/2023

5	CytoFLEX S Base Instrument BRVI PORTON	BA08001	36677849	PT CytoFlex 4 Lasers with Plate Loader Service Contract	JULY 2022	01/07/2022	31/03/2023
6	Biomek NXP Span8 With Gripper COL NDALE	A318400781	8056196	PT OQ Biomek NXP Span8 with Gripper Service Contract	MAR 2023	01/07/2022	31/03/2023
7	Biomek i7 Hybrid MC Span8 with enclosure BRISTOL	B8758521F019	81198300	PT OQ Biomek i7 Hybrid with enclosure Service Contract	MAR 2023	01/10/2022	31/03/2023
8	Biomek i7 Hybrid MC Span8 with enclosure COL NDALE	B8758521F020	81210253	PT OQ Biomek i7 Hybrid with enclosure Service Contract	FEB 2023	01/08/2022	31/03/2023
9	Biomek i7 Hybrid MC Span8 with enclosure LEEDS	B8758521F016	81198299	PT OQ Biomek i7 Hybrid with enclosure Service Contract	MAR 2023	01/10/2022	31/03/2023
10	Biomek i7 Hybrid MC Span8 with enclosure LEEDS	B8758521F014	81191274	PT OQ Biomek i7 Hybrid with enclosure Service Contract	MAR 2023	01/10/2022	31/03/2023
11	Biomek i7 Hybrid MC Span8 with enclosure MANCHESTER	B8758521F009	81181255	PT OQ Biomek i7 Hybrid with enclosure Service Contract	JAN 2023	01/07/2022	31/03/2023
12	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521E005	81049796	PT OQ Biomek i7 Hybrid with enclosure Service Contract	JAN 2023	01/07/2022	31/03/2023
13	Biomek i7 Hybrid MC Span8 with enclosure MANCHESTER	B8758521E003	80981684	PT OQ Biomek i7 Hybrid with enclosure Service Contract	JAN 2023	01/07/2022	31/03/2023
14	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521B014	80721905	PT OQ Biomek i7 Hybrid with enclosure Service Contract	AUG 2022	01/04/2022	31/03/2023
15	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521B013	80719669	PT OQ Biomek i7 Hybrid with enclosure Service Contract	AUG 2022	01/04/2022	31/03/2023
16	Biomek i5 Span8 with enclosure COLINDALE	B8758421F003	81177223	PT OQ Biomek i5 Span8 with enclosure Service Contract	AUG 2022	01/08/2022	31/03/2023
17	Biomek i5 Multichannel with enclosure COLINDALE	B8758322D001	82126718	PT OQ Biomek i5 MC with enclosure Service Contract	AUG 2022	01/05/2022	31/03/2023
18	Biomek i5 Multichannel with enclosure COLINDALE	B8758321F002	81168281	PT OQ Biomek i5 MC with enclosure Service Contract	AUG 2022	01/08/2022	31/03/2023
19	Biomek i5 Multichannel with enclosure COLINDALE	B8758321F001	81152298	PT OQ Biomek i5 MC with enclosure Service Contract	JAN 2023	01/07/2022	31/03/2023
20	Biomek NXP Multichannel COLINDALE	A318410293	982878	PT OQ Biomek NXP MC Service Contract	MAR 2023	01/07/2022	31/03/2023
21	Biomek NXP Span8 With Gripper COLINDALE	A318400695	4813994	PT OQ Biomek NXP MC Service Contract		01/06/2022	30/09/2022
22	Biomek NXP Multichannel COLINDALE	A318410731	5046389	PT OQ Biomek NXP Span8 with Gripper Service Contract		01/06/2022	30/09/2022
23	Biomek NXP Multichannel COLINDALE	A318410730	5041390	PT OQ Biomek NXP MC Service Contract		01/06/2022	30/09/2022

3 Contract Period and Termination

3.1 This Contract shall commence on 2nd August 2022 (the **"Commencement Date"**) and shall unless terminated earlier, or extended, in accordance with its terms, expire on 31 March 2023 (the **"Term"**).

3.2 Without prejudice to any other right of termination set out in this Contract, the Authority may terminate this contract, in whole or in part, for convenience by giving the Supplier not less than twelve (12) weeks' notice in writing.

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4 Price of Services

4.1 Subject to Clause 7.2, the maximum value of the Services that can be ordered under this Contract is £231,015.86 (two hundred and thirty-one thousand, fifteen pounds and eighty-six pence) **(the "Contract Price")**. Full details of the Contract Price is contained in Appendix 1 of this Order Form. For the avoidance of doubt, the Authority is not committed to pay the full Contract Price.

4.2 The Contract Price excludes VAT at the applicable rate but is inclusive of all parts and labour for all breakdowns / ad hoc callouts.

5 Performance of Services

5.2 The Supplier shall perform the Services at the Premises and Locations set out in Appendix 3 – Premises and Locations.

5.3 All planned performance of the Services shall be pre-advised by the Supplier to the Authority's primary contact stated in 5.3.1 below **("the Primary Contact")** at least 48 hours prior to the Services being performed on any or all of the Instruments at the relevant Premises and Locations:

5.3.1 [redacted]

5.4 The Supplier shall provide the following data when notifying the Primary Contact:

5.4.1 Supplier name;

5.4.2 Authority's purchase order **("PO")** number;

5.5 The Primary Contact will confirm:

5.5.1 Booking reference number;

5.5.2 Date and time of Supplier attending the relevant Premises and Locations; and

5.5.3 Premises and Locations address where the Services shall be performed.

5.6 The Authority may refuse unscheduled performance of Services. In such event, the Supplier shall rearrange such performance of Services utilising the service delivery process set out in this Clause 5.

6 Return Conditions

6.1 Not used.

7 Supplementary Conditions and Key Provisions

7.1 Acceptance

7.1.1 The following criteria for the acceptance of the Services performed by the Supplier by the Authority shall apply **("Acceptance"):**

a) Where the Services provided are for Instruments under PTOQ service agreements in accordance with Appendix 2 - Specification of Requirements, the Supplier shall produce and submit to the Authority a service report in accordance with Appendix 2d - Service Report (Sample) **("Service Report").**

b) Where the Services provided are for Instruments under PT service agreements in accordance with Appendix 2 - Specification of Requirements, the Supplier shall produce and submit to the Authority a Service Report.

7.1.2 If Services are deemed not to be Accepted by the Authority, the Supplier shall reperform the Services at their own cost.

7.2 Invoicing Terms

7.2.1 Payment terms are net 30 days from receipt of a valid invoice.

7.2.2 Following receipt of the Supplier's countersigned copy of the Contract, the Authority will send a unique PO number. The Supplier must be in receipt of a valid PO number before submitting an invoice.

7.2.3 The Supplier's first invoice shall be submitted after the Commencement Date for the Services of Instruments that have a Start Date in clause 2.1, Table 1 up to and including the Commencement Date. All subsequent invoices shall be presented after the Start Date for the relevant Instruments as stated in clause 2.1, Table 1. of the Services

7.2.4 The Supplier's first invoice, as mentioned in clause 7.2.3 above, shall subject to clauses 7.2.5 to 7.2.10 be payable upon receipt and shall not be subject to the Acceptance criteria in clause 7.1 above. All subsequent invoices presented by the Supplier to the Authority shall be for Services performed by the Supplier and Accepted by the Authority.

7.2.5 All invoices must be sent for approval and shall include the proof of Acceptance to the Authority's designated finance mailbox e-mail: [redacted] and their agreed representative before being submitted for payment.

7.2.6 The Authority's billing address that must be stated on all invoices is as follows:

Accounts Payable,

UK Health Security Agency,

Manor Farm Road,

Porton Down,

Salisbury,

SP4 0JG.

VAT No: [redacted]

7.2.7 All invoices must be sent quoting a valid PO number. The Supplier shall provide a current statement of accounts on a monthly basis; this is a standard commercial process and should show all invoices raised and amounts outstanding.

7.2.8 The Supplier shall provide compliant invoices that include, as a minimum, a valid PO number, PO line item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non-compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.

7.2.9 In support of Goods delivered and the Services provided, the Supplier shall provide to the Authority a signed delivery note confirming receipt of the Goods and provision of the Services at the Authority's nominated Delivery Locations.

7.2.10 Supplier queries regarding payment must be forwarded to the Authority's Accounts Payable section by email to: [redacted]

8 Authority Obligations

8.1 The Authority shall ensure access to Premises and Locations by the Supplier is provided for the provision of the Services in accordance with clause 4.2 of the Call-Off Terms and Conditions.

8.2 The Authority shall (where relevant) provide Policies, site guidelines/instructions in advance of the Supplier attending site including the provision of any protective material such as PPE.

8.3 The Authority reserves the right to immediately remove from the Authority's site any Staff who do not conform to the reasonable instructions, policies, rules and regulations of the Authority.

9 Contract Managers

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The Supplier's Contract Manager is:

[redacted]

Email: [redacted]

Phone: [redacted]

The Authority's Contract Manager is:

[redacted]

E-mail: [redacted]

10 Frequency of meetings

10.1 The Authority's Contract Manager (or their delegate) and Supplier's Contract Manager shall meet monthly (or such other frequency as reasonably requested by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of the Contract including, but not limited to:

- Performance of Services - on time and in full.
- The Supplier shall provide to the Authority, on a monthly basis, 2 (two) Business Days prior to each meeting, a management report in the same or similar format as Appendix 6 – Management Information Reporting together with any other pertinent information such as, but not limited to:
  - Callouts by laboratory staff, including root cause with reference to Instrument, associated serial number and incident number;
  - Issues that may have arisen (where relevant) following PM necessitating reperformance of the required Services;
- Invoicing; and
- Discuss such other matters as the Parties may consider appropriate.

10.2 At the Authority's request, and within five (5) Working Days of such request, the Supplier shall provide such management information to the Authority as the Authority may reasonably request from time to time (including without limit any information about the Supplier's supply chain and its compliance in relation to sustainability requirements). The Contract Managers shall meet no less than monthly to discuss the operation of this Contract.

11 Quality Assurance Standards for the Services

The Supplier shall ensure the accreditations set out in Appendix 4 – ISO Certificate shall be maintained throughout the Term.

12 Requirements for Use by Dates

12.1 Not Applicable

13 Data Protection Protocol

13.1 Not Applicable

This Contract has been entered into on the day and date given below:

Signed by
for and on behalf of the Supplier

DocuSigned by:
[redacted]

Full Name: [redacted]

Job Title/Role: [redacted]

Date Signed: 02/08/2022

Signed by
for and on behalf of the Authority

DocuSigned by:
[redacted]

Full Name: [redacted]

Job Title/Role: [redacted]

Date Signed: 02/08/2022

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Appendix 1 – Contract Price

Pos.	Instrument and Note	Serial Number	Instance No	Contract Type	List Total
1	CytoFLEX S Base Instrument BRVI PORTON	AW48001	36085744	PT CytoFlex 4 Lasers with Plate Loader Service Contract	[redacted]
2	Biomek NXP Multichannel COL NDALE	A318410492	1128766	PT OQ Biomek NXP MC Service Contract	[redacted]
3	CytoFLEX S Base Instrument BRVI PORTON	AW48002	36085745	PT CytoFlex 4 Lasers with Plate Loader Service Contract	[redacted]
4	Biomek NXP Multichannel COL NDALE	A318410414	1077250	PT OQ Biomek NXP MC Service Contract	[redacted]
5	CytoFLEX S Base Instrument BRVI PORTON	BA08001	36677849	PT CytoFlex 4 Lasers with Plate Loader Service Contract	[redacted]
6	Biomek NXP Span8 With Gripper COL NDALE	A318400781	8056196	PT OQ Biomek NXP Span8 with Gripper Service Contract	[redacted]
7	Biomek i7 Hybrid MC Span8 with enclosure BRISTOL	B8758521F019	81198300	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
8	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521F020	81210253	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
9	Biomek i7 Hybrid MC Span8 with enclosure LEEDS	B8758521F016	81198299	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
10	Biomek i7 Hybrid MC Span8 with enclosure LEEDS	B8758521F014	81191274	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
11	Biomek i7 Hybrid MC Span8 with enclosure MANCHESTER	B8758521F009	81181255	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
12	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521E005	81049796	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
13	Biomek i7 Hybrid MC Span8 with enclosure MANCHESTER	B8758521E003	80981684	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
14	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521B014	80721905	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
15	Biomek i7 Hybrid MC Span8 with enclosure COLINDALE	B8758521B013	80719669	PT OQ Biomek i7 Hybrid with enclosure Service Contract	[redacted]
16	Biomek i5 Span8 with enclosure COLINDALE	B8758421F003	81177223	PT OQ Biomek i5 Span8 with enclosure Service Contract	[redacted]
17	Biomek i5 Multichannel with enclosure COLINDALE	B8758322D001	82126718	PT OQ Biomek i5 MC with enclosure Service Contract	[redacted]
18	Biomek i5 Multichannel with enclosure COLINDALE	B8758321F002	81168281	PT OQ Biomek i5 MC with enclosure Service Contract	[redacted]
19	Biomek i5 Multichannel with enclosure COLINDALE	B8758321F001	81152298	PT OQ Biomek i5 MC with enclosure Service Contract	[redacted]
20	Biomek NXP Multichannel COLINDALE	A318410293	982878	PT OQ Biomek NXP MC Service Contract	[redacted]
21	Biomek NXP Span8 With Gripper COLINDALE	A318400695	4813994	PT OQ Biomek NXP MC Service Contract	[redacted]
22	Biomek NXP Multichannel COLINDALE	A318410731	5046389	PT OQ Biomek NXP Span8 with Gripper Service Contract	[redacted]
23	Biomek NXP Multichannel COLINDALE	A318410730	5041390	PT OQ Biomek NXP MC Service Contract	[redacted]
				Total Contract Price	**£316,387.13**

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Appendix 2:

Specification of Requirements

The Supplier shall perform the Services in accordance with the following:

a) For NX and NXP Instruments covered under PTOQ service agreements, Staff shall perform the Services in accordance with the entirety of the Biomek NX/NXP Operational Qualification 3 document enclosed within Appendix 2a. A Service Report shall be produced by the Staff carrying out the PM and provided to the Authority.

b) All I5 and I7 Instruments shall be covered under PTOQ service agreements. The Supplier shall therefore perform the Services in accordance with Appendix 2b. A Service Report shall be produced by the Staff carrying out the PM and provided to the Authority.

c) All CytoFLEX Instruments shall be covered under PT service agreements. Staff shall perform the Services in accordance with the CytoFLEX Platform Preventative Maintenance document enclosed within Appendix 2c. A Service Report B shall be produced by the Staff carrying out the PM and provided to the Authority.

d) All Ad Hoc Callouts by the Authority to the Supplier's helpdesk via email or telephone shall be responded to by the Supplier within one (1) Working Day. If the Supplier confirms that a visit to the respective Premises and Locations is required, then Supplier shall attend within two (2) Working Days.

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Instructions for Use

Biomek NX/NX^{P}

Operational Qualification 3

Serial Number: _____

Date: _____

A29024AD
June 2013

Beckman Coulter, Inc. 250 S. Kraemer Blvd.

BECKMAN COULTER

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Brea, CA 92821 U.S A.

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Biomek NX/NX^{P} Operational Qualification 3
A29024AD (June 2013)

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Revision History

Issue AD, 6/13
The following sections have changed subsequent to revision AC:

Biomek NX/NXP Operational Qualification 3

- *Instrument Operational Qualification*
- *Operational Qualification Kit Components*
- *System Performance—Qualification Tests*
- *Span-8 Pod Disposable Tips*

Biomek NX/NXP Operational Qualification 3 Data Sheets

- *Operational Qualification Records*
- *Pre-Qualification Test Data Sheet*
- *Qualification Test Data Sheet*

System Performance Guidelines

- *Guidelines*

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

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DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Contents

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Biomek NX/NX^{P} Operational Qualification 3

Preface

Instrument Operational Qualification

Beckman Coulter's Instrument Operational Qualification Program includes Beckman Coulter Field Service Engineers specially trained in the operation, installation, and qualification procedure for the specific instrument. The Instrument Operational Qualification Program is designed to reduce the amount of time and effort spent on complying with equipment guidelines in GMP (21 CFR 211.68, 211.160, 211.194) and GLP (21 CFR 58.63, 58.81, and 21 CFR 58.195).

Operational Qualification provides a complete document of all procedures and test results, the use of certified and traceable test equipment and standards, and flexible scheduling options. While intended to minimize the amount of time and effort in equipment maintenance, calibration, and performance validation, qualification does not replace the need for an overall equipment validation plan. Maintenance and instrument performance should be monitored on a routine basis in accordance with Standard Operation Procedures (SOPs). Beckman Coulter recommends qualification on all major instruments at least once a year. A more stringent program can be designed to accommodate existing SOP guidelines.

Introduction

Beckman Coulter Operational Qualification verifies instrument performance, confirming that the instrument is performing correctly and to standard specifications when using standard test methods.

The performance measurements produced by the Operational Qualification process are documented for future reference and tracking.

Periodic Operational Qualification is adequate to verify correct system performance, and is a part of good laboratory procedures. Operational Qualification should be a part of your laboratory's Standard Operating Procedures (SOPs) along with your developed system controls and timely maintenance performed by the operator as specified in the operating documentation.
Beckman Coulter recommends that you plot your SOP control results on a wall chart showing upper and lower control limits along with the data. When an instrument's performance is monitored
on a regular basis, the control results can indicate when the system is working properly, when

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maintenance is required, and when system performance is approaching the acceptance limits and service will be required.

If system performance becomes unacceptable, Operational Qualification is one tool that can facilitate the isolation of the cause(s). Successful Instrument Operational Qualification, which does not correct performance problems, indicates other sources such as changes in qualification standards, reagents, samples or environmental influences.

Biomek NX/NX^P Operational Qualification verifies deck framing and system functionality starting with the successful completion of a preventive maintenance procedure. The protocol will verify the accuracy and performance of the system. Where possible, measurements are made with devices and standards that are calibrated and traceable to NIST standards.

Operational Qualification is not available for accessories where qualification is impractical or unnecessary.

A Qualification Data Sheet will be completed and signed by a Beckman Coulter Field Service Engineer after the completion of the Operational Qualification. If a pod fails to pass, the initial results will be recorded, the appropriate corrective action taken, and the instrument retested. If the Operational Qualification process is successful without need of corrective action, the initial results will be recorded as final and no further tests will be conducted.

A Qualification Data Sheet will be completed and signed by the Beckman Coulter Field Service Engineer after any preventive maintenance call or emergency call where qualification is affected. Only the portion of the protocol affected by the service will be redone. If the instrument fails to pass, the initial results will be recorded, the appropriate corrective action taken, and the instrument retested. If the Operational Qualification process is successful without need of corrective action, the initial results will be recorded as final and no further tests will be conducted.

Operational Qualification Kit Components

The following kit is provided for Biomek NX/NX^P Operational Qualification. Replacement items can be purchased separately from Beckman Coulter, Artel, or a Multichannel Verification System (MVS) Distributor using the part numbers in the Notes column. Contact the manufacturer for specific information on specifications and/or standard traceability.

Item	Source/Manufacturer	Notes
Artel Installation Kit includes: Plate Reader MVS Calibrator Plate Titer Plate Shaker MVS Data Manager Software User Guide	Bio-Tek Instruments, Inc. (Labeled for Artel) Artel Westbrook, ME	MVS-100
Portable Computer	N/A	N/A
MVS Baseline Solution (220-mL bottle)	Artel Westbrook, ME	MVS-201

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Item	Source/Manufacturer	Notes
MVS Diluent Solution (500 mL)	Artel Westbrook, ME	MVS-202
MVS Range A Sample Solution (220-mL bottle; 96-well 50.00–200.00 µL, 384-well 10.00–55.00 µL)	Artel Westbrook, ME	MVS-203
MVS Range B Sample Solution (110-mL bottle: 96-well 10.00–49.99 µL, 384-well 2.500–9.999 µL)	Artel Westbrook, ME	MVS-204
MVS Range C Sample Solution (110-mL bottle: 96-well 2.000–9.999 µL, 384-well 0.500–2.499 µL)	Artel Westbrook, ME	MVS-205
MVS Range D Sample Solution (110-mL bottle: Data Mgr. 3.0 & Higher: • 96-well 1.000–1.999 µL • 384-well 0.3000–0.4999 µL Data Mgr. 2.4 & Lower: • 96-well 0.500–1.999 µL • 384-well 0.1500–0.4999 µL	Artel Westbrook, ME	MVS-206
MVS Range E Sample Solution (110-mL bottle: Data Mgr. 3.0 & Higher: • 96-well, less than 1.000 µL • 384-well, less than 0.300 µL	Artel Westbrook, ME	MVS-206
MVS 96-Well Verification Plates: 25 plates per package	Artel Westbrook, ME	MVS-230
MVS Verification Plate Covers: 5 covers per package	Artel Westbrook, ME	MVS-231
384-well verification plates	N/A	N/A
Biomek AP96 P250 Non-Sterile Tips	Beckman Coulter, Inc.	PN 717251
Biomek AP384 P30 Non-Sterile Tips	Beckman Coulter, Inc.	PN 719222
Biomek AP96 P20 Non-Sterile Tips	Beckman Coulter, Inc.	PN 717254
Biomek Span-8 P250 Non-Sterile Tips	Beckman Coulter, Inc.	PN 379501
Biomek Span-8 P20 Non-Sterile Tips	Beckman Coulter, Inc	PN 379504
Biomek Span-8 P1000 Non-Sterile Tips	Beckman Coulter, Inc	PN B01122 *or* PN 987935
Reservoir holder	Beckman Coulter, Inc.	PN 372795
Quarter Modular Reservoirs	Beckman Coulter Inc.	PN 372790
AP96 Reservoirs	Matrix	PN 1064-15-8
AP384 Reservoirs	Matrix	PN 1064-15-7
96-well microplate for Gripper test	N/A	N/A
384-well microplate for Position Alignment and Repeatability Test	N/A	N/A

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Operational Qualification Protocols

- Pre-Qualification Test
- Preventive Maintenance
- System Qualification/Final Test
- Software Verification
- System Performance
- Closing the Operational Qualification Process

Pre-Qualification Test

General Notes

The service history of an instrument may be of help if a problem occurs with the instrument. Any results recorded on the *Preventive Maintenance Checklist* or the *Pre-Qualification Test Data Sheet* are taken for the purposes of service history, and are for service references only. These tests are included in the protocol for the convenience of the Beckman Coulter Field Service Engineer.

Instrument Pre-Qualification

The purpose of Instrument Pre-Qualification is to evaluate and record instrument performance before any adjustments are made. Pre-Qualification is not required during the initial installation of the instrument.

System Performance

Prior to starting the System Performance test, complete the following:

1. Use Manual Control to Home all Axes.
2. Check to see that the deck is framed.

Multichannel Pod

For each AP96P200 Head:

1. Open MC P200 Pre-Qualification protocol in MVS Database. Follow instructions.

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2 Open and complete transfer steps in Biomek methods MC P200 Pre-Qualification.

- Pipette diluent and Range C sample solution to one plate.
  - Pipette 195.0 µL volume diluent to plate.
  - Pipette 5.0 µL volume Range C sample solution to plate.
- Pipette diluent and Range A sample solution to one plate.
  - Pipette 100.0 µL volume diluent to plate.
  - Pipette 100.0 µL volume Range A sample solution to plate.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

For each AP96P20 Head:

1 Open MC P20 Pre-Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek methods MC P20 Pre-Qualification.

- Pipette diluent and Range D sample solution to one plate.
  - Pipette 199.0 µL volume diluent to plate.
  - Pipette 1.00 µL volume Range D sample solution to plate.
- Pipette diluent and Range B sample solution to one plate.
  - Pipette 180.0 µL volume diluent to plate.
  - Pipette 20.0 µL volume Range B sample solution to plate.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

For each AP384P30 Head:

1 Open MC P30 Pre-Qualification protocol in MVS Database. Follow instructions.

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Biomek NX/NXP Operational Qualification 3
Pre-Qualification Test

2 Open and complete transfer steps in Biomek methods MC P30 Pre-Qualification.

- Pipette diluent and Range C sample solution to one plate.
  - Pipette 54.00 µL volume diluent to plate.
  - Pipette 1.00 µL volume Range C sample solution to plate.
- Pipette diluent and Range A sample solution to one plate.
  - Pipette 35.00 µL volume diluent to plate.
  - Pipette 20.00 µL volume Range A sample solution to plate.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

Span-8 Pod Fixed Tips

For Span-8 Pod with 250-µL Syringes and Fixed Tip:

1 Open Span8 250-µL Pre-Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method Span8 250-µL Fixed Pre-Qualification.

- Pipette diluent and Range C sample solution to columns 1–3 of plate.
  - Pipette 195.00 µL volume diluent to columns 1–3.
  - Pipette 5.00 µL volume Range C sample solution to columns 1–3.
- Pipette diluent and Range A sample solution to columns 4–6 of plate.
  - Pipette 100.00 µL volume diluent to columns 4–6.
  - Pipette 100.00 µL volume Range A sample solution to columns 4–6.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

For Span-8 Pod with 500-µL or 1-mL Syringes and Fixed Tip:

1 Open Span8 500-µL_1-mL Pre-Qualification protocol in MVS Database. Follow instructions.

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2 Open and complete transfer steps in Biomek method Span8 500-□L_1-mL Fixed Pre-Qualification.

- Pipette diluent and Range B sample solution to columns 1–3 of plate.
  - Pipette 190.00 □L volume diluent to columns 1–3.
  - Pipette 10.00 □L volume Range B sample solution to columns 1–3.
- Pipette diluent and Range A sample solution to columns 4–6 of plate.
  - Pipette 100.00 □L volume diluent to columns 4–6.
  - Pipette 100.00 □L volume Range A sample solution to columns 4–6.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

Span-8 Pod Disposable Tips

For Span-8 Pod with 250-mL Syringes and Disposable Tip:

1 Open Span8 250-□L Pre-Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method Span8 250-□L Disp Pre-Qualification.

- Pipette diluent and Range C sample solution to columns 1–3 of plate.
  - Pipette 195.00 □L volume diluent to columns 1–3.
  - Pipette 5.00 □L volume Range C sample solution to columns 1–3.
- Pipette diluent and Range A sample solution to columns 4–6 of plate.
  - Pipette 100.00 □L volume diluent to columns 4–6.
  - Pipette 100.00 □L volume Range A sample solution to columns 4–6.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

For Span-8 Pod with 500-□L or 1-mL Syringes and Disposable Tip:

1 Open Span8 500-□L_1-mL Pre-Qualification protocol in MVS Database. Follow instructions.

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2 Open and complete transfer steps in Biomek method Span8 500-□L_1-mL Disp Pre-Qualification.

- Pipette diluent and Range B sample solution to columns 1–3 of plate.
  - Pipette 190.00 □L volume diluent to columns 1–3.
  - Pipette 10.00 □L volume Range B sample solution to columns 1–3.
- Pipette diluent and Range A sample solution to columns 4–6 of plate.
  - Pipette 100.00 □L volume diluent to columns 4–6.
  - Pipette 100.00 □L volume Range A sample solution to columns 4–6.

3 Read plate on Artel plate reader.

4 Record the Pass/Fail on the *Pre-Qualification Test Data Sheet* on page DS-1.

Preventive Maintenance

Perform the preventive maintenance protocol as outlined in the *Biomek NX/NX^P Service Manual,* Section 3.0.

System Qualification/Final Test

Introduction

The following outlines the steps to complete an Operational Qualification 3 for the Biomek NX/NX^P instruments. Instrument issues should have been resolved during the Preventive Maintenance phase before continuing with Operational Qualification 3. The steps must be followed as written with the results recorded on the *Software Qualification Data Sheet* on page DS-5 and the *System Test Data Sheet* on page DS-6.

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Software Verification

This procedure is applicable to Biomek Software for the Biomek NX/NX^{P}.

Protocol

1 Verify and/or record the following on the *Software Qualification Data Sheet* on page DS-5.

- Windows XP and Service Pack
- Firmware Build
- Biomek NX/NXP control software
- Internet Explorer
- Microsoft .NET FW
- Microsoft SQL Server

2 Record a Pass/Fail result for the Software/Firmware/Operating System Check on the *Software Qualification Data Sheet* on page DS-5 if all items are compatible as outlined in APPENDIX A.

3 Perform Control Software Connect Test:

- Open Biomek Software\Instrument\Hardware Setup and verify that the instrument is connected. Close Hardware Setup.
- Open Instrument/Manual Control and home all axes.

4 Record a Pass/Fail for the Software Connection Test on the *Software Qualification Data Sheet* on page DS-5 if instrument is connected and home all axes successfully performs.

5 If the Control Software Connect Test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

6 If the any Software Verification test fails again, terminate the Qualification process and notify the SAIC or Technical Specialist.

System Performance—System Tests

Prior to starting the System Performance test, home all axes and check deck framing.

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Multichannel Pod Tests

Light Curtain Test

1 Open Biomek Software and run Light Curtain Test method. This method requires one standard height microplate.

2 While the instrument is moving, break the light curtain on the instrument.

3 Select **OK** or **Retry** to clear the error message from the controller; the method should run to completion.

4 Rerun Light Curtain Test method.

5 While the instrument is moving, press the red stop button from the **Execution** menu in the software. The method should stop.

6 Record a Pass/Fail result for the Light Curtain Test on the *System Test Data Sheet* on page DS-6 if the following occurs during the test:

- The instrument movement stops when the light curtain is broken.
- The yellow status lights flash.
- The control software reports that the light curtain has been violated.
- The instrument should complete the method when **OK** is selected and the status lights should return to continuous on/yellow during the remainder of the method.
- The instrument should stop the method when the **STOP** is selected from the Execution menu and the status lights should return to green.

7 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Tip Loading Test

1 Run Tiploader test to load and unload a box of tips as specified in the table below.

	AP96 250-µL Tip	AP96 20-µL Tip	AP384 30-µL Tip
96 channel 200-µL Head	Test	Test	
96 channel 20-µL Head	Test	Test	
384 channel 30-µL Head			Test

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2 Repeat the Tiploader test with the box of tips removed from the Tiploader.

3 Record a Pass/Fail result for the Tip Loading Test on the *System Test Data Sheet* on page DS-6 if the following occurs during the test:

- Tips load and unload appropriately.
- Appropriate error message is presented if tip box is not on the Tiploader.

4 If test fails, note failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Position Alignment and Repeatability Test for AP96 Head

1 Run Alignment MC Test.

2 Transfer into all four quadrants of a 384-well plate.

3 Repeat Steps 1 and 2.

4 Record a Pass/Fail result for the Position Alignment and Repeatability Test on the *System Test Data Sheet* on page DS-6 if the following occurs:

The pod should position the tips in the center of each of the 384 wells on each occasion.

5 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Position Alignment and Repeatability Test for AP384 Head

1 Run Alignment MC Test.

2 Transfer into a 384-well plate.

3 Repeat Steps 1 and 2.

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4 Record a Pass/Fail result for the Position Alignment and Repeatability Test on the *System Test Data Sheet* on page DS-6 if the following occurs:

The pod should position the tips in the center of each of the 384 wells on each occasion.

5 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

6 If the system has a Positive Positioning ALP, run Alignment 1536 MC Test.

7 Transfer into a 1536-well plate.

8 Repeat Steps 1 and 2.

9 Record a Pass/Fail result for the Position Alignment and Repeatability Test on the *System Test Data Sheet* on page DS-6 if the following occurs:

The pod should position the tips in the center of each of the 1536 wells on each occasion.

10 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Gripper Test

1 Run Gripper Test Biomek method to move labware on deck.

2 Record a Pass/Fail result for the Gripper Test on the *System Test Data Sheet* on page DS-6 if the gripper successfully moves the specified labware to the target location.

3 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Span Pod Tests

Position Alignment and Repeatability Test

1 Run Alignment S8 Disp Test.

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2 Transfer into a 384-well plate.

3 Repeat Steps 1 and 2.

4 Record a Pass/Fail result for the Position Alignment and Repeatability Test on the *System Test Data Sheet* on page DS-6 if the following occurs:

The pod should position the tips in the center of each of the 384 wells on each occasion.

5 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Gripper Test (if present)

1 Run Gripper Test Biomek method to move labware on deck.

2 Record a Pass/Fail result for the Gripper Test on the *System Test Data Sheet* on page DS-6 if the gripper successfully moves the specified labware to the target location.

3 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

If any Operational Qualification 3 System Test fails after corrective actions, terminate the Qualification process, notify the customer, and contact a SAIC or Technical Specialist.

System Performance—Qualification Tests

For Each AP96P200 Head:

1 Open MC P200 Qualification Low protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method MC P200 Qualification.

- Pipette diluent and Range C sample solution to three plates.
  - Pipette 195.0 □L volume diluent to plates 1–3.
  - Pipette 5.0 □L volume Range C sample solution to plates 1–3.

3 Read plate on Artel plate reader.

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4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 Open MC P200 Qualification High protocol in MVS Database and follow instructions.

6 Open and complete transfer steps in Biomek method MC P200 Qualification High.

- Pipette diluent and Range A sample solution to three plates.
  - Pipette 100.0 µL volume diluent to plates 1–3.
  - Pipette 100.0 µL volume Range A sample solution to plates 1–3.

7 Read plate on Artel plate reader.

8 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

9 For a successful test:

- 5 µL, %CV 5%, Accuracy ±3%
- 100 µL, %CV 3%, Accuracy ±3%

10 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

For each AP96P20 Head:

1 Open MC P20 Qualification Low protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method MC P20 Qualification Low.

- Pipette diluent and Range D sample solution to three plates.
  - Pipette 199.0 µL volume diluent to plates 1–3.
  - Pipette 1.00 µL volume Range D sample solution to plates 1–3.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 Open MC P20 Qualification High protocol in MVS Database. Follow instructions.

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6 Open and complete transfer steps in Biomek method MC P20 Qualification High.

- Pipette diluent and Range B sample solution to three plates.
  - Pipette 180.0 µL volume diluent to plates 1–3.
  - Pipette 20.0 µL volume Range B sample solution to plates 1–3.

7 Read plate on Artel plate reader.

8 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

9 For a successful test:

- 1 µL, %CV 5%, Accuracy ±3%
- 20 µL, %CV 3%, Accuracy ±3%

10 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

For each AP384P30 Head:

1 Open MC P30 Qualification Low protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method MC P30 Qualification Low.

- Pipette diluent and Range C sample solution to three plates.
  - Pipette 54.00 µL volume diluent to plates 1–3.
  - Pipette 1.00 µL volume Range C sample solution to plates 1–3.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 Open MC P30 Qualification High protocol in MVS Database. Follow instructions.

6 Open and complete transfer steps in Biomek method MC P30 Qualification High.

- Pipette diluent and Range A sample solution to three plates.
  - Pipette 35.0 µL volume diluent to plates 1–3.
  - Pipette 20.0 µL volume Range A sample solution to plates 1–3.

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7 Read plate on Artel plate reader.

8 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

9 For a successful test:

- 1 µL, %CV 5%, Accuracy □3%
- 20 µL, %CV 3%, Accuracy □3%

10 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Span-8 Pod Fixed Tips

For Span-8 Pod with 250-□L Syringes and Fixed Tip:

1 Open Span8 250-□L Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method Span8 250-□L Fixed Qualification.

- Pipette diluent and Range C sample solution to columns 1–6 of plate.
  - Pipette 195.00 □L volume diluent to columns 1–6.
  - Pipette 5.00 □L volume Range C sample solution to columns 1–6.
- Pipette diluent and Range A sample solution to columns 7–12 of plate.
  - Pipette 100.00 □L volume diluent to columns 7–12.
  - Pipette 100.00 □L volume Range A sample solution to columns 7–12.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 For a successful test:

- 5 µL, %CV 5%, Accuracy □3%
- 100 µL, %CV 3%, Accuracy □3%

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6 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

For Span-8 Pod with 500-□L or 1-mL Syringes and Fixed Tip:

1 Open Span8 500-□L_1-mL Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek method Span8 500-□L_1-mL Fixed Qualification.

- Pipette diluent and Range B sample solution to columns 1–6 of plate.
  - Pipette 190.00 □L volume diluent to columns 1–6.
  - Pipette 10.00 □L volume Range B sample solution to columns 1–6.
- Pipette diluent and Range A sample solution to columns 7–12 of plate.
  - Pipette 100.00 □L volume diluent to columns 7–12.
  - Pipette 100.00 □L volume Range A sample solution to columns 7–12.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 For a successful test:

- 10 µL, %CV 5%, Accuracy □3%
- 100 µL, %CV 3%, Accuracy □3%

6 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Span-8 Pod Disposable Tips

For Span-8 Pod with 250-□L Syringes and Disposable Tip:

1 Open Span8 250-□L Qualification protocol in MVS Database. Follow instructions.

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2 Open and complete transfer steps in Biomek method Span8 250-□L Disp Qualification.

- Pipette diluent and Range C sample solution to columns 1–6 of plate.
  - Pipette 195.00 □L volume diluent to columns 1–6.
  - Pipette 5.00 □L volume Range C sample solution to columns 1–6.
- Pipette diluent and Range A sample solution to columns 7–12 of plate.
  - Pipette 100.00 □L volume diluent to columns 7–12.
  - Pipette 100.00 □L volume Range A sample solution to columns 7–12.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

5 For a successful test:

- 5 µL, %CV 5%, Accuracy □3%
- 100 µL, %CV 3%, Accuracy □3%

6 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

For Span-8 Pod with 500-□L or 1-mL Syringes and Disposable Tip:

1 Open Span8 500-□L_1-mL Qualification protocol in MVS Database. Follow instructions.

2 Open and complete transfer steps in Biomek methods Span8 500-□L_1-mL Disp Qualification.

- Pipette diluent and Range B sample solution to columns 1–6 of plate.
  - Pipette 190.00 □L volume diluent to columns 1–6.
  - Pipette 10.00 □L volume Range B sample solution to columns 1–6.
- Pipette diluent and Range A sample solution to columns 7-12 of plate.
  - Pipette 100.00 □L volume diluent to columns 7-12.
  - Pipette 100.00 □L volume Range A sample solution to columns 7-12.

3 Read plate on Artel plate reader.

4 Record Pass/Fail on the *Qualification Test Data Sheet* on page DS-7.

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5 For a successful test:

- 10 µL, %CV 5%, Accuracy □3%
- 100 □L, %CV 3%, Accuracy □3% (500 µL syringes and Span8 P200 tips)
- 100 µL, %CV 5%, Accuracy □3% (1 mL syringes and Span8 P1000 tips)

6 If the test fails, note the failure on the *Corrective Actions Data Sheet* on page DS-8, perform corrective actions, and repeat the test.

Refer to APPENDIX B, for pod performance guidelines. If any Qualification test fails, perform corrective actions and note any corrective action on the *Corrective Actions Data Sheet*. Repeat the applicable Qualification test. If any Qualification test fails after corrective actions, terminate the Qualification process and contact the SAIC or Technical Specialist.

Closing the Operational Qualification Process

1 After completing the Operational Qualification Protocols, clean the instrument and complete all entries in the Instrument Operational Qualification 3 Logbook.

2 Complete and affix the Qualification Decals to the front of the instrument or in the location specified by the customer.

3 Make one copy of each data sheet from the Operational Qualification 3 Logbook and forward to the district office for retention.

4 Provide to the person responsible for instrument records:

- The complete and signed Operational Qualification 3 Logbook containing:
  - A copy of the Certificate of Qualification
  - A copy of the metrology reports for all the test equipment used during the qualification process
  - Hard copies of all reports and data generated, pass or fail.

5 Include the Service Request with the Attachments Data Sheet. The Service Request contains the statement "Instrument Passed Qualifications Tests, Qualification Decal(s)# _____".

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Biomek NX/NX^{P} Operational Qualification 3 Data Sheets

Operational Qualification Records

- Pre-Qualification Test Data Sheet
- Out of Qualification Notice
- Preventive Maintenance Checklist
- Software Qualification Data Sheet
- System Test Data Sheet
- Qualification Test Data Sheet
- Corrective Actions Data Sheet
- Attachments Data Sheet
- Notices Data Sheet

NOTE Biomek NX/NX^{P} Excel Data Sheets v2.1 may be filled out electronically, printed, signed, and dated in lieu of hand-written data sheets.

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Pre-Qualification Test Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Multichannel Pod						
Pod	Head Type	Serial #	Volume Transferred	Tip/Probe	Specifications %CV / Accuracy	Pre-Qualification Results For Indication Only
						Pass / Fail / NA
						Pass / Fail / NA

Span 8 Pod								
Pod	Probe Type	Syringe	Volume Transferred	Tip/Probe	Specifications	Pre-Qualification Results For Indication Only		
						Probe	Low Volume	High Volume
						1	Pass / Fail / NA	Pass / Fail / NA
						2	Pass / Fail / NA	Pass / Fail / NA
						3	Pass / Fail / NA	Pass / Fail / NA
						4	Pass / Fail / NA	Pass / Fail / NA
						5	Pass / Fail / NA	Pass / Fail / NA
						6	Pass / Fail / NA	Pass / Fail / NA
						7	Pass / Fail / NA	Pass / Fail / NA
						8	Pass / Fail / NA	Pass / Fail / NA

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Out of Qualification Notice

Biomek NX/NX^{P} Configuration	Serial Number	Date:

Out of Qualification? ☐

Out of Qualification Notice

The instrument failed he Pre-qualification Test. Failure analysis should be conducted to determine the cause of the failure. If the cause is due to the instrument being out of qualification, the last known date of the instrument being in qualification should be identified as it may be necessary to review data generated during the 'out of qualification' period for integrity.

I have been notified that my instrument may be out of qualification at the beginning of this service and understand that this may have affected the data generated as a result of this instrument performance prior to the date of service.

Customer Signature _____ **Date** _____

I have *accepted / declined* the corrective actions that should be taken at this time. _____
Customer Initials

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Preventive Maintenance Checklist

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

	PM Prep
	Verify that all Beckman Coulter information stickers are affixed to the instrument and contain current, valid information.
	Advise customer to routinely backup the current instrument, projects and methods files.
	Copy the current instrument file and keeper to removable media for crash recovery usage.
	Verify the compatibility of all firmware using the Firmware Downloader for the current version of Biomek Software. Download appropriate version as needed.
	Verify communication between the following, if present: Stacker, Barcode reader, Active Alps, Vacuum valve unit, Cytomat.
	Run the PMC method to check operational status of the Biomek
	Base Instrument & Pneumatics
	Check the pneumatic system for water and oil. If foreign material is found, recommend the customer install a filter trap.
	Check inlet air pressure (40–100 psi): adjust as necessary.
	Check the booster pressure (110–120 psi): adjust as necessary
	Check base levelness and adjust as needed.
	MC Pod D Axis Movement
	Lubricate the linear bearings with light weight oil
	MC Grippers
	Examine gripper pads. Replace worn or damaged pads.
	Straighten gripper fingers & adjust for front to rear levelness.
	Lubricate gripper shoulder screws with light weight oil.

	X Axis Movement
	Clean the front & back linear bearings. Lubricate per service instructions using appropriate grease and technique.
	Inspect the motor & pulley assys. Repair any loose pins or replace the motor assy as needed.
	while manually moving the bridges, check for excessive movement noises. Repair as needed.
	MC Pod Y Axis Movement
	Clean the linear bearings. Remove the front limit bumpers and lubricate per service instructions using appropriate grease and technique.
	Inspect the motor & pulley assy. Verify that the pulley is pinned properly to the motor. Replace the motor assy as needed.
	Inspect the air tubing & flex cables for proper routing & repair as necessary.
	MC Pod Z Axis Movement
	Inspect motor & lead screw pulley installation. Replace pulleys as needed.
	Check pod levelness & rotation adjustments per service procedure. Adjust as needed.
	Active ALPS
	For the orbital & linear shakers, magnetic bead & positive positioning alps, verify proper operation of clamps. Repair/replace as needed.
	Verify proper operation of the ALP using manual control or device editor. Verify operation of labware present sensor.

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Preventive Maintenance Checklist (continued)

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Tip Loader		System Tests	
	Lubricate the lock rods with light weight oil.		Install the following covers: Front/Lower MC pod cover.
Span 8			Wipe and clean the side shields, deck, and ALP surfaces.
	Clean & grease the Z drive shafts using appropriate grease. Verify coupler assemblies for proper installation and operation.		while manually moving the bridges, check for excessive movement noises. Repair as needed.
	Inspect linkage arms for straightness (non "P" pods only). Replace as needed.		For Span 8 pod configuration for conductive tips, run the "Find LLS Sensitivities" wizard over a solid surface ALP.
	Inspect the Y scan tension adjustment bearing for wear or binding and replace as needed.		Run the "Find CD Sensitivities" wizard if the customer works with blood (Span 8 only).
	Inspect fixed tips (if installed). If tips are bent ask customer for replacement.		Run the PMC method to verify proper operation of the Biomek.
	Check probe alignment & adjust as needed. Refer to the proper procedure based on type of span pod installed.		Ask customer to run one of their methods to verify operation of the instrument following the PMC.
Alignments			
	Perform necessary software setups (i.e., set limits, correlations, etc.) as needed. Refer to the Biomek nstallation flow chart based on repairs made.		

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Software Qualification Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Software / Firmware / Operating System Check				
	Version Number	Build Version	Specifications	Results
Operating System			Windows XP	Pass / Fail
Biomek Software			Version 3.2 or later	Pass / Fail
SQL Version			SQL 2000 Personal Edition or 2005 Express Edition	Pass / Fail
Firmware Build			Build 4 or later	Pass / Fail
Internet Explorer			Version 6.0	Pass / Fail
Microsoft . NET Framework			Version 1.1	Pass / Fail

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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System Test Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Functional Tests	Specifications	Results
Light Curtain Tests		
Light Curtain	Motion stops when curtain is interrupted	Pass / Fail / NA
Tiploader Tests		
Load / Unload tips	Properly Loads / Unloads all tips.	Pass / Fail / NA
Tip Box Sensor Test	System returns appropriate error message when tip box is not present	Pass / Fail / NA
Pod Tests		
Position Alignment	Tip / Mandrel positions over center of wells.	Pass / Fail / NA
Position Repeatability	Repeats to the same positions.	Pass / Fail / NA
Gripper Move Tests		
Move 96 well plate	Successful move of labware between two locations with proper alignment on ALP.	Pass / Fail / NA
Move Tip Box		Pass / Fail / NA
Control Software Connect Test		
Control Software Connect Test	Successful connection	Pass / Fail / NA
Home Axes from Manual Control	Successful Home of XYZD	Pass / Fail / NA

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Qualification Test Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Multichannel Pod						
Pod	Head Type	Serial #	Volume Transferred	Tip/Probe	Specifications %CV / Accuracy	Qualification Results
						Pass / Fail / NA
						Pass / Fail / NA

Span 8 Pod								
Pod	Probe Type	Syringe	Volume Transferred	Tip/Probe	Specifications %CV / Accuracy	Qualification Results		
						Probe	Low Volume	High Volume
						1	Pass / Fail / NA	Pass / Fail / NA
						2	Pass / Fail / NA	Pass / Fail / NA
						3	Pass / Fail / NA	Pass / Fail / NA
						4	Pass / Fail / NA	Pass / Fail / NA
						5	Pass / Fail / NA	Pass / Fail / NA
						6	Pass / Fail / NA	Pass / Fail / NA
						7	Pass / Fail / NA	Pass / Fail / NA
						8	Pass / Fail / NA	Pass / Fail / NA

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Corrective Actions Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Test Name:	
Corrective Action:	

Test Name:	
Corrective Action:	

Test Name:	
Corrective Action:	

Test Name:	
Corrective Action:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Attachments Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

#	Description	Initials
1	Engineer Certificate of Qualification / Requalification	
2	MVS Calibrator Plate Calibration Certificate	
3	MVS Calibrator Plate Data Summary	
4	Artel Prequalification Data Sheets	
5	Artel Qualification Data Sheets	
6	Field Service Report	
7		
8		
9		
10		
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12		
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17		
18		

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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Notices Data Sheet

Biomek NX/NX^{P} Configuration	Serial Number:	Date:

Completion Notification

The Operational Qualification 3 Process as described in the OQ3 Protocol was successfully completed on:

Date: _____ **Engineer Name (print):** _____

Engineer Signature: _____

Acceptance Notification

I have received the completed Instrument Operational Qualification 3 Logbook and Decal(s) for the system listed below:

Instrument	Serial Number	Decal Number
Biomek NX/NX^{P} Multichannel		

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (print)	Signature	Title	Date

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APPENDIX A

Software/Firmware Compatibility

Biomek NX/NX^{P} Software/Firmware System Versions

Biomek NX/NX^{P} Software/Firmware System Versions

Operating System	Windows XP
Control Software Version	Versions 3.2 or later
SQL Server Version	2000 Personal Edition or 2005 Express Edition
Internet Explorer	Version 6.0
Microsoft .NET FW	Version 1.1.4322
Firmware Build	Build 4 or later

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APPENDIX A

Software/Firmware Compatibility

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APPENDIX B

System Performance Guidelines

Guidelines

System Type	Biomek NX Multichannel	
Model Cat No	989402	
Tip Type	P20 / P200 Disposable Tips	
Head Type	AP96 P200	
Volume	5 □L	100 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

System Type	Biomek NX Multichannel	
Model Cat No	989402	
Tip Type	P20 Disposable Tips	
Head Type	AP96 P20	
Volume	1 □L	20 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

System Type	Biomek NX Multichannel
Model Cat No	989402
Tip Type	P30 Disposable Tips
Head Type	AP384 P30

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System Performance Guidelines

System Type	Biomek NX Multichannel	
Volume	1 □L	20 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

System Type	Biomek NX Span-8	
Model Cat No	989884 or 989886	
Tip Type	Fixed 60/100 mm	
Syringe Size	250 □L	
Volume	5 □L	100 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

System Type	Biomek NX Span-8	
Model Cat No	989884 or 989886	
Tip Type	P20 / P200 Disposable Tips	
Syringe Size	250 □L	
Volume	5 □L	100 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

System Type	Biomek NX Span-8	
Model Cat No	989884 or 989886	
Tip Type	Fixed 60/100 mm	
Syringe Size	500 □L_1-mL	
Volume	10 □L	100 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3

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System Type	Biomek NX Span-8	
Model Cat No	989884 or 989886	
Tip Type	P20 or P50/P200 Disposable Tips P200/P1000 Disposable Tips	
Syringe Size	500 mL 1 mL	
Volume	10 □L	100 □L
Accuracy (□ □ %)	3	3
Precision (□ %)	5	3 (500 µL syringes) 5 (1 mL syringes)

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Warranty and Returned Goods Requirements

All standard Beckman Coulter, Inc. policies governing returned goods apply to this product. Subject to the exceptions and upon the conditions stated below, the Company warrants that the products sold under this sales agreement shall be free from defects in workmanship and materials for one year after delivery of the products to the original Purchaser by the Company, and if any such product should prove to be defective within such one year period, the Company agrees, at its option, either (1) to correct by repair or at the Company's election by replacement, any such defective product provided that investigation and factory inspection discloses that such defect developed under normal and proper use, or (2) to refund the purchase price. The exceptions and conditions mentioned above are as follows:

1. Components or accessories manufactured by the Company which by their nature are not intended to and will not function for one year are warranted only to reasonable service for a reasonable time. What constitutes a reasonable time and a reasonable service shall be determined solely by the Company. A complete list of such components and accessories is maintained at the factory.
2. The Company makes no warranty with respect to components or accessories not manufactured by it. In the event of defect in any such component or accessory, the Company will give reasonable assistance to Purchaser in obtaining from the manufacturer's own warranty.
3. Any product claimed to be defective must, if required by the Company, be returned to the factory, transportation charges prepaid, and will be returned to Purchaser with transportation charges collect unless the product is found to be defective, in which case the product must be properly decontaminated of any chemical, biological, or radioactive hazardous material.
4. The Company shall be released from all obligations under all warranties, either expressed or implied, if any product covered hereby is repaired or modified by persons other than its won authorized service personnel, unless such repair by others is made with the written consent of the Company.
5. If the product is a reagent of the like, it is warranted only to conform to the quantity and content and for the period (but not in excess of one year) stated on the label at the time of delivery.

It is expressly agreed that the above warrant shall be in lieu of all warranties of fitness and of the warranty of merchantability, and the company shall have no liability for special or consequential damages of any kind or from any cause whatsoever arising out of the manufacture, use, sale, handling, repair, maintenance, or replacement of any of the products sold under the sales agreement.

Representatives and warranties made by any person, including dealers and representatives of the Company, which are consistent or in conflict with the terms of this warranty, shall not be binding upon the Company unless reduced in writing and approved by an expressly authorized officer of the Company.

Parts replaced during the warranty period are warranted to the end of the instrument warranty.

Note:
Performance characteristics and specifications are only warranted when Beckman Coulter replacement parts are used.

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Appendix 2b – Biomek i-Series Automated Workstation Operational Qualification Manual

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Operational Qualification

Biomek i-Series

Automated Workstation
Operational Qualification Manual

Serial Number: _____

System ID Number: _____

Software Version: _____

Decal Number: _____

Date Performed: _____

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C09308AA
December 2017

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

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Biomek i-Series

Operational Qualification Manual

C09308AA (December 2017)

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- In the USA and Canada, call us at 1-800-369-0333.
- Outside of the USA and Canada, contact your local Beckman Coulter Representative.

EC REP
Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH - 1260 Nyon 1, Switzerland
Tel: +41 (0) 22 365 36 11

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This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

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Contents

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Contents

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Tables

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

DocuSign Envelope ID: 48BA795D-97F2-4B77-BC0B-832CAE8EA9ED

Tables