BIOMÉRIEUX	Service Plan DAVINCI Doc code : 8420 / SP / 44	Revision 7 May 2008

Service Plan

DAVINCI

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	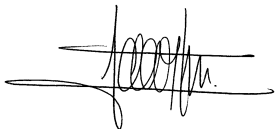
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Changes

Rev. 1 : Initial release of Service Plan (launch training november 2002)
Rev. 2 : Update after first official GCS training (april 2003)
Rev. 3 : Update after release of Service Manual v 1.0 & new teaching tools (january 2004)
Rev. 4 : Update concerning (june 2005) :
- discontinuation of Starter Package (artno 200403)
- discontinuation of PCAnywhere and McAfee software
- update of Preventive Maintenance activities
- addition of Operational Qualification procedure (BTL021880)
- update of Spare Part List

Rev. 5 : Update concerning (august 2006):
- information concerning new “disposable tip for sampling” feature added
- update of paragraph “Warranty”
- update of Preventive Maintenance activities
- update of Spare Part List
- addition of decontamination checklist

Rev. 6 : Update concerning (july 2007):
- update of Spare Parts List

Rev. 7 : Update concerning (may 2008):
- update of Preventive Maintenance list according to Service Manual v2.0
- update of Spare Parts List
- (minor) corrections on Decontamination and Packing checklist

1. INTRODUCTION

The DAVINCI system is a fully automated microplate processor. DAVINCI performs all steps required for performing a qualitative assay (typ. bloodbanking) in microplates :

a) Distribution of samples from primary tubes
b) Distribution of reagents and controls in the microplate(s)
c) Incubation at room and elevated temperatures
d) Shaking (linear, performed by reader module)
e) Washing
f) Sample And Reagent Addition Monitoring (SARAM)
g) Endpoint reading
h) Validation and reduction of data
i) Reporting
j) Interface to a host or other data management system for worklist download and result upload

In combination with a lab data manager system (e.g. MECS PE), DAVINCI can be used in either a single or multistation configuration, or even in a hybrid setup with other equipment.
The following paragraphs summarize various chapters of the Operator Manual and the Service Manual. For a full description please refer to the appropriate chapters of these manuals.

2. SERVICE AND PREVENTIVE MAINTENANCE APPROACH

The basic concept of the DAVINCI system is **modularity**. This means that the main functionalities are provided by separate modules that are easily exchangeable. This not only reduces the time to repair the instrument, it also increases the reliability of the system because malfunctioning modules are easily replaced by new modules.

In addition to complete modules, a number of specific **spare parts** are available. These spare parts can be used by qualified service engineers when the functionality of a defective module, or the complete system, can be restored locally. A number of spare parts are also needed for the regular Preventive Maintenance (PM).

It remains the responsibility of the service engineer to check the functionality after every service intervention using the provided tools and procedures.
The recommended tool to perform this check is the Verification functionality (Diagnostic Kit) implemented into the main application software.

This kit consists of:

- Ready-to-use reagents
- Validation tools for reader and incubator
- Software verification routines

and the procedures are fully integrated into the DAVINCI application software (v1.3 or higher).

In case defective modules (including their standard accessories) need to be returned to bioMerieux, it is mandatory that the original packaging material and transport protections are used. This largely reduces the risk of transport damage. Use of other packaging material is not allowed !! Also, ESD precautions must be followed.
The appropriate forms (Problem Report and Disinfection Status) must be included with the defective module and the serial number and desinfection status must be clearly indicated on the outside of the shipping cartons.
The module itself must be packed in a well-closed plastic bag. The (ESD) protection bag in which the replacing module (part) was packed is suitable for this purpose (when not damaged).

During start-up, the system will automatically perform a number of **self-diagnostics** to check the correct functioning of the various modules and their states (e.g. check on empty containers). Additional checks will be done on the verification expiry dates of the various modules. Discrepancies will be reported to the operator for correction through on-screen messages.
Modules of which the verification period is expired may still be used (programmable option of the assay protocols) and the results will be flagged accordingly. The operator is recommended to run the Verification procedures in order to re-check and qualify the corresponding module(-s) for their intended use.
Automatic checks are performed during regular processing as well and in case a module enters an error condition, appropriate messages will be shown to the operator.
Running processes may become stopped (depending upon the module type, the error condition and the steps followed in the error-recovery process).
The results of these checks are saved in so-called **log files**. These files should be inspected by the service engineer during preventive maintenance visits or in case of error situations.

The maintenance of the DAVINCI system is divided into two distinct tasks.

1. The first task needs to be accomplished by the operator or end user and involves simple daily/weekly/monthly maintenance and performance check procedures by means of the Verification feature. For details please refer to the appropriate chapters of the Operator Manual.
   Running the Verification procedures is the **main** responsibility of the end user. All procedures are implemented in such a way that they can be performed by a regular DAVINCI user. The required tools must be ordered separately from with the instrument.

2. The second task (Preventive Maintenance) needs to be accomplished by a qualified service engineer and must be executed at least every six months. To reduce the time needed for servicing, the actions that may be performed less frequent (only once/year) may be skipped once every two preventive maintenance visits. For a full detailed overview please refer to annex 7 of this document, chapter 8 of the Operator Manual and chapter 6 of the Service Manual.

3. SERVICE FEATURES AND ATTENTION POINTS

3.1 Service software :
The DAVINCI application software does only provide limited service options. The main servicing features are provided by the DAVINCI Service- and Teacher-software and these two programs offer the following main functionalities :

- module diagnostics, low level control and calibration
- system position calibration (teaching of transport and pipettor arms)
- washer manifold zero positioning calibration
- verification of the reference position (for pipettor arms)

For further details please refer to the DAVINCI Service Manual.

The DAVINCI Service Software is not intended to be used by normal operators or end-users. It is only intended for qualified service engineers because it requires a thorough knowledge of the instrument and its behaviour.
The Check Reference Position option of the Teacher software is also included into the main application software. This is accomplished through the 'Check Reference Position' maintenance protocol. Secondly, the 'Teach Washer Zero Position' option of the Service Software is provided through the 'Teach Wash' maintenance protocol within the application software.
Both options can be run by the normal operator with appropriate access rights. There is no need for them to go into the Service Software.

In addition to the DAVINCI Service- and Teacher Software, other separate programs (Tools) are available to perform extra tests (through so called macro's), database initialization, backup and restore. These programs are also solely intended for use by qualified service engineers and are described in chapter 5 of the Service Manual.

3.2 Verification (Diagnostic Kit) :
The Verification (Diagnostic Kit) feature is fully integrated into the DAVINCI application software in order to perform a verification of all essential processing steps. It can also be used to assist during troubleshooting of mechanical or assay related problems.
The Reader Verification Plate (RVP) and Incubator Verification Tool (IVT) used during the verification process must be re-calibrated at regular intervals.

For details see the following table :

Tool	Calibration	
	Expiry period	Recommended interval
RVP	3 years	2 years
IVT	2 years	2 years

For re-calibration of the IVT, the tool must be returned to bioMerieux, including the original case, protective packaging and a disinfection statement.

Re-calibration of the RVP is done by the manufacturer. Details about shipping and contact addresses can be obtained from Global Supply Chain department.
Re-calibration may not be possible if incorrect handling has resulted in damage to the device (or optical glasses). In that case a new tool should be ordered.

3.3 Log files :
The DAVINCI system maintains a log file that can be inspected by a service engineer to review the system functionality or to diagnose error situations. The log file is accessible either locally, by network or by remote modem.

3.4 Networking :
The inbuilt network access functionality (on-board network interface card - NIC - with a 10/100Base-T UTP connection) can be tested by a service engineer using :

- chipset diagnostic software in Windows 2000 Control Panel
- Windows 2000 networking utility packages (ipconfig, ping)

The actual networking configuration needs to be done during the system installation, and support by the local laboratory MIS department may be required. They will be able to provide the correct settings and accounts.

3.5 Power supply :
The main power supply of the analyzer is an auto-switching type, allowing for connection to input voltages in the range of 85V to 264V AC, 47-63Hz. However, the PC and monitor are regular products capable of input voltages of 115 or 230 V (+/- 10%) at 50-60 Hz. The latter values will be the allowed input voltages for the complete DAVINCI system (= analyzer + PC + monitor).
No Uninterruptable Power Supply (UPS) unit is provided with the system. It is mandatory to connect the DAVINCI system to either a uninterruptable main power supply or, even better, to incorporate an external UPS unit for the complete DAVINCI system. In this case processing will continue even when the main power fails. It remains the responsibility of the operator to start a shut-down procedure before the backup power supply system expires.

The following table summarizes the power consumption of the system components :

component	typ. (W)	max. (W)
Analyzer	250	460
PC	120	220
Monitor	120	300

These values can be used to select an appropriate UPS unit (at least a 1400VA unit, e.g. APC BP1400, will be needed to support the maximum load. This model will give a 20 minutes runtime at typical load, or approximately 7 minutes at maximum load).
From these figures also the BTU/hr values can be calculated : typ. 1670 (max. 3340).

3.6 Remote Access

The allow remote access by service engineers, the Norton PCAnywhere software package can be installed on the system. Delivery of this software by bioMérieux as part of the DAVINCI package has been discontinued and when needed the software (version 10.5 or higher) must be obtained locally.

Upon installation of the DAVINCI at the customer location, the service engineer can install this additional software onto the system and make the appropriate settings and connections to the in-house telephone system.
An **Operational Qualifaction procedure** (for details see enclosure 8) should be followed to ensure the correct operation of the system after installation of this extra software package.

An internal (56K, V.90, analogue) modem is standard installed into the first series of DAVINCI PC :

- systems sn 5130000101 – 5130000106 : US Robotics 56K Voice Win
- systems sn 5130000107 – 5130000148 : Lucent V90 56K PCI
- systems sn 5130000149 – 5130000177 : Microlink 56K PCI
- systems sn 5130000178 and up : no modem installed

All necessary drivers are already installed on the DAVINCI system.

It is required that a direct analogue telephone connection is available in the laboratory. The alternative is to use a “voice-first” connection type, details are provided on the online help section of the PCAnywhere software.

3.7 Anti-virus software

To circumvent possible system failures due to infection with computer viruses, trojan horses, etc, it is recommended to install an extra anti-virus software package (e.g. McAfee VirusScan) onto the system. Delivery of this software by bioMérieux as part of the DAVINCI package has been discontinued and therefor the software must be obtained locally.

Upon installation of the DAVINCI at the customer location, the service engineer should install this software onto the system and make the appropriate settings.

An **Operational Qualifaction procedure** (for details see enclosure 8) should be followed to ensure the correct operation of the system after installation of this extra software package.
It is the responsibility of the local subsidiary, in cooperation with the customer IT department, to keep this package up-to-date with respect to the virus definition files and scan engine version.

4. SERVICEABILITY

The following overview summarizes the operator and technical service maintenance actions. For a full description please refer to the appropriate chapters of the related manuals (chapter 8 of the Operator Manual and chapter 6 of the Service Manual).

4.1 Operator maintenance and checking:
4.1.1 Daily maintenance/check:
When starting the system :

- Visual check of tubing, syringes and diluter valves (leakage, air bubbles, ..)
- Initialization and system flush
- Washer test (dispense & aspirate) procedure

When shutting down the system :

- Deletion of completely processed plates (database)
- Empty common waste
- Empty disposable tips waste
- Removal of no longer needed reagents,containers and plates
- Shutdown procedure (optional backup) and rinsing of the system
- Removal of any spillage
- Re-fill system liquid container

Time needed to perform this procedure : 20-30 minutes

4.1.2 Additional weekly maintenance / cleaning of the DAVINCI:

- Daily maintenance/check
- Clean analyzer, washer prime trough, wash station (cabinet drawer when needed)
- Clean steel needles (with detergent and 'clean_needles' protocol)
- Clean disposable tip cones (with detergent and/or alcohol)
- Clean plate carriers (with detergent)
- Clean & dry all liquid and vacuum containers
- Carefull inspection of diluter syringes/valves for leakage or loose connections
- Cleaning of touch-screen
- Shut-down and rinse procedure, including backup of data

Time needed to perform this procedure : 45 .. 50 minutes

4.1.3 Additional monthly maintenance:

- Rinse washer with the 'clean_washer' protocol
- Clean incubator slots
- Clean system liquid container with detergent and de-ionized water
- Run Verification procedures for reader, washer and pipettors.
- Check aerosol outlet filter of Pump Liquid Unit (PLU)

Time needed to perform this procedure : 2.5 - 3 hours

4.1.4 Additional three-monthly maintenance:

- Clean keyboard trackball
- Re-calibrate touchscreen
- Replace system liquid in-line filter
- Clean washer manifold

Time needed to perform this procedure : 0.5 hours

4.1.5 Additional six-monthly maintenance:

- Run Verification procedure (overnight) for incubator module.

Time needed to perform this procedure : 6-7 hours

Additional maintenance steps when the DAVINCI will not be used for a period longer than three days :

- removal of all reagents containers
- emptying and cleaning of waste, wash and system liquid containers
- coverage by a protecting sheet

4.2 Service engineer preventive maintenance (max. 6 month interval):

- actions according to the Service Manual (chapter 6)
- lubrication and cleaning of specified parts
- run Verification performance check procedures to check functionality after service intervention (action instead of monthly maintenance check by operator)

Time needed to perform this procedure : 8 hours

Note: The maintenance intervals given above assume a working time of the instrument of 8 hours per day, 5 days a week, in a normal laboratory environment. Upon more intense usage of the instrument or usage in demanding environmental conditions (dust, heat, humidity) the maintenance intervals should be shortened accordingly.

5. TRAINING

bioMérieux organizes product and technical training for Application Specialists (AS) and Service Engineers (SE).
The common training part for both specialists lasts 2 days. This is followed by a more in-depth application training for AS of 5 days and a detailed technical training of 7 days for SE. These training sessions are given separately (non-overlapping) at the Marcy Training Center.
The main target of the training is to provide the subsidiaries with the necessary technical and application information, to support in an efficient way the local installations and to be able to train the customers.
Only trained subsidiaries will be allowed to introduce the instrument in their countries. It is strongly recommended to follow the training just before the first installation is planned.

Service Engineer

Only a qualified Service Engineer will be able to carry out the following tasks : installation (incl. Host/MECS PE interface), calibration, replacement of defective parts and troubleshooting.

Product Specialist

The necessary information needed to train the customers will also be handled during the training organized for Application Specialists. This training will provide enough information regarding the following points : daily operation, marketing aspects, user guidelines, clinical aspects, troubleshooting guide and assay protocol adaptations.

The customer training by the Application Specialist for the operator or end-user must incorporate the following topics :

- Basic system configuration
- Application software & daily operation
- Operator maintenance procedures
- Verification procedures
- Interfacing to Laboratory Data Manager (MECS PE)
- Trouble shooting (system and assays)
- Update of virus definition files and scan engine (of anti-virus software) (when applicable)

Depending upon the local knowledge, experience with automated instruments and the specific user configuration (assays), a typical customer training course will take between 3 and 5 working days. It is the responsibility of the local organization to arrange this customer training by the Application Specialist.
For all details regarding this training please refer to the Operator Manual.

6. INSTALLATION

Prior to any installation, a detailed investigation/inspection of the local laboratory is mandatory. See annex 1 to 3 of this Service Plan for further details.
Also a detailed overview of all involved actions, checks and adaptations to existing infrastructure is highly recommended. This incorporates (amongst others) the mandatory use of bar codes for sample identification, the availability of an uninterrupted power supply (for example by UPS units), the availability of a direct access external telephone connection for remote support and the interface to existing computer/network systems (hosts).

It is highly recommended to start with a pre-installation, for instance at the local offices. This pre-installation should incorporate the installation / setup / testing of the DAVINCI system, the network environment, application software packages like a MECS PE and the operational check of the assay procedures on the total DAVINCI system.
If necessary, the support by bioMerieux International (GCS) is available.

The on-site installation incorporates the following steps :

- unpacking and installation of individual system components (e.g. remote access software and anti-virus package incl. update to the latest revisions)
- system interconnecting and test of interfaces
- position calibration check of DAVINCI
- configuration of users, passwords and access levels
- functional check of DAVINCI (both Verification and assay protocols)
- check data exchange from/to MECS PE or host system
- operator/end-user training
- operational check by running real assays
- regular follow-up during first weeks/month(s) to ensure correct operation of system and user interaction/maintenance
- modem connection test for remote support

For all details regarding the unpacking and physical installation of the DAVINCI system please refer to the Operator Manual chapter 2 and 4.

7. DISINFECTION

For normal operation of the DAVINCI, it not required to perform a (regular) complete disinfection. However, disinfection is mandatory when (parts of) the system are returned to bioMerieux, e.g. for repair or re-calibration of the Reader Verification Plate (RVP) or Incubator Verification Tool (IVT).
Furthermore, disinfection is advised when the DAVINCI is relocated from one laboratory to an other.

When (part of) the instrument is returned to bioMerieux, it must be accompanied by a signed "Disinfection Status Form" (see annex 4). Instruments, or parts of, without such a "Disinfection Status Form" will not be accepted !!

Also refer to the corresponding section(s) of the Service Manual for additional information and annex 10 of this Service Plan for a decontamination and packing checklist.

8. SERVICE DOCUMENTATION

The following documentation for servicing of the DAVINCI system is currently available :

- Operator Manual version 1.0 (or higher) (artno 45688030)
- Service Manual version 2.0 (or higher) (artno 45688089)
- training information/manual (CDROM)
- GCS Portal website (bulletins, manuals, …)

9. SERVICE TOOLS AND AIDS

A number of specialized tools / parts are available to enable correct installation, servicing and calibration of the DAVINCI system or its modules.
Besides these tools some other commonly available tools are required too :

- an electric screw driver/drill with a Phillips no 2 bit to open the transportation crate
- set of standard metric Allen keys (1.2 (0.050”), 1.5, 2, 2.5, 3 and 5 mm)
- Phillips screw drivers no.1 and 2
- Elbow type Phillips screw driver no. 3
- Flat head screw driver (appr. 2 mm) to secure the connectors
- Metric open-ended spanner 8, 13 and 17 mm or an adjustable one
- Miniature mirror (dental type)
- Small flashlight
- Multi meter (volt, amp, ohm)

For the full overview of the specialized tools / parts please refer to annex 5.

10. SPARE PARTS

On the GCS Portal website (https://gcs.biomerieux.fr) you can find an up-to-date Spare Parts List containing the on-stock available items. Also the pictures will be made available once parts have been photographed upon their arrival in the warehouse.

Spare parts, which are not having an article code, or are not included in the list, can be ordered as NON STOCK items. A new bioMerieux article code will be assigned to the part(s) involved.
When ordering NON STOCK items, take into account that the delivery time will be longer than usual (may take up to 5-6 weeks).

In enclosure 9 you will find the Spare Part List as defined at the moment of release of this Service Plan. Always refer to the GCS Portal for the latest information.

The increased attention for inventory control and accurate forecasting, while taking the relatively high pricing of some spare parts into account, implies that local stock should be kept at a minimal level. This means that locally only a stock of essential spare parts should be kept available.
An overview of the recommended and essential spare parts that should be ordered, is listed in enclosure 9. Note that the minimum stock level per part depends upon the total instrument installed base. This is also indicated in enclosure 9.

11. WARRANTY

Warranty is granted for 15 months after delivery from the manufacturer (Stratec) to bioMerieux, or 12 months after the product is installed, whichever time period is shorter.
All warranty requests need to be forwarded to the Spare Parts department of Global Supply Chain.

12. SERVICE CONTRACTS

In enclosure 6 the proposed Service Contract coverage and related pricing are listed. Please remember that the prices mentioned are based on estimates and preliminary field experience. However, monitoring of service cost for the DAVINCI system is most important and enables you to fine tune the Service Contract prices.

Next to price adaptations due to cost-price changes, annual adaptations for index adjustments are a must.
In general the Recommended Selling Price of a medium service agreement is about 10% of the instrument-selling price.

13. LOCAL SERVICE PLANNING

This DAVINCI Service Plan is intended as a general guideline. It may be necessary to adapt it to meet the local guidelines and circumstances.

14. ENCLOSURES

1. “Standard laboratory operating environment requirements” form
2. “Customer survey for system delivery/installation requirements” form
3. “Checklist for bioMérieux representative for a pre-installation requirements” form
4. “Disinfection status” form
5. Service /Installation tools list
6. Service Agreement Pricing and Service Coverage
7. Preventive Maintenance form
8. Operational Qualification procedure
9. Spare Part List
10. DAVINCI Decontamination and packing checklist

General Note:

It is hoped that all the above mentioned points will cover your needs. However, Global Customer Service of bioMérieux Boxtel is looking forward to your comments and feedback. Please consider that your comments and suggestions will help us to improve the Service Plan to the benefit of other countries.

ENCLOSURE 1: "Standard laboratory operating environment requirements" form

DAVINCI

STANDARD LABORATORY OPERATING ENVIRONMENT REQUIREMENTS

Environmental requirements

1. Ambient temperature:
   - operating 15 through 30°C
   - non-operating 0°C through 40°C, when drained.

2. Relative humidity:
   - operating 20% through 80% (non condensing)
   - non-operating 5% through 95% (non condensing).

3. Operating altitude:
   - up to 3000 meter above mean sea level

4. Heat dissipation:
   - typically 1670 BTU/hr (max 3340 BTU/hr)

Location of system instrumentation

1. The instrument must be positioned away from direct sunlight and areas with bright overhead lights. The instrument should not be placed in the direct path of air draft, heater or air conditioner vents or doors that could cause strong temperature fluctuations.

2. The Customer must certify that the floor structure where the DAVINCI system is to be installed, is capable of bearing a weight of about 400 kg.

3. The DAVINCI analyzer is placed onto the included cabinet. Benchtop installation is not supported. The maximum dimensions of each configuration are (with touch screen):

width	: 175 cm
height (with cover open)	: 195 cm
depth	: 100 cm

4. A free space of 60 cm should be maintained in front of the cabinet to be able to open the doors and pull out the drawer. A free space of 10 cm should be kept at the rear of the instrument to allow proper ventilation.

5. To maintain serviceability, the customer must allow the equipment to be maneuvered to a position that will allow a minimum of un obstructed clearance of 100 cm of any service panel and top of equipment.

Electrical requirements

1. A properly grounded AC power circuit capable of providing 10 A at 115 or 230 V (50-60 Hz) to the DAVINCI system.

2. The AC power outlet (3 sockets + 1 optional for a printer) must be within 2 meter of the installed instrument.

3. To ensure proper operation of the DAVINCI, the supporting electrical circuit must be maintained as a dedicated Power Source (i.e. not servicing large power consuming devices as centrifuges, air conditioners, water baths, refrigerators, freezers or any devices that radiate significant electro-magnetic energy) and free from excessive voltage disturbances and high frequency noise.

4. In places where the AC power circuit has variations greater than 10%, an external UPS for the complete system should be installed. A minimal capacity of 1400VA will be required.

Modem requirements:

1. A single phone line with a wall jack capable of accepting a RJ11C type of connector must be within 1.8 meter (6 feet) from the DAVINCI system for MODEM capabilities. The phone line for the MODEM must be voice grade, analog, signal type capable of supporting one of the following standards: BELL 103, V22, V22bis, V32, V32bis with MNP2-4 / V42 error correction and/or MNP 5 / V42bis data compression.

2. The MODEM will operate using the same type of phone lines as that are used for a FAX - machine (2/4 wire leased line and/or PSTN).

ENCLOSURE 2 : "Customer survey for system delivery / installation requirements" form

DAVINCI

CUSTOMER SURVEY FOR SYSTEM DELIVERY / INSTALLATION REQUIREMENTS

A specific customer contact must be designated by name and phone number to coordinate with bioMérieux for the delivery/installation of the DAVINCI system. The bioMérieux Field Service Engineer will request this information during the site inspection visit. The following additional information will be required from the customer contact during the site inspection.

a) What are the days / hours of operation of the customer's receiving dock ?

Comments:_____

b) Are there any customer established or local code restrictions on the size or type of transport vehicle that can deliver to the customer's receiving dock ?

Comments:_____
_____

The customer's receiving dock and the internal delivery route between the receiving dock (including elevator) and the location designated for system installation must meet the following physical requirements :

Maximum external dimensions of the DAVINCI packaging :

height	:	123 cm
width (mind turn areas)	:	143 cm
weight support	:	280 kg

Comments:_____
_____

ENCLOSURE 3 : "Checklist for bioMérieux representative for a pre-installation site inspection" form

DAVINCI

CHECKLIST FOR BIOMERIEUX REPRESENTATIVE FOR

A PRE-INSTALLATION SITE INSPECTION

[ ] SATISFACTORY
[ ] ACTION REQUIRED

Temperature range : 15°C to 30°C

Comments: _____

[ ] SATISFACTORY
[ ] ACTION REQUIRED

Room relative humidity : 20% to 80% (non-condensing)

Comments: _____

[ ] SATISFACTORY
[ ] ACTION REQUIRED

Location of system :

1. The instrument must be positioned away from direct sunlight and areas with bright overhead lights. The instrument should not be placed in the direct path of air draft.
   Comments: _____

2. Customer certifies that the floor structure where the DAVINCI system is to be installed, is capable of supporting a weight of 400 kg.
   Comments: _____

3. Enough space to locate the instrument and its accessories. Enough free space in front of and at rear of the instrument
   Comments: _____

4. A single line phone must be within 1.8 meters (6 feet) of computer system for remote access modem capability to be utilized.
   Comments: _____

5. To maintain serviceability, the customer must allow the equipment to be maneuvered to a position that will allow a minimum unobstructed clearance of 100 cm of any service panel and top of equipment.
   Comments: _____

[ ] SATISFACTORY
[ ] ACTION REQUIRED

Electrical requirements :

1. A properly grounded AC power circuit capable of providing 10 A at 115 or 230V (50-60 Hz) to the DAVINCI.
   Comments: _____

2. The AC power outlet (3 sockets + 1 optional for a printer) must be within 2 meter of the instrument installed.
   Comments: _____

3. To ensure proper operation of the DAVINCI system, the supporting electrical circuit must be maintained as dedicated Power Source (i.e. not servicing large power consuming devices including, but not limited to, centrifuges, air conditioners, water baths, refrigerators, freezers or any devices that radiate significant electro-magnetic energy) and free from excessive voltage disturbances and high frequency noise.
   Comments: _____

4. In places where the AC power circuit has variations grater than 10%, an external UPS for the complete system should be installed. A minimal capacity of 1400VA will be required.
   Comments: _____

[] SATISFACTORY
[] ACTION REQUIRED

Modem requirements:

1. A single phone line with a wall jack capable of accepting a RJ11C type of connector must be within 1.8 meter (6 feet) from the DAVINCI system for MODEM capabilities. The phone line for the MODEM must be voice grade, analog, signal type, capable of supporting one of the following standards: BELL103, V22, V22bis, V32, V32bis with MNP2-4 / V42 error correction an/or MNP5 / V42bis data compression.

Comments:

2. The MODEM will operate using the same type of phone line as that is used for a FAX- machine (2/4 wire leased line and/or PSTN).

Comments:

Customer acknowledgment :

I certify that a bioMérieux Representative has reviewed the findings of this DAVINCI Site inspection / installation with me. I understand that if any deficiencies are noted during installation, I will be notified by mail as to the impact these deficiencies may have upon the warranty coverage of this DAVINCI system.

Customer Signature _____ Title _____
Customer Facility Name _____ State _____
bioMérieux Representative _____ Date _____

ENCLOSURE 4 : "Disinfection Status" form

DAVINCI

DISINFECTION STATUS FORM

Shipper: _____ Date:_____

Project number : _____

[] Return to bioMérieux France
[] Repair by Manufacturer
[] Other : _____

Instrument : _____

Serial Number: : _____

Number of spare parts : _____

Disinfection Status (mentioned by Shipper):

[] Never used (neither for demo's)
[] Used; disinfected in compliance with the Disinfection Procedure
[] Used; only with water; not disinfected

Accompanying Parts (to be specified in addendum)

Used method of Disinfection

[] With Disinfection Aid
[] With 'box'
[] Other (see under 'Remarks')

Reference to Service Manual : _____

Number of attached BROWN-strips : _____

Remarks:

Addenda : _____

Total number of pages (incl. addenda): _____

Date : _____ Signed by Disinfection Engineer : _____

Delivered to : _____ Signature : _____

ENCLOSURE 5: DAVINCI specific service / installation tools list

Description	Artno	Need	Intention
Lubrication kit	45688032	*	Service procedures
Washer zero position Teacher tool	45688092	*	Washer zero position position adjustment
Pipetting station Teach plate	45688033	*	Pipetting position adjustment
Reagent Bay Teach tool	45688096	*	Reagent loading bay pipettor position adjustment
Sample Bay Teach tool	45688095	*	Sample loading bay pipettor position adjustement
Download adapter cable	45688034	*	Firmware download to incubator, washer, loading tower
4-Probe download adapter cable	45688036	*	Firmware download to pipettor arms
Plate transport teach ruler	45688084	*	Transport position adjustment
Washer O-ring kit	45688070	*	To replace lost sealing O-rings of washer manifold
Reader alignment pins, pair	45688093	*	To align reader PCB and optics
Reader alignment plate, 96 hole plate	45688094	*	To auto-align reader via service software
Reader alignment plate, optical block			To align internal transport mechanism and optics
Service Tool Kit	45688099	*	Contains : 45688092, 45688033, 45688096, 45688095, 45688034, 45688036, 45688084, 45688093, 45688094

* = minimum requirement for installation

ENCLOSURE 6: Service Agreement pricing and Service Coverage

DAVINCI SERVICE AGREEMENT PRICING

Pricing of the service agreement should be based on :

- Preventive maintenance (2 times per year)
  Travel costs : local situation
  Travel time : local situation
  Labor costs : 8 hours
  Parts : see preventive maintenance (enclosure 7)

- Service
  Tel support number of times X labor costs : depending on customer
  Number of expected visits : estimate
  Travel costs : local situation
  Travel time : local situation
  Average labor costs : estimate, 4 hours max.
  Average costs for parts to be replaced : see preventive maintenance and RSPL

- Costs for software update (combine with PM) (set limit for coverage)

- Depreciation and other costs for loaner system local situation

- Operator training (after initial training) discount local situation

Note: The maintenance intervals given above assume a working time of the instrument of 8 hours per day, 5 days a week, in a normal laboratory environment. Upon more intense usage of the instrument or usage in demanding environmental conditions (dust, heat, humidity) the maintenance intervals should be shortened accordingly.

DAVINCI

SERVICE COVERAGE

Coverage details	Standard	Medium	Premium
Number of preventive maintenance visits (including hardware updates)	n.a.	2	2
On-site emergency service calls	n.a.	Y	Y
Minimum call out charge and travel	n.a.	Y	Y
Replacement parts limited to max. value (preventive maintenance parts)	n.a.	Y (xxx EUR)	Y (xxx EUR)
Replacement parts free of charge (parts for repair activities)	n.a.	Y	Y
Software update limited to max. value	n.a.	Y (xxxx EUR)	Y (xxxx EUR)
Telephone support	n.a.	n.a.	n.a.
Loaner system back-up ("manual" benchtop instruments in order to continue testing)	n.a.	Y	Y
Extended coverage to 24 hrs / 7 days a week coverage	n.a.	N	Y
Discount arrangement for operator training (after initial training)	n.a.	Y (25 %)	Y (50 %)
xxxx EUR = upto max. value of xxxx EUR	Y = Yes	N = No	n.a. = not applicable

ENCLOSURE 7 : Preventive Maintenance Form

DAVINCI

PREVENTIVE MAINTENANCE

The preventive maintenance (PM) has been estimated to take place at least 2 times per year, assuming a working time of the instrument of 8 hours per day, 5 days a week, in a normal laboratory environment. Upon more intense usage of the instrument or usage in demanding environmental conditions (dust, heat, humidity) the maintenance intervals should be shortened accordingly.

The PM has been divided into the different system subassemblies : software, pipettors & diluters, washer, bar code scanners, transport system, incubator and some other general issues.
The parts that have to be replaced during the PM are indicated. After the replacement of the suggested parts if applicable, verification (and when applicable, recalibration) is necessary.

Location : ……..…….. **Serial no** : ……..

Overview of tasks :
(please refer to the DAVINCI Service Manual chapter 6 for additional instructions and references)

Task	6-Monthly PM	Yearly PM
General		
Perform backup	X	X
Delete old data	X	X
Pipettor		
Replace diluter pump syringes	X	X
Clean and lubricate pipettor mechanics	X	X
Lubricate pipettor spreading mechanism	X	X
Inspect and replace system liquid tubings (8 pcs)	O	X
Replace diluter 3-way valves		X
Replace the probe adapter coax cables		X
Replace steel needles[1]		X

Clean the disposable tips funnel		O
Replace system liquid inline filter		X
Replace wash station waste tubing		O
Check / calibrate the coordinates	X	X
Washer		
Replace PLU aerosol filter	X	X
Clean overflow trough	X	X
Inspect / replace aspirate tubings[2]	O	X
Replace waste (vacuum) tubings[2]		X
Inspect and clean the washer manifold	X	X
Calibrate the zero & first strip position	X	X
Calibrate the 4 dispense pumps	X	X
Bar Code Scanners		
Clean microplate bar code scanners	X	X
Clean loading bay(s) bar code scanner	X	X
Transport System		
Clean and lubricate transport system	X	X
Clean X- and Z-axis slide rails		X
Check transport system performance (run macro)	X	X
Incubator		
Clean incubator slots		X
Clean / check functionality of incubator cooling fan	X	X
Photometric Reader		
Replace the lamp		X
Inspect / clean internal spillage	O	X
Run the automatic alignments	O	X
Electronics rack		
Clean / check functionality of backplane cooling fan	X	X

Clean / check functionality of power supply cooling fan	X	X
Computer		
Clean PC / check functionality of cooling fans	X	X
Analyser		
Overall cleaning (vacuum cleaning)	X	X
Analyser decontamination		If necessary
Software		
Perform backup of system settings and global files	X	X
Delete old plate data (Clean Database)[3]	X	X
Delete obsolete files (.tmp, .emf, .trw) from d:\mpa\temp	X	X
Delete obsolete files (.abs) from d:\mpa\data\readings[4]	X	X
Delete obsolete files from c:\Documents and Settings\davinci\Local Settings\Temp[5]	X	X
Delete obsolete files from d:\mpa\data\LIS[6]	X	X
Verification		
Run the full verification after maintenance	X	X

X = mandatory task **O = optional task**

Note 1: this only applies to instruments configured with metal needles for sampling.
Note 2: be aware about the differences in tubings for instruments starting with serial number 5130000147. Check the spare parts list descriptions.
Note 3: this action will invalidate the status (OK -> Due) of the module verifications.
Note 4: do **NOT** delete file 'RefPlateModel.dat'
Note 5: only delete files after all data has been transferred to the external system.
- 'ldmbxxxx.$$$' files originate from LDM Basic (MECS PE) interface,
- 'ASTM1381.TXT', 'uploadxx.dat' and 'ASTM1394-x.dwn' files originate from serial ASTM host interface.

Note 6: only delete files after all data has been transferred to the external system.
- 'MPA-yyyymmddhhmmss.dwn' and 'MPA-yyyymmddhhmmss.up' files originate from ASTM File Link host interface.

Parts checklist :

Pipettor

[ ] Replacement of dirty tubings
- 45688150 1 x Tubing Kit , Pipettor System Liquid
- 45688149 1 x Tubing Kit , Pipettor Waste

[ ] Replacement of the syringes, valves, filter and needles
- 45688027 4 x Syringe , 500 µl
- 45688026 4 x Syringe , 1000 µl
- 45688062 8 x Valve , 3 way (diluter)
- 45688025 4 x Pipetting needle, sample (when applicable)
- 45688155 1 x Filter , inline , system liquid

[ ] Replacement of the liquid detector cables
- 45688164 8 x Liquid Detector cable daVINCI (new type (blue), no wedge included)

or
- 45688166 2 x Repl Kit Liq Det Cable daVINCI (set of 5 cables & wedges each)

Washer

[ ] Replacement of dirty tubings
- 45688097 1 x Tubing Kit , Washer , Internal (sn<147)

or
- 45688168 1 x Tubing kit wash intern (sn>=147)
- 45688152 1 x Tubing Kit , PLU Waste (sn<147)

or
- 45688167 1 x Tubing kit PLU waste (sn>=147)
- 45688153 1 x Tubing Kit , Wash Buffer Aspiration
- 45688151 1 x Tubing Kit , Overflow (sn<147)

or
- 45688154 1 x Tubing Kit , Overflow (sn >= 147)

[ ] Replace PLU aerosol filter
- 45688076 1 x Filter , Air exhaust , aerosol (filter + tubing + connector)

Reader

[ ] Replace the lamp
- 45688046 1 x Lamp 13.8V 30W

After replacement of the lamp, it is necessary to verify the reader with the RVP and C2C protocol.

Field engineer : ..... Date : …./..../……..

Customer : ……..

Enclosure 8 : Operational Qualification procedure (BTL021880)

ABBREVIATIONS

ASTM	American Society of Testing and Materials
C2C	Channel to channel
DRP	Dispense Reference Plate
IVT	Incubator Verification Tool
OQ	Operational Qualification
RVP	Reader Verification Plate
WFV	Washer Fill Volume
WRV	Washer Residual Volume

INTRODUCTION

The Operational Qualification, in short OQ, is a step-by-step procedure that runs over all the functions of a fully installed DAVINCI system. The OQ verifies the correct functioning of the DAVINCI system, including the host interface (when applicable).

The OQ comprises the following:

- Performing a full system verification
- Performing a routine assay run
- Printing of results
- Host communication (when applicable)

Materials and methods

Materials

DAVINCI instrument with most recently released application software
Host system or external data reduction software package (when applicable)
Reader Verification Plate (RVP), provided with the instrument
Incubator Verification Tool (IVT), provided with the instrument
Un-coated microplates (article code 278303)
Calibrated pipettes (200 µl and 500 µl)

Protocols:
Released verification protocols
Routine assay protocol

Reagents:
Diagnostic kit (article code 280103)
Routine assay kit

Samples:
Samples or controls, that react positive in the routine assay and samples that react negative in the routine assay.

Methods

Verification of the hardware modules

Tip: By opening the "Maintenance and Verification" window a list of verification options is shown. Choosing an option and clicking the button "start" show a description of the verification procedure. To run the verification protocols click "continue".

To verify the correct functioning of the DAVINCI system the following verification protocols have to be run:

Reader Verification:
RVP
C2C

Pipettor Verification:
DRP
ReagVer
SampVer

Washer Verification
WRV
WFV black
WFV red
WFV yellow
WFV blue

Incubator Verification
IVT (overnight)

The application software will indicate the outcome of these verification runs. All modules statuses should become "OK".

Verification of the data reduction and print results

After running all verification protocols successfully, run a routine assay with some known positive and negative samples and/or controls. This must include (when applicable) the transfer from/to the host system (work-list and results) or external data reduction software package (results only).
Re-calculate the results according to the package insert and compare these with the results from the DAVINCI "results" in the "plate events" logging to check the DAVINCI data reduction.
Print a report "Plate list" to check print functionality (when applicable).
Make a final printout of the host computer (or external data reduction software) results (when applicable) and compare the results with the DAVINCI results from the "plate list" logging printout, to check the external communication (results upload).

RESULTS

The **Reader Verification** will be “ok” if the “RVP” and “C2C” have been run successfully.
The **Pipettor Verification** “will be “ok”, when the “DRP”, “SampVer” and “ReagVer” have been run successfully.
The **Washer Verification** will be “ok”, when the “WRV” and all 4 “WFV” assays have been run successfully.
The **Incubator Verification** will be “ok” if the “IVT” has been run successfully.

Data reduction is correct when re-calculated results according to the package insert match results from “plate events” logging.
The print functionality (when applicable) is correct if the printout via “Plate list” corresponds to the “Plate list” report on screen.
The external communication functions well, when the results as printed by the host or external software package correspond to the DAVINCI results.

Discussion and Conclusion

The reader verification must be “ok” before the Pipettor Verification and the Washer Verification can be run.
When executing the Washer Verification, it is advised to start the “Washer Residual Volume” protocol before the “Washer Fill Volume” protocols.
Verifying the correct functioning of the incubator slots will take considerable time. For this reason it is advised to run the IVT protocol overnight.

The OQ is finished successful, when:
- Reader Verification passed
- Pipettor Verification passed
- Washer Verification passed
- Incubator Verification passed
- Data reduction of a routine assay run is correct
- Print function is correct (when applicable)
- Host or external data reduction software package communication works correctly (when applicable)

Enclosure 9 : Spare Part List (update April 2008)

Note : for the latest spare parts list please refer to the GCS Portal (https://gcs.biomerieux.fr), section "Support / Spare Parts / Spare Parts List / La Balme / daVINCI"

Spares		Recommended stock for installed base of x instrument(s)				
MFG P/N	**MFG Designation**	**1 - 5**	**10**	**20**	**100**	**PM article**
6500000113	BARCODE READER, 14 LANE			1	2	
7429560000	BARCODE READER, 5 LANE (WITH MOUNTING BRACKET)			1	2	
7513060500	CABLE HOLDER KIT, PIPETTOR					
45688175	CONNECTOR LIQUID WASTE/SHUTTLE	1	2	2	4	
45688039	COOLER INSERT , INCUBATOR				1	
45688061	DILUTER MODULE DAVINCI	1	2	2	4	
45688029	DISPOSABLE TIP ADAPTER DAVINCI	2	4	4	8	
45688020	DISPOSABLE TIP FUNNEL (NEW TYPE FOR SN 107 - UP)					optional
45688078	FILTER , 405 NM				1	
45688079	FILTER , 450 NM				1	
45688080	FILTER , 492 NM				1	
45688077	FILTER , 540 NM				1	
45688163	FILTER , 610 NM				1	
45688081	FILTER , 620 NM				1	
45688082	FILTER , 690 NM				1	
45688076	FILTER , AIR EXHAUST , AEROSOL (+ TUBING , + CONN)	2	4	4	8	Y
45688155	FILTER , INLINE, SYSTEM LIQUID	2	4	4	8	Y
45688051	FLEX CABLE , 12 P WITH PLUG (FROM X-SLEDGE TO Y-SLEDGE)	1	2	2	4	
45688075	FLEX CABLE , 2 X 13 P WITH PLUG (XYZ TRANSPORT)	1	1	2	4	
45688051	FLEX CABLE , 12P W/PLUG (PIP, INTERF PIP YZ TO Z-CTRL)	1	2	2	4	
45688052	FLEX CABLE , 20 P WITH PLUG (FROM PCB,MAIN 2 ARM PIP BRD)	1	2	2	4	
45688157	GUIDING RAIL BLACK (LOADING BAY), SET OF 12 PCS		1	1	2	
45688042	HEATING PLATE		1	2	4	
45688040	HEATING PLATE , TOP		1	1	1	
45688038	INCUBATOR MODULE			1	1	
45688046	LAMP, 13.8 V / 30 W (READER)	1	2	2	4	Y
45688164	LIQUID DETECTOR CABLE DAVINCI	2	4	4	8	Y
45688156	LIFTING DEVICE	1	1	1	1	
7438023007	LINE FILTER KIT			1	2	
45688177	LOADING BAY 5 LANE (W/COVER)			1	1	
45688176	LOADING BAY 14 LANE (W/COVER)			1	1	
45688043	LOADING TOWER MODULE			1	1	
45688071	MANIFOLD , WASHER	1	1	2	4	optional
45688028	NEEDLE ADAPTER DAVINCI	2	4	4	8	

45688070	O-RING KIT , WASHER	1	2	2	4	
45688049	PCB , 4 PROBE Z CONTROL		1	1	2	
45688057	PCB , 6 CHANNEL STEPPER		1	1	2	
45688054	PCB , COP		1	1	1	
45688074	PCB , DISTRIBUTION (REPLACED BY 45688074-1)					
45688074-1	PCB , DISTRIBUTION					
45688053	PCB , FUSE				1	
45688041	PCB , INCUBATOR		1	1	1	
45688047	PCB , INTERFACE PIPETTE Y/Z		1	1	1	
45688161	PCB , LED 14 LANE BAY		1	1	1	
45688160	PCB , LED 5 LANE BAY		1	1	1	
45688044	PCB , LOADING TOWER		1	1	1	
45688066	PCB , MAIN 14 LANE BAY				1	
45688048	PCB , MAIN 2 ARM PIPETTOR	1	1	2	2	
45688065	PCB , MAIN 5 LANE BAY				1	
45688055	PCB , MIO		1	1	2	
45688056	PCB , OUTPUT STAGE			1	1	
45688058	PCB , PLU				1	
7438023016	PCB , WASHER MAIN BOARD			1	2	
7225115300	PCB , X TRANSPORT (TYPE 2)				1	
7226519001	PCB , Y TRANSPORT W/SENSOR					
7225111450	PCB , Y TRANSP W/O SENSOR TYPE 2					
45688025	PIPETTING NEEDLE , SAMPLE	4	8	8	16	Y
45688158	PIPETTOR ARM COVER					
7438023006	PIPETTOR ASSY 4 PROBE Z-DRIVE (right arm)				1	
45688174	PIPETTOR ASSY 4 PROBE Z-DRIVE FIX DIST (left arm)				1	
7225025500	PIPETTOR WASH STATION					
7438023021	PLASTIC LIDS FOR ADAPTER (10 PCS)	1	1	1	1	optional
7513060600	PLATE CARRIER, SET OF 5 PCS					
45688037	POWER SUPPLY , 24 V / 400 W				1	
45688063	PUMP , NF30 MEMBRANE (PUMPS RIGHT ARM)	1	2	2	4	
45688064	PUMP , NF60 MEMBRANE (PUMP LEFT ARM + PUMP WASH STATION)	1	1	1	2	
45688060	PUMP , VACUUM MEMBRANE (CONNECTED TO VACUUM CONTAINER)			1	2	
3600000053	PUMP DISPENSE	2	2	4	8	
45688045	READER MODULE				1	
45688166	REPL KIT LIQ DET CABLE DAVINCI				2	Y
45688162	SENSOR, WASHER Z-LIGHT BARRIER				2	
7227340000	SENSOR, X-INIT TRANSP (TYPE 2)			1	1	
45688026	SYRINGE , 1000 uL , XP (HAMILTON)	4	8	8	16	Y
45688027	SYRINGE , 500 uL (HAMILTON)	4	8	8	16	Y

45688151	TUBING KIT , OVERFLOW (SN < 147)		1	1	1	Y
45688173	TRANSPORT XYZ MODULE				1	
45688154	TUBING KIT , OVERFLOW (SN >= 147)		1	1	2	Y
45688150	TUBING KIT , PIP SYSTEM LIQUID		1	2	4	Y
45688149	TUBING KIT , PIPETTOR WASTE		1	2	4	Y
45688152	TUBING KIT , PLU WASTE (SN < 147)		1	2	4	Y
45688167	TUBING KIT , PLU WASTE (SN >= 147)		1	2	4	Y
45688153	TUBING KIT , WASH BUFFER ASP		1	2	4	Y
45688097	TUBING KIT , WASHER , INTERNAL (SN < 147)	1	2	2	4	Y
45688168	TUBING KIT , WASHER , INTERNAL (SN >= 147)	1	2	2	4	Y
45688062	VALVE, 3-WAY (DILUTER)	2	4	8	16	Y
7226421009	WASHER MODULE				2	
45688159	WASHHEAD ASSEMBLY COMPLETE				2	
3600000045	WASTE TRANSFER PUMP (ETS-15)				2	
45688088	Y-PUSHER		1	1	1	
45688050	Z-DRIVE ROD	2	4	4	8	
Tools						
45688036	4 PROBE DOWNLOAD ADAPTER CABLE , 3 PINS CONNECTOR					
280103	DIAGNOSTIC KIT (LIQUIDS)	1	2	2	8	Y
45688034	DOWNLOAD ADAPTER CABLE					
284119	INCUBATOR VERIFICATION TOOL (IVT)					
45688032	LUBRICATION KIT	1	2	2	2	Y
45688030	MANUAL , OPERATOR					
45688089	MANUAL , SERVICE					Y
45688093	READER ALIGNMENT PINS , PAIR					
45688094	READER ALIGNMENT PLATE , 96 HOLE PLATE					
284117	READER VERIFICATION PLATE (RVP)					
45688083	REVIVAL SYRINGE FOR WASHER DISPENSE PUMP					
45688099	SERVICE TOOL KIT (BOX WITH ALL CALIBRATION TOOLS)	1	2	2	4	
45688033	TEACH PLATE , PIPETTING STATION					
45688092	TEACH PLATE , WASHER (ZERO POSITION)					
45688084	TEACH RULER , PLATE TRANSPORT					
45688096	TEACH TOOL , REAGENT BAY					
45688095	TEACH TOOL , SAMPLE LOADING BAY					
278303	UNCOATED MICROPLATE , GREINER	1	2	2	8	Y
Others						
45688024	CAN (TO FILL THE SYSTEM LIQUID CONTAINER)					
272241	CAP , CONTROL VIAL (2000 PCS)					
45688085	COMMON WASTE CONTAINER , 10 L (+ LEVEL SENSOR , +				1	

	TUBINGS)					
200404	CONTAINER , REAGENT, 50 mL (50 PCS)	1	1	2	8	
200405	CONTAINER , REAGENT, 90 mL (50 PCS)	1	1	2	8	
7226721002	CONTAINER WASH BUFFER		1	1	2	
45688090	CONTAINER, SYSTEM LIQUID 10 L				1	
7438022702	CONTROL RACK, 16X16MM (1 PC) (TYPE K)					
272240	CONTROL VIAL (344 PCS)					
200406	DISPOSABLE TIP , 1100 uL (10 X 96 PCS)	5	10	20	100	
200407	DISPOSABLE TIP , 300 uL (10 X 96 PCS)	10	20	40	200	
45688087	FOAM BOTTLE, PLU (SN < 147)					
7226721401	FOAM BOTTLE, PLU (SN >= 147)					
45688169	REAGENT RACK 3X90 ML (TYPE W)					
45688170	REAGENT RACK 5X50 ML (TYPE X)					
45688171	REAGENT RACK 4X90 ML (TYPE Y)					
45688172	REAGENT RACK 6X50 ML (TYPE Z)					
200420	SAMPLE RACK 16X100 MM (TYPE A), SET OF 7 PCS					
200419	SAMPLE RACK 13X75 MM (TYPE H), SET OF 7 PCS					
200421	SAMPLE RACK 13X100 MM (TYPE J), SET OF 7 PCS					
7429121000	SAMPLE RACK TRAY (14 LANES)					
45688086	VACUUM BOTTLE, PLU (SN < 147)					
45688165	VACUUM BOTTLE, PLU (SN >= 147)					

Enclosure 10 : DAVINCI DECONTAMINATION AND PACKING CHECKLIST

Note : This checklist is for guidance and information only and has not been approved by US Regulatory.

INSTRUMENT S/N: 5130000_____
INITIAL ALL RESPONSES IN SECTIONS 1-7. **PRINT, SIGN, AND DATE** AT END OF DOCUMENT.

MATERIALS USED:
SODIUM HYPOCHLORITE DILUTED TO A 1% SOLUTION (BLEACH)
70% ETHANOL (ALCOHOL)
DEIONIZED WATER (WATER)
LOCALLY PROCURED MILD DETERGENT (e.g. 3% solution Mucasol / Extran MA01): _____
PERSONNEL PROTECTIVE EQUIPMENT AS APPLICABLE
BIOHAZARDOUS WASTE CONTAINERS
MISCELLANEOUS CONTAINERS AND NON-LINTING AS NEEDED

BUBBLE WRAP
PACKING TAPE
MISCELLANEOUS SHIPPING BOXES FOR LOOSE ITEMS
STRATEC DAVINCI SHIPPING CRATE AND TRANSPORTATION/PACKING FOAM

Section 1

WIPE DOWN ALL PRESENT COMPONENTS OF COMPUTER SYSTEM WITH ALCOHOL.

	COMPLETE	NOT PRESENT
• COMPUTER	_____	_____
• MONITOR	_____	_____
• PRINTER	_____	_____
• KEYBOARD	_____	_____
• BARCODE SCANNER	_____	_____
• ASSOCIATED CABLES	_____	_____
• _____	_____	

Section 2

WIPE DOWN INSTRUMENT WITH ALCOHOL. COMPLETE

- EXTERIOR _____
- INTERIOR OF INSTRUMENT, AND OF MODULES :
  - SAMPLE & REAGENT BAYS _____
  - WASHER MODULE INTERIOR & OVERFLOW TRAY _____
  - READER MODULE INTERIOR _____

CLEAN WITH MILD DETERGENT:

- CABINET _____
- CABINET DRAWER _____

ATTACH PC, OPEN SERVICE SOFTWARE, ACCESS INCUBATOR DEVICE DRIVER.
OPEN EACH SLOT OF INCUBATOR AND WIPE CLEAN WITH ALCOHOL.
CLOSE LAST SLOT. _____

SHUT DOWN PC, DISASSEMBLE, SET INPUT VOLTAGE OF PC TO 220V. _____

Section 3

	COMPLETE	NOT PRESENT
RINSE WASHER ASPIRATE CHANNELS WITH ALCOHOL, THEN WATER	_____	_____
RINSE DISPOSABLE TIP WASTE BUCKET WITH BLEACH, THEN WATER.	_____	_____
CLEAN TIP EJECTION STATION WITH ALCOHOL .	_____	
REMOVE TIP EJECTION STATION FUNNEL. SUBMERGE IN ALCOHOL, THEN WIPE CLEAN.	_____	
PLACE PIPETTOR WASH STATION WASTE TUBING IN EXTERNAL CONTAINER. RINSE WASH STATION WITH ALCOHOL, THEN WITH WATER	_____	
SUBMERGE ALL REAGENT RACKS IN ALCOHOL AND WIPE CLEAN.	_____	

NUMBER PRESENT: 5X50 ML ____ 6X50 ML ____ 3X90 ML ____ 4X90 ML ____

	COMPLETE
SUBMERGE ALL SAMPLE / CONTROL RACKS IN ALCOHOL AND WIPE CLEAN.	_____

NUMBER PRESENT: CONTROL ____ SAMPLE ____

SUBMERGE ALL MICROPLATE CARRIERS IN ALCOHOL AND WIPE CLEAN.	_____

NUMBER PRESENT: ____(/20)

Section 4

REMOVE AND DISCARD IN BIOHAZARD CONTAINER:	COMPLETE
• WASHER MANIFOLD	_____
• 4 PIPETTING NEEDLES	_____
• WASHHEAD ASSY WASTE TUBING – WASHER MODULE INTERNAL ASPIRATE	_____
• WASHHEAD ASSY WASTE TUBING – WASHER MODULE TO PLU	_____
• WASHHEAD ASSY WASTE TUBING – PLU INTERNAL TUBING TO BOTTLES & PUMPS	_____
• WASHHEAD ASSY WASTE TUBING – PLU TO WASTE TANK	_____
• PLU AEROSOL FILTER	_____
• TUBING FROM PIPETTOR WASH STATION TO WASTE PUMP	_____
• PIPETTOR WASH STATION WASTE PUMP	_____
• TUBING FROM WASH STATION WASTE PUMP TO WASTE TANK	_____

Section 5

INSPECT THE FOLLOWING FOR ALGAE OR OTHER GROWTH. IF NO GROWTH IS PRESENT, COMPLETE THE [INDICATED ACTION]. OTHERWISE, DISCARD.

	GROWTH	NO GROWTH	COMPLETE	MISSING
VACUUM BOTTLES [RINSE W/ BLEACH THEN WATER]	_____	_____	_____	____
COMMON WASTE [RINSE W/ BLEACH THEN WATER]	_____	_____	_____	____
WASTE SHUTTLE TANK [RINSE W/ BLEACH THEN WATER]	_____	_____	_____	____
BLACK WASH BUFFER TANK [RINSE W/ WATER]	_____	_____	_____	____
RED WASH BUFFER TANK [RINSE W/ WATER]	_____	_____	_____	____
YELLOW WASH BUFFER TANK [RINSE W/ WATER]	_____	_____	_____	____
BLUE WASH BUFFER TANK [RINSE W/ WATER]	_____	_____	_____	____
SYSTEM LIQUID TANK [RINSE W/ WATER]	_____	_____	_____	____

	GROWTH	NO GROWTH
WASHER OVERFLOW TUBING [NONE]	_____	_____
TUBING FROM SYS LIQUID TANK TO DILUTER [NONE]	_____	_____
TUBING FROM DILUTER TO PIPETTOR ARMS [NONE]	_____	_____

Section 6

	COMPLETE
REMOVE PIPETTOR Z-RODS AND ADAPTERS. WRAP IN BUBBLE WRAP.	_____
REMOVE SYRINGES. WRAP IN BUBBLE WRAP.	_____
SECURE WASHER MODULE WASH HEAD WITH SHIPPING SCREW OR EQUIVALENT.	_____
WRAP ALL SAMPLE, CONTROL AND REAGENT RACKS IN BUBBLE WRAP.	_____
WRAP ALL PLATE CARRIERS IN BUBBLE WRAP.	_____
WRAP BLUE FRONT COVER IN BUBBLE WRAP.	_____

Section 7

	COMPLETE
PLACE COMPUTER, MONITOR, KEYBOARD, BARCODE SCANNER AND CABLES FROM SECTION 1, FUNNEL FROM SECTION 3, NO-GROWTH ITEMS 1-9 IN SECTION 5, AND ALL ITEMS FROM SECTION 6 IN SHIPPING BOXES.	_____
SECURE REAGENT, SAMPLE ARMS AND PLATE TRANSPORT SYSTEM WITH SHIPPING FOAM. PLACE INSTRUMENT IN SHIPPING CRATE.	_____
PLACE BLUE FRONT COVER IN SLOTTED HOLES OF TRANSPORTATION FOAM ABOVE THE INSTRUMENT	_____
PLACE CABINET IN SHIPPING CRATE.	_____

ENSURE NO ITEMS ABOVE ARE LEFT BLANK. NOTE ANY EXCEPTIONS TO THIS CHECKLIST HERE; IF NONE, INDICATE "NONE."

PROVIDE BELOW YOUR PRINTED NAME, SIGNATURE, INITIALS, AND DATE YOUR TASKS WERE COMPLETED. ATTACH THIS DOCUMENT BEHIND THE DISINFECTION FORM (SEE ENCLOSURE 4), AND ENSURE THE DISINFECTION FORM IS FILLED OUT COMPLETELY. LEAVE NO BLANKS; USE "NOT APPLICABLE" OR "N/A", OR "NOT KNOWN", AS APPROPRIATE. ATTACH COMPLETED DISINFECTION FORM WITH INSTRUMENT PACKAGING IN ACCORDANCE WITH CURRENT INTERNATIONAL SHIPMENT REQUIREMENTS. OBTAIN ADDITIONAL GUIDANCE FROM BIOMERIEUX IF NEEDED.

PRINTED NAME SIGNATURE INITIALS

DATE

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DATE

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DATE