

Benchmark ULTRA System Description



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Benchmark ULTRA - Patient Centric Pathology

System Overview

- Flexible Automation for Multi-Modal (Random and Continuous Access) Slide Preparation System
- Accurate and fast results for a better Pathology service
- Highly convenient system frees human resources while enhancing quality and streamlining workflow

The Benchmark ULTRA system is the next generation in IHC/ISH staining instrumentation. Using 30 individual slide processors, its patient centric workflow integrates **Multi-Modal Access** for real time STAT (urgent requests) processing. Turnaround times are significantly reduced, resulting in faster reporting of patient results and enabling the next generation in lean laboratory workflow.

Operation

The BenchMark ULTRA system is the first to perform simultaneous IHC and ISH testing on a single Multi-Modal (random and continuous access) platform. Multi-parameter testing such as dual and triple stains may be performed independently of other slides, allowing for rapid results. The BenchMark ULTRA system is optimized for a full range of prediluted and concentrated immunohistochemical assays, as well as a variety of in situ hybridization tests, simplifying complex molecular testing into a routine automated procedure. The BenchMark ULTRA system can be linked to your Laboratory Information System to manage information from a single computer for increased workflow efficiency and patient safety.

Interface

The BenchMark ULTRA system has a new graphical user interface (GUI) which allows continuous monitoring of slide and reagent status. This GUI provides a laboratory workflow tool which combines efficient, one-click navigation with intuitive, easy-to-use graphics. Continuous status updates, customizable reports, and flexible set-up give your lab the ability to optimize your user interface to best meet your needs.

Advantages

Multi-Modal access

- Any Test, Any Technology, Any time: Multi-Modal (continuous and random) access to 30 individual staining chambers, so you can add and remove single slides when needed, without interrupting workflow.
- Faster turnaround times: enables continuous processing and runs up to 30% faster than previous instrumentation generations.
- STAT capable: STAT samples can be added at any time for expedited patient diagnosis.
- Batch free: add samples when you want to so you don't have to plan your day around batch cut off times. BenchMark ULTRA fits to your lab organization and workflow.
- Continuous information: intuitive, new software interface lets you see exactly when patient samples will be available.

- Visual laboratory management: ULTRA's new intuitive software interface lets you see the exact status of patient samples.

Superior workflow efficiency

- Case centric workflow: Process the entire patient or pathologist case load simultaneously to eliminate sorting.
- ISH and IHC: With continuous and random access, simultaneous ISH and IHC testing can realistically be completed the same day.
- Multiplexing: New flexible software enables double and triple IHC/ISH staining as well as combination gene and protein staining.
- New molecular tests: New in situ procedures enable next generation molecular tissue testing in your lab today.
- LIS and more: LIS connectivity for automatic information sharing.

Advanced System Concept

- Seamless integration of instrumentation, reagents, software and applications optimized into a solution for each laboratory needs.
- Reagents carriers designed for performance and convenient error free operation
- Flexible software easy touch-button operation allowing control and management via
- Excellent consulting, training and after sales services provided by skilled well trained professionals

The evolution of the Benchmark System Series

Benchmark ULTRA is an evolution of the proven Benchmark XT; uses the same technologies that made Ventana famous for quality in Histology but differs in some functional aspects such as:

BenchMark XT, proven reliability:

- Walk away automation (baking through staining)
- Batch of 30 slides with random access for enhanced throughput and workflow
- Simultaneous processing of IHC and ISH independent of each other
- Molecular assay (ISH) capable
- Ventana VANTAGE™/LIS connectivity
- Proven high-quality reagent systems

BenchMark ULTRA, all of the features of BenchMark XT plus:

- Multi-Modal access utilizing 30 independent staining drawers
- Faster turnaround time for maximum slide throughput and workflow efficiency
- Flexible molecular assays for greater adaptability
- Intra-run bulk reagent handling
- Enhanced user interface
- Ability to perform titration tests simultaneously with fully automated patient slides

Feature comparison

	Benchmark ULTRA	Benchmark XT
Simultaneous IHC/ISH	Yes	Yes
Continuous Access	Yes	
Random Access	Yes	Yes
STAT Processing	Yes	
BTS® Technology	Yes	Yes
One-Touch Dual and Triple Staining	Yes	Yes
Simultaneous Titration and Automated Slide Processing	Yes	
LIS/ VANTAGE™ Ready	Yes	Yes

Tech. spec. - 1.2

Distinctive Benchmark System Series features

- Complete Multi-Modal automation of IHC/ISH assays frees techs time for sorting slides and reduces patient case turn-around-time
- Patient centric processing provides all tests requested to the pathologist in a single plate
- Automation of the most advanced breast panel assays including the unique SISH assays.
- 30 independent processing units, no need to sort slides according with protocols
- **Fast turnaround time of 2,5 hours per slide (average)** Tech. spec. 1.8
- Disposable dispensers without rinsed probes for no-contamination reagent dispensing
- Independent temperature control (and other protocol parameters) for each processing unit
- Unlimited combination of assays in any of the 30 processing units
- **Full LIS integration allows test download, label printing and results upload** Tech. spec. 1.16
- Range of different vial sizes to optimize convenience and avoid hand-on work and time
- Large bulk ancillary reagents enough for at least 90 slides (3 runs) replaceable on-the-fly for continuous operation
- Unique choice of detection systems through the largest range of secondary antibodies and substrates including biotin free antibodies (multimer)
- Alcohol free dewaxing.

Benchmark System Series technologies explained**BTS™**

Redefine Your Time through the labor savings by automating baking through staining:

- Baking
- Deparaffinization (xylene free)
- Cell Conditioning

- Staining
Quality through Consistency and Reproducibility, Convenience and Productivity.

BenchMark™ System Series Multi-technology

The BenchMark™ System Series is the world's first fully integrated histology solution offering multiple technologies (IHC, ISH and FISH), including the easy to read and interpret SISH assays. In fact IHC and ISH slides may be processed together during the same run – This feature allows, for example, any late arriving IHC samples to be processed and run overnight with the ISH slides thus making them available for the pathologist the following morning.

Fast Track™ Reagent Registration

Provides registration of all reagent information into the computer with a touch of the wand to the button on the reagent package. This button is embedded with information that will ensure tracking integrity of the reagents. This information includes: Reagent Name (and clone if applicable), Dating and Lot Number

Reports

Flexibility in reporting results. The system will generate several types of reports such as run reports, protocol reports, inventory reports and quality control reports.

Ebar™ (Electronic Barcode Labeling System).

The Ebar™ generates a barcode that is placed on each slide and ultimately tracked throughout the testing process from baking through staining.

System Control Center

The BenchMark ULTRA system has a new graphical user interface (GUI) which allows continuous monitoring of slide and reagent status. This GUI provides a laboratory workflow tool which combines efficient, one-click navigation with intuitive, easy-to-use graphics. Continuous status updates, customizable reports, and flexible set-up give your lab the ability to optimize your user interface to best meet your needs.

- Connect up to 8 Ventana systems
- Software features
 - Delayed start
 - Maintenance minder
 - When to perform Maintenance
 - Backup start of each run
 - Warnings on Backup
 - Barcode
 - Patient Info

Reagent Carousel

- 35 Reagent Dispenser Capacity
- Reagents are pre-packaged ready to be placed on the instrument
- Enhanced quality control through

The Fast Track™ feature

- Lot number, Expiration date, Volumes - All pertinent information for that particular reagent is downloaded into and tracked by the system
- Dispensers are barcode labeled to allow the instrument to easily identify the type of reagent and its particular position on the instrument – this feature allows provides the user flexibility and ease of loading.
- No need to map the reagents onto the system
 - Easy to load in five (5) “Wedge” like sections each holding seven (7) reagent dispensers
 - Storage cap – provides easy overnight storage of reagent “Wedge”
 - Grooves direct fluid away from the slides

ThermoFlex™ Slide Tray

The Thermoflex™ Slide Tray can accommodate up to thirty (30) slides. Within this slide tray area there are several features, which make the BenchMark system unique in both its design and approach to automation. These features are:

- The Dual Rinse which, insures proper rinsing of tissue and provides flexible application of EZ Prep, SSC and Reaction Buffer
 - The Jet Wash is designed to accommodate the removal of aqueous solutions to maximize probe concentrations through the dispensing of EZ Prep, SSC and Reaction Buffer for *in situ* hybridization.
 - The Multispense provides precision application of CC1, CC2, EZ Prep, SSC and Reaction Buffer.
 - The LCS Dispenser dispenses our patented Liquid Coverslip, which eliminates tissue drying artifacts. This dispenser is designed to insure total slide coverage with minimal reagent – 100 uL per slide.
 - The Barcode Blowoff
 - Five (5) patented Liquid Vortex Mixers, each designed to insure proper mixing of reagents to obtain complete tissue coverage. In addition , assay kinetics is optimized and run-to-run variability is eliminated.
 - The ThermoPads™ are precise individually controlled slide heaters. Each of the thirty (30) slide positions is individually heated through conduction up to 95 degrees centigrade within four (4) minutes and cooled back down to ambient temperatures within seven (7) minutes. Since each slide is individually heated, various specimen types which may be run simultaneously.
- 30 slide capacity, 30 individual protocols processed simultaneously and independently
 - IHC / ISH slides may be processed simultaneously in the same run
 - ThermoFlex™ Platform
 - 30 individual ThermoPads™
 - ThermoPads™ provide an individually controlled heating unit that provides a direct application of heat onto the slides which maximizes assay kinetics.
 - ThermoPads™ are the key to BTS™ technology providing exceptional automated baking through staining performance.

Dual Rinse

- Ensures proper rinsing of tissue
- Flexible application of fluids (optimizes runs)

Jet Wash (in situ Hybridization)

- Removes aqueous solutions to maximize probe concentrations
- Reduces slide volumes

Multi-Spense Nozzle

- Applies EZ-Prep Solution (for deparaffinization) and Cell Conditioning Solutions (for antigen unmasking)
- Designed to provide precision dilutions
- Quality through Consistency and Reproducibility

Reagent Delivery - Hemotoxylin

- Dispense of Reagent (From Dispenser)

Liquid Coverslip (LCS)

- Patented Liquid Cover-slip ensures total slide coverage - Delivers quality results
- Minimizes overall reagent usage - Reduces reagent usage to 100ul per slide
- Maintains temperature reaction chamber (without walls) on the slide
- Ensures tissue integrity - Eliminates tissue drying artifacts

Barcode Blow-off

- Assures accurate reading of the barcode labels by the system

Vortex Mix

- Patented Liquid Vortex Mixers
- Prevents layering effect
- Provide uniform distribution of reagent and complete slide coverage
- Optimizes kinetics
- Eliminates run-to-run variability
- Three (3) outer and Two (2) inner Vortex Mixers

Automated Fluidics Module

The **On-Board Bulk Fluids** provide the necessary reagents and buffers to perform all of your IHC, ISH and FISH testing on the BenchMark system series. There are seven (8) bulk fluid positions within the staining module. The volumes contained within these bulk fluids will provide up to three (3) runs before requiring user intervention to re-fill – that's enough fluid to process ninety (90) slides! These bulk reagents are:

- 1) EZ Prep insures consistency and reproducibility during the automated baking and dewax process
 - 2) Ventana's Patented Liquid Coverslip (LCS) prevents tissue drying and insures full slide coverage resulting in consistent stain quality.
 - 3) Sodium Chloride Sodium Citrate (SSC) is used only for *in situ* hybridization testing to prevent non-specific probe binding.
 - 4) Reaction Buffer is used to clean slides and optimize test performance through dilutions.
 - 5) Cell Conditioning 1 (CC1) is used for antigen unmasking
 - 6) Cell Conditioning 2 (CC2) is used only for *in situ* hybridization
 - 7) Optional Position designed for future applications
- Optimized buffers provide quality through consistent and reproducible staining results
 - Includes eight (8) bulk reagent bottles
 - Enough on-board fluids to process ninety (90) slides (three (3) full runs)
 - Each bottle is designed with the "No-Drip" feature (quick disconnect)
 - Each bottle is labeled, color coded and numbered for easy identification
 - Bulk fluids are provided from Ventana labeled, color coded and numbered for easy identification
 - Bulk carboy's are provided with labels color coded and numbered
 - Individual fluids are monitored by the system for sufficient quantity prior to the start of each run
 - The AFM includes level sensing technology that
 - Ensures the user can always complete a 30 slide run
 - Guarantees that the instrument will never perform an assay without fluids
 - Alerts the user via the control center of fluidics status
 - Bulk fluids are provided from Ventana with the Fast Track™ feature
 - Providing an additional level of quality control
 - Lot number, Expiration date and Quantity
 - Provided in either predilutes or concentrates
 - Predilutes are directly added into the corresponding AFM reagent containers. These containers are both numbered and color coded to provide easy refill applications.
 - Concentrates are diluted in a 20 liter container (provided) and added into the corresponding AFM reagent containers. These containers are both numbered and color coded to provide easy refill applications.

Waste Module

The Integrated Waste Management System is a self-contained waste area consisting of two (2) – 20 Liter containers. The fluid level of each container is monitored by the System Control Center to prevent waste overflow. In addition each container is on wheels to facilitate easy removal of waste.

- Consists of Two (2) independent waste bottles
- Each with its own individual level sensor
- Instrument will provide warning to empty waste bottles
- The 2 waste level sensors alert the operator when to empty the waste preventing any unnecessary spills.
- Each bottle designed with "No-Drip" waste cap

Primary antibodies available for Benchmark System Series

Detection systems available for Benchmark System Series

ISH probes available for Benchmark System Series

BenchMark® ULTRA Specifications

General Instrument Characteristics	
Capability Automated	IHC, ISH, SISH, FISH, FITC, Multi-parameter Staining (Dual, Triple, Qdot®), Baking, Deparaffinization, Cell Conditioning and Staining
Slide Carousel	1 – 30 slides with independent temperature control for each position
Reagent Carousel	35 reagent positions
Slides	25 x 75 mm or 26 x 76 mm
Modularity	One to eight staining systems may be controlled from one personal computer system
Water	Quality NCCLS Type I water or equivalent
Bulk Reagents	Up to 7 different bulk reagents in 3 to 6 liter on-board containers
Configuration	Free Standing
Certifications	CSA and EMC compliant
Environmental Requirements	
BTU / Hour	Output 400 BTU/Hr idle, 1000 BTU/Hr running
Room Temperature	20°C to 32°C (68°F to 90°F)
Humidity	10% to 90%, non-condensing
Location	Flat, level surface. No direct sunlight or drafts. Remove from direct source of heat and moisture.
Physical Characteristics	
Size — closed (Width x Depth x Height)	111.76 x 84.07 x 158.50 cm
Size (w/rear cover removed)	111.76 x 71.88 x 158.50 cm
Weight	294.8 kg
Clearances	38.1 cm/10.2 cm/15.2 cm (Top/Sides/Rear)
Temperature Control	
Slide Temperature Range	37 °C to 100°C ± 2°C
Electrical Specifications (Europe)	
Voltage	230 VAC ± 10%
Current	4 amps
Frequency	50 Hz