

VeriSeq NIPT Solution v2

Site Prep Guide

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Introduction

This guide provides specifications and guidelines for preparing your site for the installation and operation of the Illumina® VeriSeq™ NIPT Solution v2. The guide addresses the following topics:

- ▶ Delivery and installation considerations
- ▶ Facility requirements
- ▶ Electrical requirements
- ▶ Environmental considerations
- ▶ Network considerations
- ▶ Security considerations
- ▶ Product certifications
- ▶ User-supplied consumables and equipment

NextSeq 550Dx Site Prep

The VeriSeq NIPT Solution v2 requires a next-generation sequencing instrument. If you plan to use the Illumina NextSeq™ 550Dx instrument, refer to the *NextSeq 550Dx Instrument Site Prep Guide (document # 1000000009869)* for installation, operation, and security details.

Additional Resources

The VeriSeq NIPT Solution v2 support pages on the Illumina website provide additional system resources. These resources include software, training, compatible products, and the following documentation. Always check support pages for the latest versions.

Resource	Description
<i>VeriSeq NIPT Solution v2 Package Insert (document # 1000000078751)</i>	Provides instructions for the overall VeriSeq NIPT Solution v2 workflow and library preparation. Maintenance and troubleshooting procedures are included.
<i>VeriSeq NIPT Solution v2 Sample Prep Checklist (document # 1000000076883)</i>	Provides a checklist of the library preparation steps. The checklist is intended for experienced users.
<i>VeriSeq NIPT Solution v2 Consumables & Equipment List (document # 1000000076886)</i>	Provides an interactive checklist of user-provided consumables and equipment.
<i>VeriSeq NIPT Solution v2 Software Guide (document # 1000000067940)</i>	Provides an overview of the VeriSeq NIPT Solution v2 software, including instructions for configuration and use of the VeriSeq Onsite Server v2.
<i>NextSeq 550Dx Instrument Site Prep Guide (document # 1000000009869)</i>	Provides specifications and guidelines for preparing your site for installation and operation of the Illumina NextSeq 550Dx instrument.

Delivery and Installation

Use the information provided in this section to prepare for delivery and installation of the VeriSeq Onsite Server v2 and the Hamilton® VeriSeq NIPT Microlab® STAR™.

VeriSeq Onsite Server v2 Delivery and Installation

An authorized service provider delivers, unpacks, and positions the VeriSeq Onsite Server v2. An Illumina representative installs the VeriSeq Onsite Server v2. The space must be ready before delivery.

**CAUTION**

Only authorized personnel can unpack, install, or move the VeriSeq Onsite Server v2.

VeriSeq Onsite Server v2 Carton Dimensions and Contents

The VeriSeq Onsite Server v2 and accessories are shipped in one carton. Use the following dimensions to determine transport, setup, and storage plans.

Measurement	Carton Dimensions
Width	85.1 cm (33.5 in)
Height	41.0 cm (16.0 in)
Depth	62.2 cm (24.5 in)
Weight	33.1 kg (73 lbs)

The carton contains the server and the following components:

- ▶ Power cords, country-specific (2)
- ▶ White bezel
- ▶ Keys for bezel
- ▶ Display port to DVI adapter
- ▶ Certificate of Conformity (signed and dated)

VeriSeq NIPT Microlab STAR Delivery and Installation

A Hamilton representative delivers, unpacks, and positions the VeriSeq NIPT Microlab STAR. The space must be ready before delivery.

**CAUTION**

Only authorized personnel can unpack, install, or move the VeriSeq NIPT Microlab STAR.

Artificial Plasma Storage Requirements

For installation and training, you will need a 2°C to 8°C refrigerator to store artificial plasma samples. A maximum of 14 artificial plasma boxes will be shipped with each VeriSeq NIPT Microlab STAR. Artificial plasma box size is as follows:

Measurement	Dimensions
Height	14.8 cm (5.8 in)
Width	11.7 cm (4.6 in)
Depth	13.1 cm (5.2 in)

Alternative Plasma Storage Requirements

If artificial plasma is unavailable, installation and training procedures use an alternative option for plasma. For the storage of these plasma samples, you will need a -85°C to -65°C freezer. A maximum of eight of these plasma boxes are shipped with each VeriSeq NIPT Microlab STAR. These boxes have the following dimensions:

Measurement	Dimensions
Height	13 cm (5.1 in)
Width	15.4 cm (6.1 in)
Depth	15.2 cm (6 in)

Facility Requirements

Use the specifications and requirements provided in this section to set up your facility space.

Equipment Dimensions

Equipment	Height	Width	Depth	Weight
VeriSeq Onsite Server v2	43.8 cm (17.3 in)	17.8 cm (7 in)	63.5 cm (25 in)	25.9 kg (57 lbs)
VeriSeq NIPT Microlab STAR with Autoload	90.3 cm (35.6 in)	199 cm (78.3 in)	100.6 cm (39.6 in)	160 kg (353 lbs)

VeriSeq Onsite Server v2 Placement Requirements

Position the VeriSeq Onsite Server v2 to allow for:

- ▶ Power cord connection to two power outlets and quick disconnection.
- ▶ Proper ventilation.
- ▶ Two standard power sockets within 1.8 m (6 ft) of the server.
- ▶ One network socket located within 1.8 m (6 ft) of the server (or longer network cable provided by customer).
- ▶ One static reserved IP address.
- ▶ Service access.



NOTE

If you choose to position the server in a rack, it requires a rack unit size of 4U.

A server positioned upright must be accessible from all sides with the following minimum clearance dimensions:

Access	Minimum Clearance
Sides	Allow at least 61.0 cm (24.0 in) on each side of the server.
Rear	Allow at least 10.2 cm (4.0 in) behind the server
Top	Allow at least 61.0 cm (24.0 in) above the server. If the server is positioned under a shelf, make sure that the minimum clearance requirement is met.

VeriSeq NIPT Microlab STAR Placement Requirements

Position the VeriSeq NIPT Microlab STAR to allow for:

- ▶ Proper ventilation.
- ▶ Five standard power sockets within 1.8 m (6 ft).
- ▶ Two additional standard power sockets for service purposes within 1.8 m (6 ft).
- ▶ One network socket located within 1.8 m (6 ft) (or longer network cable provided by customer).

- ▶ Bench space to the right or left of the instrument to accommodate the PC and monitor.
- ▶ Space underneath the instrument to accommodate the vacuum pump, waste bins, waste bottle, and CPAC control unit (accessory equipment provided with purchase of the VeriSeq NIPT Microlab STAR).
- ▶ Clearance for a waste bin underneath the CO-RE head tips waste chute to the left of the instrument (~26 cm or 10.2 in).

Accessory Equipment	Height	Width	Depth
INHECO Multi TEC Control Unit	26.4 cm (10.4 in)	18.5 cm (7.3 in)	24.9 cm (9.8 in)
Vacuum pump	25 cm (9.8 in)	22 cm (8.7 in)	23 cm (9.1 in)
Waste bottle	41 cm (16.1 in)	18 cm (7.1 in)	18 cm (7.1 in)

Reagent Storage Requirements

The following tables provide storage temperature and dimensions for VeriSeq NIPT Solution v2 reagents. Make sure to take into account storage requirements for your sequencing system's reagent kit.

Table 1 VeriSeq NIPT SMP Prep Kit (24), Part # 20025895

Part #	Description	Dimensions	Weight	Storage
20025869	VeriSeq NIPT Extraction Box (24)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	620 gr (1.4 lbs)	Room temperature
20026030	VeriSeq NIPT Library Prep Box (24)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	330 gr (0.7 lbs)	-25°C to -15°C
15066811	VeriSeq NIPT Accessory Box	16 cm × 12 cm × 14 cm (6.3 in × 4.7 in × 5.5 in)	330 gr (0.7 lbs)	2°C to 8°C
15071543	VeriSeq NIPT Workflow Tubes and Labels	17 cm × 10 cm × 1 cm (6.7 in × 3.9 in × 0.4 in)	20 gr (0.04 lbs)	Room temperature

Table 2 VeriSeq NIPT SMP Prep Kit (48), Part # 15066801

Part #	Description	Dimensions	Weight	Storage
15066803	VeriSeq NIPT Extraction Box (48)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	620 gr (1.4 lbs)	Room temperature
15066809	VeriSeq NIPT Library Prep Box (48)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	330 gr (0.7 lbs)	-25°C to -15°C
15066811	VeriSeq NIPT Accessory Box	16 cm × 12 cm × 14 cm (6.3 in × 4.7 in × 5.5 in)	330 gr (0.7 lbs)	2°C to 8°C
15071543	VeriSeq NIPT Workflow Tubes and Labels	17 cm × 10 cm × 1 cm (6.7 in × 3.9 in × 0.4 in)	20 gr (0.04 lbs)	Room temperature

Table 3 VeriSeq NIPT SMP Prep Kit (96), Part # 15066802

Part #	Description	Dimensions	Weight	Storage
15066807	VeriSeq NIPT Extraction Box (96)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	680 gr (1.5 lbs)	Room temperature
15066810	VeriSeq NIPT Library Prep Box (96)	16 cm × 15 cm × 11 cm (6.3 in × 5.9 in × 4.3 in)	330 gr (0.7 lbs)	-25°C to -15°C
15066811	VeriSeq NIPT Accessory Box	16 cm × 12 cm × 14 cm (6.3 in × 4.7 in × 5.5 in)	330 gr (0.7 lbs)	2°C to 8°C

Part #	Description	Dimensions	Weight	Storage
15071543	VeriSeq NIPT Workflow Tubes and Labels	17 cm × 10 cm × 1 cm (6.7 in × 3.9 in × 0.4 in)	20 gr (0.04 lbs)	Room temperature

Pre-PCR Area

Establish dedicated areas and lab procedures to prevent PCR product contamination before you begin work in the lab. PCR products can contaminate reagents, instruments, and samples, delaying normal operations and causing inaccurate results.

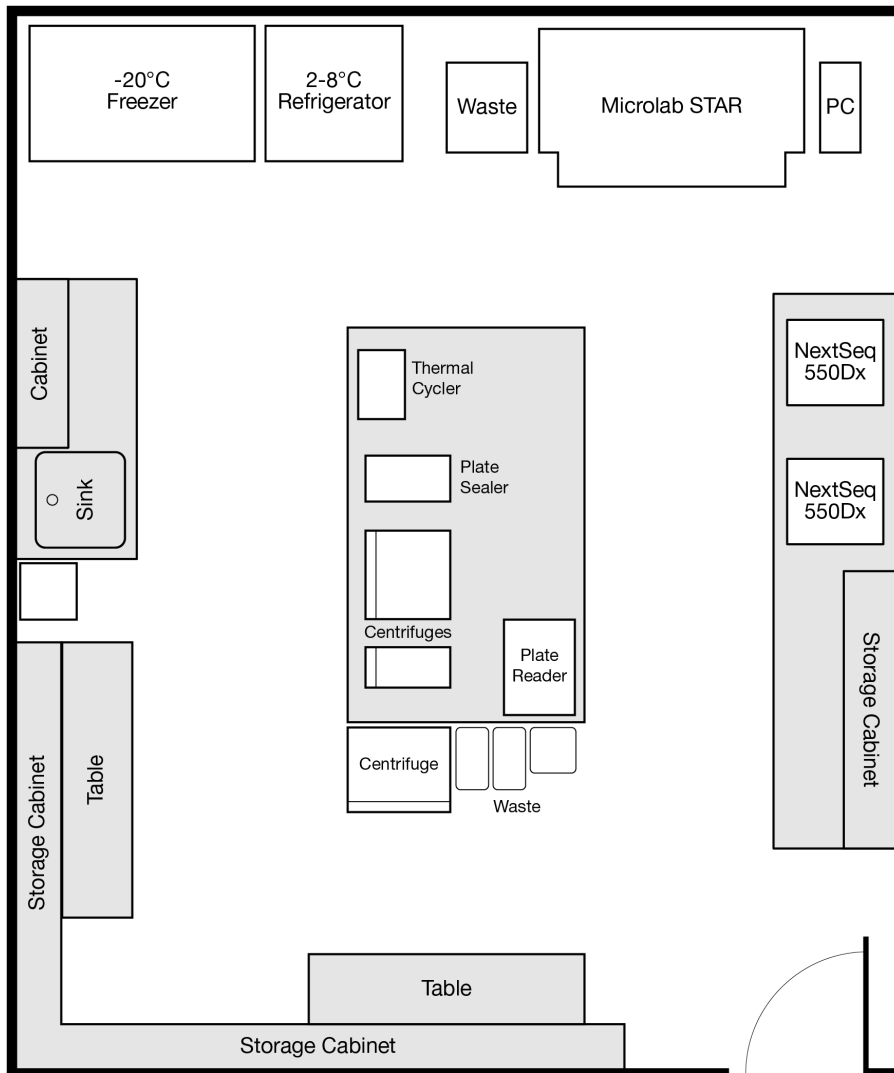
Use the following guidelines to avoid cross-contamination.

- ▶ Establish a pre-PCR area with dedicated entrances for pre-PCR processes.
- ▶ Make sure that lab personnel do not have to pass through any post-PCR lab areas to access the pre-PCR area.
- ▶ Place the VeriSeq NIPT Microlab STAR in the pre-PCR area.
- ▶ Do not pass material or equipment from any post-PCR area to the pre-PCR area.
- ▶ Because the VeriSeq NIPT Solution v2 workflow does not include a PCR step, your next-generation sequencing system can be located in the pre-PCR area unless it is being used for other applications.

Example Lab Layout

The following figure provides an example layout for 1 VeriSeq NIPT Microlab STAR, 2 Illumina NextSeq 550Dx instruments, and ancillary lab equipment. This example layout requires approximately 35 square meters (377 sq ft). The VeriSeq Onsite Server v2 and UPS do not have to be placed in the lab and are intentionally not shown in the example layout.

Figure 1 VeriSeq™ NIPT Solution v2 Example Lab Layout (not to scale)



Barcode Printing Requirements

Use the following guidelines when printing barcode labels for the Streck blood tube.

Table 4 Barcode Specifications

Specification	Description
Type	Black bars with white background.
Symbology	Code 128, Subset B. This symbology covers ASCII characters 32 to 127 (0–9, A–Z, a–z) and special characters.
Code Density, Tolerance	Minimum module width (x dimension) including a print tolerance: ≥ 0.1651 mm (0.0065 in). Maximum module width (x dimension) including a print tolerance: ≤ 0.508 mm (0.02 in). Best reading performance with x dimension ≥ 0.254 mm (0.01 in).
Number of Check Characters	One character.
Quiet Zone	≥ 10 times the x dimension, but at least 3 mm (0.11811 in).
Print Quality	The barcode print must be of a high quality. A printed barcode with an ANSI/CEN/ISO grade A or B is required. Offset, typographic, intaglio, and flexographic printing are suitable. Mechanical dot matrix and thermo matrix printing are not suitable. The surface may be treated, sealed, or plastic-coated.

Figure 2 Barcode Dimensions



	Dimension	Min.	Max.
A	Label length	-	80 mm
B	Code length	-	74 mm
C	Quiet zone	3 mm	-
D	Label width	12 mm	-
E	Code width	12 mm	-
F	Distance from code to label edge	-	1 mm

Electrical Requirements

VeriSeq Onsite Server v2 Power Specifications

Power	Specification
Input Voltage	100–240 Volts AC @ 47–63 Hz
Power consumption	525 watts

VeriSeq NIPT Microlab STAR Power Specifications

Power	Specification
Input Voltage	100–240 Volts AC @ 50–60 Hz
Power consumption	600 Watts

Receptacles

Your facility must be wired with the following receptacles.

Voltage	Specifications
100–120 Volts AC	<ul style="list-style-type: none"> Two 15-amp grounded, dedicated lines with proper voltage and electrical ground are required. North America and Japan — Receptacle: NEMA 5-15
220–240 Volts AC	<ul style="list-style-type: none"> Two 10-amp grounded lines with proper voltage and electrical ground are required. If the voltage fluctuates more than 10%, power line regulators are required.

Protective Earth



The instrument has a connection to protective earth through the enclosure. The safety ground on the power cord returns protective earth to a safe reference. The protective earth connection on the power cord must be in good working condition when using this device.

Power Cords

The VeriSeq Onsite Server v2 has international standard IEC 60320 C13 receptacles and is shipped with two region-specific power cords.

Hazardous voltages are removed from the server only when the power cords are disconnected from the AC power source.

To obtain equivalent receptacles or power cords that comply with local standards, consult a third-party supplier such as Interpower Corporation (www.interpower.com).



CAUTION

Never use an extension cord to connect the server to a power supply.

Fuses

The VeriSeq Onsite Server v2 contains no user-replaceable fuses.

Uninterruptible Power Supply

Illumina recommends using a user-supplied uninterruptible power supply (UPS). Illumina is not responsible for data loss caused by interrupted power, regardless of whether the server is connected to a UPS. Standard generator-backed power is often not uninterruptible, so a brief power outage can occur before power resumes. These power outages interrupt analysis and data transfer.

The following table includes UPS recommendations for the server. The output voltage for the recommended models varies based on your region.

Specification	APC Smart UPS 1500 VA LCD 100 V Part # SMT1500J (Japan)	APC Smart UPS 1500 VA LCD 120 V Part # SMT1500C (North America)	APC Smart UPS 1500 VA LCD 230 V Part # SMT1500IC (International)
Maximum Output Capacity	980 W / 1200 VA	1000 W / 1440 VA	1000 W / 1500 VA
Input Voltage (nominal)	100 VAC	120 VAC	230 VAC
Input Frequency	50/60 Hz	50/60 Hz	50/60 Hz
Input Connection	NEMA 5-15P	NEMA 5-15P	IEC-320 C14 Schuko CEE7/EU1-16P British BS1363A
Dimensions (H x W x D)	22.5 cm x 17.2 cm x 43.9 cm	21.9 cm x 17.1 cm x 43.9 cm (8.6 in x 6.7 in x 17.3 in)	21.9 cm x 17.1 cm x 43.9 cm
Weight	26 kg	24.6 kg (54.2 lbs)	24.1 kg
Typical Run Time (50% load)	30 minutes	30 minutes	30 minutes
Typical Run Time (100% load)	15 minutes	15 minutes	15 minutes

Environmental Considerations

Element	Specification
Temperature	Maintain a lab temperature of 19°C to 25°C (22°C ±3°C). This temperature is the operating temperature of compatible next-generation sequencing instruments. Do not allow the ambient temperature to vary by more than ±2°C.
Humidity	Maintain a noncondensing relative humidity between 20–80%.
Altitude	Locate solution components at an altitude below 2,000 m (6,500 ft).
Air Quality	Operate solution components in an indoor environment with air particulate cleanliness levels per ISO 14644-1 Class 9 (ordinary room / laboratory air), or better. Keep solution components away from sources of dust.
Ventilation	Consult your facilities department for ventilation requirements sufficient for the level of heat output expected from solution components.

Heat Output

Equipment	Measured Power	Thermal Output
VeriSeq Onsite Server v2	525 Watts	1,791 BTU/h
VeriSeq NIPT Microlab STAR	600 Watts	2,047 BTU/h

Noise Output

The VeriSeq Onsite Server v2 is air-cooled. Noise from the fan is audible when the server is processing.

Equipment	Noise Output (dB)	Distance
VeriSeq Onsite Server v2	42.7 dB	1 m (3.3 ft)
VeriSeq NIPT Microlab STAR	< 65	data not available

A measurement of < 62 dB is within the level of a normal conversation at a distance of approximately 1 m (3.3 ft).

Network Considerations

Review the following network considerations and requirements before installing the VeriSeq Onsite Server v2.



NOTE

You must complete and return the *VeriSeq On-Site Server V2 Pre-Installation Form* before your installation. Some of the information in this section is required for the form.

Server setup requires the following network components:

- ▶ The default gateway address
- ▶ The DNS Server IP address
- ▶ One static, dedicated IP address
- ▶ A subnet mask for the static IP address
- ▶ An SMTP server
- ▶ The hostname or IP address of an accessible NTP server.
- ▶ **[Optional]** The hostname or IP address of a second NTP server to use as a backup.

General networking support includes the following requirements and recommendations:

- ▶ A 1 gigabit connection between the server and network. Make this connection directly or through a network switch.
- ▶ To archive data, use a network storage device that uses the Common Internet File System (CIFS).
- ▶ Ask your IT professional to review network maintenance activities for potential compatibility risks with the system.

Network Ports

The VeriSeq Onsite Server v2 uses network ports for services as described in the following table.

Table 5 VeriSeq Onsite Server v2 Network Ports

Value	Service	Protocol
80	HTTP	Transmission Control Protocol (TCP)
443	HTTPS	TCP
123	Network Time Protocol (NTP)	User Datagram Protocol (UDP)
137	Samba	UDP
138	Samba	UDP
139	Samba	TCP
445	Samba	TCP
22	Secure Shell (SSH)	UDP

Remote Access Requirement

Remote access to your network is required to assist the Illumina support team to rapidly troubleshoot and resolve issues. Make sure the VeriSeq NIPT Microlab STAR PC and any sequencing systems can be made available to an outside network. Any remote assistance software used by the Illumina support team includes end-to-end data security, does not require opening any holes in your firewall, and will comply with the following precautionary measures:

- ▶ Remote access sessions must be initiated and attended by the customer and can be terminated at any time.
- ▶ Customer permission is always required before any screen sharing, remote control, or data transfer is initiated.
- ▶ Support staff actions are visible to the customer at all times.
- ▶ Local security controls are never overridden.
- ▶ All network activities are logged and customers can record sessions for review.

Security Considerations

The following security considerations and recommendations support the secure deployment of the VeriSeq NIPT Solution v2 in a laboratory. Review this content with your laboratory IT and security specialists.

Security Controls

The VeriSeq NIPT Solution v2 contains the following built-in security measures.

- ▶ **Encrypted Data Transmission:** All communication and file transfer between the components of the VeriSeq NIPT Solution v2 is encrypted. Traffic related to APIs and user interfaces for components are encrypted using TLS v1.2 protocol. The sequencer file transfer uses the SSPI protocol.
- ▶ **Access Controls:** The VeriSeq NIPT Microlab STAR control computer software and the VeriSeq Onsite Server v2 provide role-based user authentication for access. All VeriSeq NIPT Microlab STAR communication with the VeriSeq Onsite Server v2 requires authentication.
- ▶ **Logging:** User activity on the VeriSeq NIPT Microlab STAR computer, the VeriSeq Onsite Server v2, and the sequencing instrument is logged.
- ▶ **Data Storage Security:** Database backups of the VeriSeq Onsite Server v2 can be encrypted using an AES-256 key. The server does not permit external logins to its operating system except using a single authorized Illumina service personnel credential.
- ▶ **Testing:** The VeriSeq Onsite Server v2 has undergone security analysis through threat modeling, penetration testing, and malware scanning.
- ▶ **Third Party Components:** A software bill of materials (SBOM) is available upon request from Illumina Technical Support.

Security Recommendations

To promote the security of the VeriSeq NIPT Solution v2, follow these recommendations as appropriate.

Perimeter Defense Controls

Use firewalls or proxy servers to make sure that the VeriSeq NIPT Solution v2 is isolated from other computers and communication systems not required to operate the system. During normal operation, all internet access to the device should be blocked.

Network intrusion detection and prevention systems should be in operation at the perimeter of site networks to prevent external attacks.

Segmentation of Networks

The VeriSeq NIPT Solution v2 should be on a network segment that restricts communication to just the components required for operation. Consider using a virtual local area network (VLAN) and associated access control lists (ACLs).

On occasion, a remote technical support connection is required. Construct your network infrastructure to allow temporary external access to be enabled and then disabled before normal operation commences.

Secure Network Passwords

In the Assay Software, network passwords for the VeriSeq NIPT Microlab STAR API and the sequencer folder automatically require updating by system administrators. Only administrators should configure these passwords, and they should make sure these passwords use sufficient complexity. Do not share these passwords with general users.

Use of Library Prep Instrument Domain Users

Use domain level users when selecting users for the VeriSeq NIPT Microlab STAR control computer roles.

Physical Access Controls

The VeriSeq Onsite Server v2 stores recent raw sequencing run data, analysis and report files, and a database of all batches and associated results. The disk in the server is not encrypted, and sites deploying the solution must strictly limit and monitor personnel access to the server to physically secure this data.

Follow these recommendations as appropriate for your site.

- ▶ Install system components in labs and server rooms with physical access controls to prevent unauthorized staff from gaining access to computers and interfaces.
- ▶ Put in place operating procedures to review the VeriSeq NIPT Solution v2 staff roles and remove access to system components where appropriate.
- ▶ Make sure that credentials for staff who leave the organization are quickly disabled.

Email Server

Configure the VeriSeq NIPT Solution v2 to send system alerts to users via an email server external to the system. Follow these security recommendations as appropriate for this server.

- ▶ Scan the email server regularly for malware.
- ▶ Update the server regularly for security vulnerabilities.
- ▶ Configure the server to communicate with Transport Layer Security (TLS).

Network Attached Storage (NAS)

The VeriSeq NIPT Solution v2 can be configured to use a third party external NAS for storage of sequencing run data. Follow these recommendations as appropriate.

- ▶ Implement the NAS manufacturer's security guidance.
- ▶ Configure the NAS to use SMB encryption.

Encrypted Backups

The system administrator should consider enabling encrypted database backups. If unencrypted backups are utilized, store the files securely to prevent unauthorized access.

Illumina Proactive

If you use a NextSeq 550Dx, you can connect to IlluminaProactive, a remote instrument support service. Before enabling this service, customers should review the *IlluminaProactive Data Security Sheet* to confirm that the security and privacy measures meet the standards of their institution.

LIMS

The VeriSeq NIPT Solution v2 allows an external LIMS system to connect to the VeriSeq Onsite Server v2 via shared folders and an API. The computer hosting the LIMS should have access controls implemented, regular malware scans, and an operating system with security patches applied.

Make sure that the LIMS server is running a version of SMB for mounting shared folders that supports encryption.

Antivirus Software

An antivirus software of your choice is highly recommended on the VeriSeq NIPT Microlab STAR control computer to protect against viruses. It is recommended that you perform an antivirus scan after the installation of the VeriSeq NIPT Microlab STAR.

To avoid data loss or interruptions, configure the antivirus software as follows:

- ▶ Set for manual scans. Do not allow automatic scans.
- ▶ Perform the manual scans only when the instrument is not in use.
- ▶ Set updates to download without user authorization, but not install.
- ▶ Do not make updates during instrument or server operation. Make updates only when it is safe to reboot the control computer.
- ▶ Do not reboot the computer automatically upon update.
- ▶ Exclude the application directory and data drives from any real-time file system protection. Apply this setting to the C:\Illumina and Z:\ilmn directories.
- ▶ Turn off Windows Defender. This Windows product can affect the operating system resources used by Illumina software.

Windows Updates

To ensure system reliability, the VeriSeq NIPT Microlab STAR control computer is installed with Windows automatic updates disabled. Illumina does not recommend enabling Windows automatic updates. Instead, to secure your data, it is recommended that all Windows critical security updates are applied manually to the VeriSeq NIPT Microlab STAR control computer on a regular schedule. The instrument must be idle when updates are applied as some updates require a full system reboot. General updates can put the system operating environment at risk and are not supported.

If security updates are not possible, alternatives to turning on Windows Update include:

- ▶ More robust firewalling and network isolation (virtual LAN).
- ▶ Local USB storage.
- ▶ User behavior and management to avoid improper use of the control computer and ensure the appropriate permission-based controls.

For more information on Windows Update alternatives, contact Illumina Technical Support.

Third-party Software

Illumina supports only the software provided at installation.

Chrome, Java, Box, and other third-party software are untested and can interfere with performance and security. For example, RoboCopy interrupts streaming performed by the control software suite. The interruption can cause corrupt and missing sequencing data.

User Behavior

The instrument control computer and server are designed to perform the VeriSeq NIPT Solution v2. Do not consider them general-purpose computers. For quality and security reasons, do not use them for web browsing, checking email, reviewing documents, or other unnecessary activity. These activities can result in degraded performance or loss of data.

Product Certifications and Compliance

The VeriSeq Onsite Server v2 is certified to the following standards.

Nation	Certification
Argentina	IRAM
Australia	RCM
China	CCC: GB4943.1-2011, GB9254-2008, GB17625.1-2003
European Union	CE; RoHS
India	BIS
Korea	KCC: Clause 3, Article 58-2 of Radio Waves Act
Mexico	NOM
Russia	EAC
South Africa	SABS
Taiwan	BSMI: CNS14336-1, CNS13438
United States	FCC Class A; UL 60950

User-Supplied Consumables and Equipment

The following user-supplied consumables and equipment are used for sequencing, maintenance, and troubleshooting.

Equipment Required, Not Provided

Equipment	Supplier
20 µl single-channel pipettes	General lab supplier
200 µl single-channel pipettes	General lab supplier
1000 µl single-channel pipettes	General lab supplier
Pipette Aid	General lab supplier
Refrigerator, 2°C to 8°C	General lab supplier
Freezer, -25°C to -15°C	General lab supplier
Freezer, -85°C to -65°C	General lab supplier
Microcentrifuge	General lab supplier
Vortexer	General lab supplier
Centrifuge and rotor assembly for blood collection tubes	

Recommended:

- Allegra X12R Series Centrifuge, 1600 g
- Allegra Centrifuge GH-3.8 Rotor with buckets
- Allegra Centrifuge Bucket Covers, set of two
- Allegra Centrifuge Adapter Assembly, 16 mm, set of four
- Beckman Coulter, item # 392304 (230 V)
- Beckman Coulter, item # 369704
- Beckman Coulter, item # 392805
- Beckman Coulter, item # 359150

Equipment	Supplier
Equivalent: <ul style="list-style-type: none"> • Refrigerated centrifuge capable of 1600 × g with no-brake option • Swinging bucket rotor with buckets • Bucket inserts, 24, 48, or 96 tube capacity, 76 mm minimum depth • Insert adapters to support 16 × 100 mm blood collection tubes 	General lab supplier
Centrifuge and rotor assembly for microplates	
Recommended: <ul style="list-style-type: none"> • Sorvall Legend XTR Centrifuge • HIGHPlate 6000 Microplate Rotor • One of the following support bases for microplates: <ul style="list-style-type: none"> • MicroAmp 96-Well Support Base • 96-Well PCR Plate Carrier 	<ul style="list-style-type: none"> • Thermo Fisher Scientific, catalog # 75004521 (120 V) or catalog # 75004520 (230 V) • Thermo Fisher Scientific, catalog # 75003606 • Thermo Fisher Scientific, catalog # 4379590 • Thermo Fisher Scientific, catalog # AB-0563/1000
Equivalent: <ul style="list-style-type: none"> • Centrifuge capable of 5600 × g • Swinging plate rotor with 96-well plate carriers, 76.5 mm minimum depth • Support base for microplates 	General lab supplier
One of the following microplate readers (fluorometer) with SoftMax Pro v6.2.2 or higher: <ul style="list-style-type: none"> • Gemini XPS • SpectraMax M2 	<ul style="list-style-type: none"> • Molecular Devices, part # XPS • Molecular Devices, part # M2
SpectraMax High-Speed USB, Serial Adapter	Molecular Devices, part # 9000-0938
Thermal cycler with the following specifications: <ul style="list-style-type: none"> • Heated lid • 4°C to 98°C temperature range • ±2°C temperature accuracy • 2°C per second minimum ramp rate • Compatible with Twin.tec PCR Plate 96-well, full skirt 	General lab supplier

Optional Equipment, Not Provided

Equipment	Supplier
Pluggo Decapper System	LGP Consulting, part # 4600 4450
SpectraMax SpectraTest FL1 fluorescence validation plate	Molecular Devices, part # 0200-5060
Tube Revolver/Rotator, 15 ml tubes, 40 rpm, 100–240 V	Thermo Scientific, catalog # 88881001 (US) or catalog # 88881002 (EU)

Consumables Required, Not Provided

Consumable	Supplier	Quantity Required for PQ Run (48-sample batch)
1000 µl Conductive Non-Sterile Filter Tips	Hamilton, part # 235905	339
300 µl Conductive Non-Sterile Filter Tips	Hamilton, part # 235903	637

Consumable	Supplier	Quantity Required for PQ Run (48-sample batch)
50 µl Conductive Non-Sterile Filter Tips	Hamilton, part # 235948	455
<p>Deep-well reservoir with the following specifications:</p> <ul style="list-style-type: none"> • SLAS 1-2004 microplate format with 96 pyramidal or conical bottom wells and a 240 ml minimum capacity. • Polypropylene with preference for low DNA binding for all sample contact surfaces. • Internal dimensions (liquid level) are compatible with automated aspiration and dispensing steps of VeriSeq NIPT Microlab STAR. • Height dimensions are compatible with automated movements of VeriSeq NIPT Microlab STAR. 	<p>General Lab Supplier</p> <p>Compatible reservoirs:</p> <ul style="list-style-type: none"> • Corning Axygen, product # RES-SW96-HP-SI • Agilent, product # 201246-100 	6
<p>Reagent tub with the following specifications:</p> <ul style="list-style-type: none"> • Tub that fits securely into the carrier of the VeriSeq NIPT Microlab STAR with tapered bottom and a 20 ml minimum capacity. • Polypropylene that is free from RNase-/DNase. • Internal dimensions (liquid level) are compatible with automated aspiration and dispensing steps of VeriSeq NIPT Microlab STAR. • Height dimensions are compatible with automated movements of VeriSeq NIPT Microlab STAR. 	<p>General Lab Supplier</p> <p>Compatible tubs:</p> <ul style="list-style-type: none"> • Roche, product # 03004058001 	11
<p>Deep-well plates with the following specifications:</p> <ul style="list-style-type: none"> • SLAS 1-2004, 3-2004, and 4-2004 microplate format with 96 pyramidal or conical bottom wells and a 2 ml minimum well capacity. • Polypropylene with preference for low DNA binding for all sample contact surfaces and torque-resistant frame. • Well dimensions (liquid level) are compatible with automated aspiration and dispensing steps of VeriSeq NIPT Microlab STAR. • Plate height dimensions are compatible with automated movements of VeriSeq NIPT Microlab STAR. 	<p>General Lab Supplier</p> <p>Compatible plates:</p> <ul style="list-style-type: none"> • Eppendorf, part # 0030505301 • Eppendorf, part # 30502302 • USA Scientific, part # 1896-2000 	3
<p>384-well plate with the following specifications:</p> <ul style="list-style-type: none"> • Microplate with 384 wells, optimized for low-volumes, with a 50 µl minimum well capacity. • Polystyrene with light-blocking and low DNA binding for all sample contact surfaces. • Well dimensions (liquid level) are compatible with automated aspiration and dispensing steps of VeriSeq NIPT Microlab STAR. • Plate height dimensions are compatible with automated movements of VeriSeq NIPT Microlab STAR. 	<p>General Lab Supplier</p> <p>Compatible plates:</p> <ul style="list-style-type: none"> • Corning, product # 3820 	1
<p>96-well plate with the following specifications:</p> <ul style="list-style-type: none"> • Microplate with a torque-resistant frame and 96 wells with tapered bottoms, raised rims, and a 150 µl minimum well capacity. • Polypropylene that is free from RNase-/DNase with low DNA binding for all sample contact surfaces. • Well dimensions (liquid level) are compatible with automated aspiration and dispensing steps of VeriSeq NIPT Microlab STAR. • Plate height dimensions are compatible with automated movements of VeriSeq NIPT Microlab STAR. 	<p>General Lab Supplier</p> <p>Compatible plates:</p> <ul style="list-style-type: none"> • Eppendorf, part # 0030129512 • Eppendorf, part # 30129580 • Eppendorf, part # 30129598 • Eppendorf, part # 30129660 • Eppendorf, part # 30129679 • BioRad, part # HSP9601 	12

Consumable	Supplier	Quantity Required for PQ Run (48-sample batch)
One of the following seals: <ul style="list-style-type: none"> • Microseal 'F' Foil • Foil seals 	<ul style="list-style-type: none"> • Bio-Rad, catalog # MSF1001 • Beckman Coulter, item # 538619 	-
DNase/RNase-free water	General lab supplier	-
Ethanol, 100% (200 proof), molecular biology grade*	General lab supplier	-
Cell-Free DNA BCT CE	Streck, catalog # 218997	48
Push Caps	Sarstedt, order # 65.802	48
2 ml Screw-cap tubes	General lab supplier	-
20 µl filter tips for 20 µl pipettor	General lab supplier	-
200 µl filter tips for 200 µl pipettor	General lab supplier	-
1000 µl filter tips for 1000 µl pipettor	General lab supplier	-
25 ml Serological Pipettes	General lab supplier	-
10 ml Serological Pipettes	General lab supplier	-
Recommended: <ul style="list-style-type: none"> • Deconex[®] SOLARSEPT • Deconex[®] 61 DR 	Borer Chemie AG	-
Equivalent: <ul style="list-style-type: none"> • An alcohol-based rapid disinfectant spray • A solution of disinfecting detergent 	General lab supplier	-

* Non-molecular biology grade ethanol can negatively impact performance of the assay.

Optional Consumables, Not Provided

Consumable	Supplier
Tube, screw cap, 10 ml (for control samples only)	Sarstedt, order # 60.551
Tube, screw cap, 50 ml	General lab supplier
Dulbecco's Phosphate-Buffered Saline (DPBS) for no template control (NTC)	General lab supplier

Revision History

Document	Date	Description of Change
Document # 1000000076975 v06	August 2021	Updated EU Authorized Representative address.
Document # 1000000076975 v05	April 2021	Added Alternative Plasma Storage Requirements section.
Document # 1000000076975 v04	March 2021	Added Network Ports section to Network Considerations. Updated Plasma Storage information for Artificial Plasma. Updated Consumables list for new labware specifications. Updated Windows Updates settings instructions to make clear the recommendation to manually update.
Document # 1000000076975 v03	September 2020	Updated Security Considerations section with new Security Controls and Security Recommendations sections. Updated Environmental Conditions to clarify purpose of temperature specifications. Updated description of NextSeq 550Dx Site Prep Guide to note the inclusion of security details. Updated language in Remote Access Requirement to indicate components should be able to be available to an outside network. Added recommendation to perform an antivirus scan of ML STAR computer after installation.
Document # 1000000076975 v02	April 2020	Updated EU Authorized Representative address. Updated Australian Sponsor address.
Document # 1000000076975 v01	May 2019	Updated Security Considerations section from recommending an isolated LAN to recommending a LAN protected by a firewall. Updated Antivirus Software section to recommend the installation of an antivirus and clarify usage parameters. Added information on Windows Update, Third-Party Software, and User Behavior to the Security Considerations section. Added quantity of consumables required for PQ run.
Document # 1000000076975 v00	March 2019	Initial release.

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Safety data sheets (SDSs)—Available on the Illumina website at support.illumina.com/sds.html.

Product documentation—Available for download from support.illumina.com.



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