

iScan™ Dx Instrument

Rapid, accurate, IVDR-compliant imaging of Illumina BeadChips

- Accurate, reproducible data performance required for IVDR-compliance in diagnostic laboratories
- Innovative, high-resolution scanner offers submicron BeadChip resolution
- Flexible configuration lets labs select array formats, applications, and automation options to meet their diagnostic needs



High-resolution BeadChip scanner for diagnostic assays

Microarrays offer diagnostic labs an economic solution for fast and accurate genotyping, copy number variation (CNV) analysis, and DNA methylation analysis. The iScanDx Instrument is a high-resolution imager for Illumina BeadChips that complies with European Union (EU), *In Vitro* Diagnostics Regulation (IVDR) 2017/746 (Figure 1). As the scanning component of the Infinium™ BeadChip workflow, the iScanDx Instrument generates and detects fluorescent intensities associated with individual bead types on the array, performs data aggregation, and outputs the aggregated intensities for each bead type for analysis. The iScanDx Instrument is designed for easy incorporation into IVDR-compliant workflows.

Exceptional imaging performance

The iScanDx Instrument uses high-performance lasers, optics, and detection systems to offer submicron resolution and high-throughput analysis. The innovative imaging system produces high signal-to-noise ratio, high sensitivity, low limit of detection, and a broad dynamic range for exceptional data quality for use in a wide range of diagnostic applications.

For increased throughput, the iScanDx Instrument is compatible with the AutoLoader 2.x, which reduces hands-on time and enables 24-hour-a-day scanning. The modular components create a tunable system that can be configured to meet the level throughput needed for diagnostic labs. The result is extremely rapid scan times (Table 1) without sacrificing data quality or reproducibility.

Table 1: The iScanDx Instrument performance at a glance^a

Feature	Description
Average scan time per sample	1.25 min
Average scan time per BeadChip ^b	~30 min
Maximum weekly throughput	5760 samples

a. Approximate values, scan times, and maximum throughput may vary depending on laboratory and system configurations
 b. Scan time estimate is for 24- and 48-sample BeadChips with 1 μm beads



Figure 1: The iScanDx Instrument—A fully automated platform compatible with autoloading robotics and laboratory information management systems that offers a robust, high-throughput, IVDR-compliant scanning solution for Illumina BeadChips.

Automation compatible

For labs with throughput requirements that exceed the capacity of manual operation, Illumina offers optional equipment and software to automate the iScanDx Instrument. This increases throughput and supports 24 hour per day scanning.

For walkaway BeadChip loading and scanning with the iScanDx Instrument, the AutoLoader 2.x maximizes scanner use by providing continuous, unattended operation and the ability to load one or two scanners at a time. This enables processing of thousands of samples per week, resulting in improved assay efficiency while decreasing overall cost. The AutoLoader 2.x has a minimal footprint, so that even a dual-scanner configuration easily fits on a typical lab bench (Figure 2).

Intuitive workflow and sample management

Accurate sample information, workflow enforcement, and data tracking are ensured with an optional integrated Illumina Laboratory Information Management System (LIMS). Illumina LIMS features an easy-to-use custom interface, positive sample tracking (posID), and tools to manage entire projects. Integrated tools support project

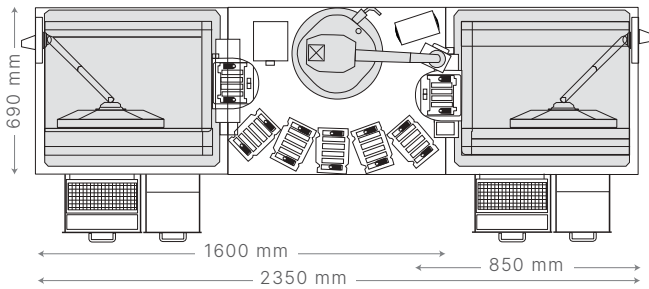


Figure 2: Example dual scanner benchtop configuration with an AutoLoader 2.x—Two iScanDx Instruments with an AutoLoader 2.x can easily fit on a typical lab bench. System height excluding monitor is 510 mm. Other configurations are also possible.

management tasks such as managing concurrent projects, tracking progress, viewing queues, and assigning samples to a project, principal investigator, or institution. A fully automated LIMS-controlled iScanDx Instrument reduces the burden on support staff and minimizes costly errors when processing hundreds or thousands of samples per day.

Reproducibility of the iScanDx Instrument scans

The instrument software evaluates each run against quality control metrics. The scan metrics for each BeadChip display in the Scan Metrics table at the top of the Review screen, which is used to review intensity values in the red

and green channels, and to check focus and registration metrics for each BeadChip stripe. The table can also be used to determine whether intensity data was normalized for each scanned BeadChip section.

The following BeadChip types were used to evaluate the intra-instrument scan intensity repeatability:

- BeadChip with 1.0 μm beads and 48 samples
- BeadChip with 1.2 μm beads and 8 samples
- BeadChip with 1.2 μm beads and 24 samples

Four test BeadChips were each scanned four times on the same iScanDx Instrument (with four iScanDx Instruments used for this study) to render raw IDAT files. These files contain the intensity values for each BeadType (probe type). The final raw data sets contain 64 IDAT files from 16 test BeadChips for each BeadChip type.

The per-BeadType intensity values for each sample were bleaching-corrected across four scans and the per-BeadType coefficient of variation (CV) values were calculated for the bleaching-corrected intensities. Next, the sample-wise scan intensity CV was represented by the median of the per-BeadType CV values in that sample. The overall intra-instrument scan intensity repeatability for each type of BeadChip was calculated by averaging the sample-wise scan intensity CV values from all of the samples in 16 test BeadChips. The scan repeatability for the red and green channels were analyzed separately ([Table 2](#)).

Table 2: Intra-instrument scan intensity repeatability for the iScanDx Instrument

BeadChip type	Channel	CV min (%)	CV max (%)	CV mean (%)	CV median (%)	No. of samples
1.0 μm beads (48 samples)	Green	1.9	2.7	2.1	2.1	768
	Red	2.2	3.1	2.5	2.5	
1.2 μm beads (8 samples)	Green	1.6	2.3	2.0	2.0	128
	Red	1.6	2.4	2.1	2.1	
1.2 μm beads (24 samples)	Green	1.7	7.3	2.2	2.2	357
	Red	2.0	7.2	2.4	2.4	

Workstation and software

The iScanDx Instrument includes an instrument control computer that controls all aspects of the scanner. This automated system provides laser control, precision mechanics control (including focus motor), detection of excitation signals, image registration, image extraction, and data output. The iScanDx Instrument IDAT output file format is compatible with [Illumina Connected Analytics](#) for downstream analysis.

Installation and support

Comprehensive installation and training are included with every scanner purchase. Illumina Field Application Scientists perform extensive onsite training for the purchased array application following installation by a Field Service Engineer. Illumina Technical Support Scientists provide ongoing technical support.

Warranty and service

The Illumina service organization is committed to excellence, with a strong drive to ensure customer satisfaction. A comprehensive 12-month warranty that covers the scanner, hardware, and installed option packages is included with each system purchase. The standard warranty includes:

- Emergency on-site service calls during normal business hours
- Software upgrades for the applications purchased
- Parts, labor, and consumables for system maintenance or repairs
- Phone support and assistance

Flexible extended warranty options make sure that every system continues to operate at optimum performance.

Summary

Diagnostic labs require solutions that help them comply with regulatory and healthcare needs. The IVDR-compliant iScanDx Instrument provides high-quality microarray data generation, offering an accessible entry point for labs into high-throughput diagnostic studies. Available automation options provide the flexibility needed to match sample throughput in the lab. The system includes access to dedicated, expert-level support, ensuring that users get the most out of the iScanDx Instrument.

Learn more

[iScanDx Instrument](#)

iScanDx Instrument specifications

Parameter	Specification
Pixel resolution	0.53 μ m
Laser excitation	532 nm and 658 nm dual-laser excitation
Image file output	JPG data file output
System dimensions (W x H x D)	52 cm x 46 cm x 66 cm
Weight	70 kg (154 lb)
Site requirements	
Power	Dedicated circuit, 100–120/200–240 VAC, 50/60 Hz, 360 VA, 15A for 110 V Reader/12A for 220 V Reader
Environmental conditions	Up to 2000 m elevation
	15–30°C
	20–80% relative humidity
	Overvoltage II installation category

Ordering information

Product	Catalog no.
iScanDx Instrument	20081314

Intended use

The iScanDx Instrument is an *in vitro* diagnostic (IVD) device intended to be used by trained personnel in a professional laboratory environment for automated and quantitative detection of fluorescent signal intensities from Illumina Infinium BeadChips (bead-based microarrays) containing nucleic acid probes for human genomic variants. The resulting fluorescent intensity signals are intended for use with user-defined IVD applications.



1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com

© 2024 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, see www.illumina.com/company/legal.html.
M-GL-01626 v2.0