Biomek i7 Dual Hybrid Workstation Automated Cytiva™ Sera-Xtracta Virus/Pathogen Kit

BECKMAN COULTER
Life Sciences

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Disclaimer

Biomek Automated Workstations are not intended or validated for use in the diagnosis of disease or other conditions.

The Cytiva™ Sera-Xtracta Virus/Pathogen kit is intended for research use only. It is not intended for use in any clinical or *in vitro* procedures for diagnostic purposes. Do not use internally or externally in humans or animals.

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Cytiva™ Sera-Xtracta Virus/Pathogen Kit

- The Cytiva™ Sera-Xtracta Virus/Pathogen kit uses bead-based technology to isolate viral/bacterial nucleic acid (RNA and DNA).
- It is optimized to isolate nucleic acid from swab samples collected in universal transport media.
- 100µL-400µL of transport media can be purified per sample.
- Superparamagnetic SeraSil-Mag™ beads selectively bind total nucleic acid while removing unwanted material efficiently through quick wash steps.

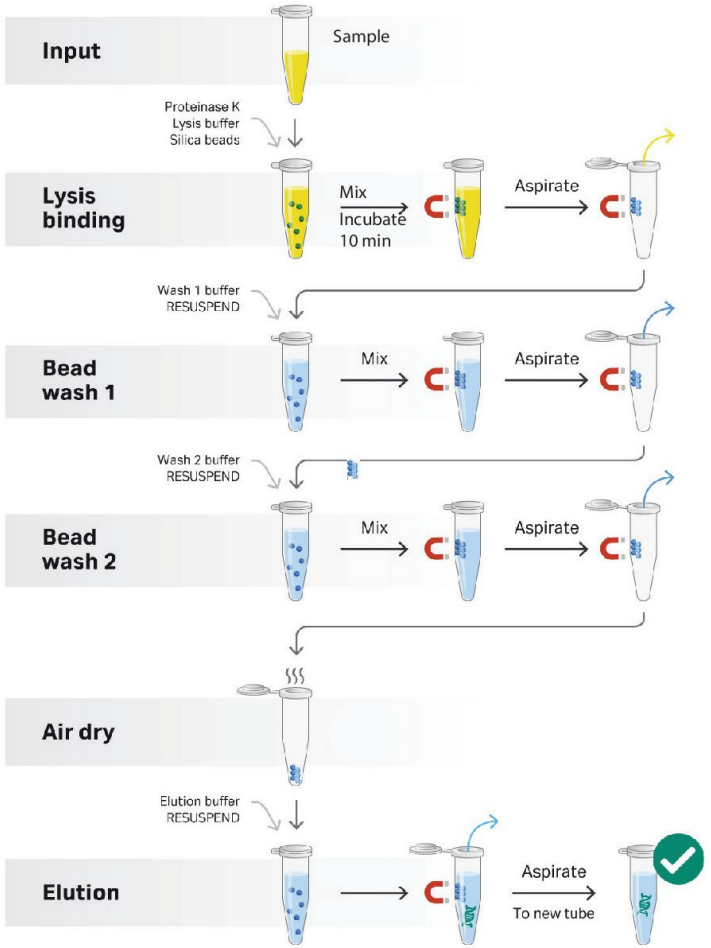

Fig 1. Sera-Xtracta Virus/Pathogen kit workflow

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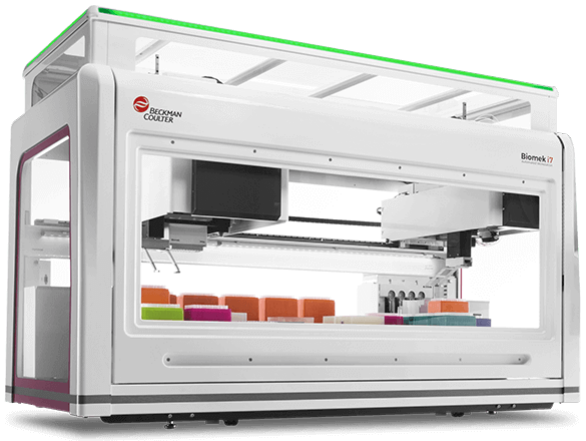
Automated Method Description:

The Cytiva™ Sera-Xtracta Virus/Pathogen kit on Biomek i7 Dual-Hybrid automated workstation method allows the user to isolate viral/bacterial nucleic acids from up to 96 swab samples at a time. The method uses multichannel plate stamping to avoid column effects. It requires only one user interaction should users incubate their samples via the integrated Inheco Deep-Well Incubator or on-deck Inheco Thermoshake AC Peltier.

A



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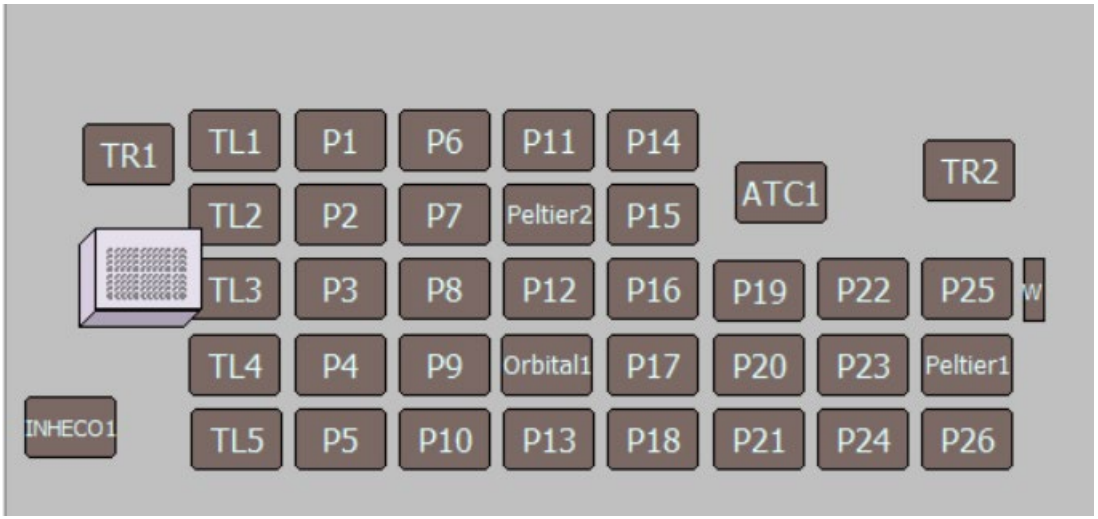

Fig 2.. A. Biomek i7 Dual-Hybrid automated workstation. B. Diagram of the deck layout employed in this method.

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Major Process	24 Samples	48 Samples	96 Samples
Instrument Setup	30 min	30 min	30 min
Reagent Aliquoting	13 min, 30 Sec	24 min, 38 sec	34 min, 21 sec
Lysis Binding	21 min, 24 sec	21 min, 24 sec	21 min, 24 sec
Wash 1	16 min, 3 sec	16 min, 3 sec	16 min, 3 sec
Wash 2	13 min, 49 sec	13 min, 49 sec	13 min, 49 sec
Elution	5 min, 41 sec	5 min, 41 sec	5 min, 41 sec
Total	**1hr, 40 min, 27 sec**	**1 hr, 52 min, 35 sec**	**2hr, 1min, 18 sec**

Table 1. Time of completion for 24, 48, and 96 sample inputs.

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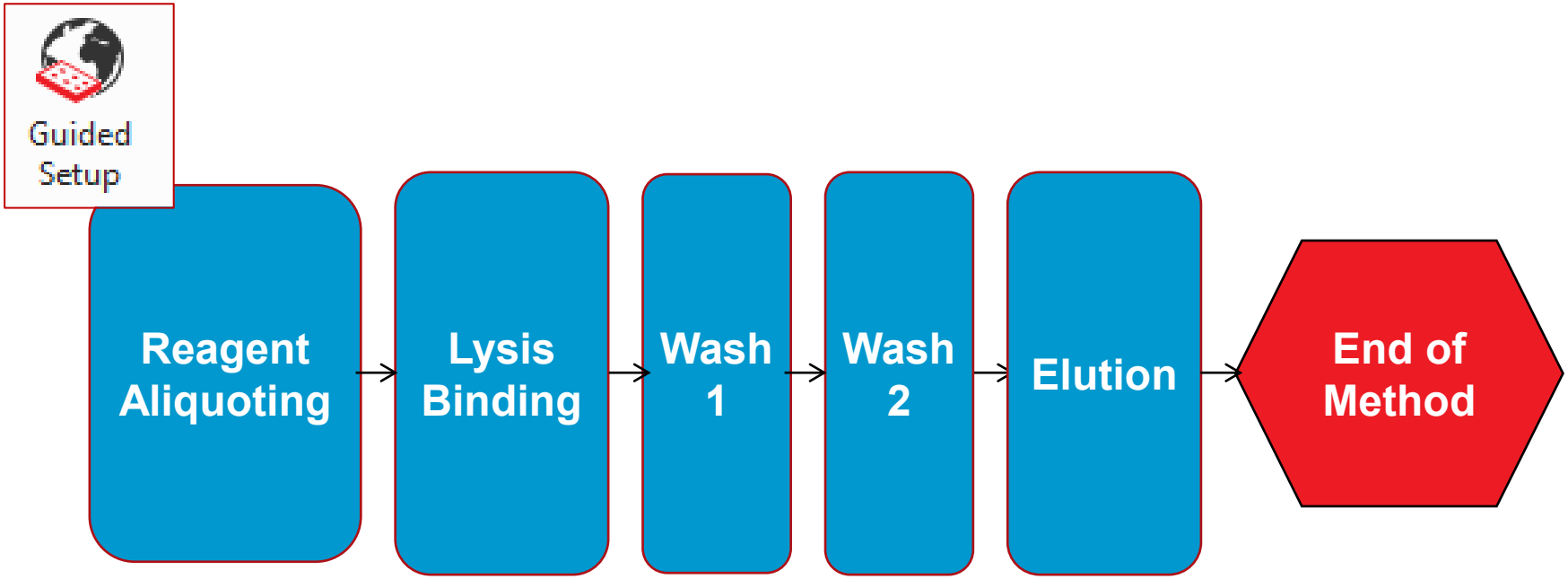

Fig 3. Sera-Xtracta Virus/Pathogen automated workflow.

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Demonstrated Method Interface Makes it Easy to Run

Biomek Method Launcher

1. Makes method available outside of the editor

2. Protects against accidental changes from multiple users

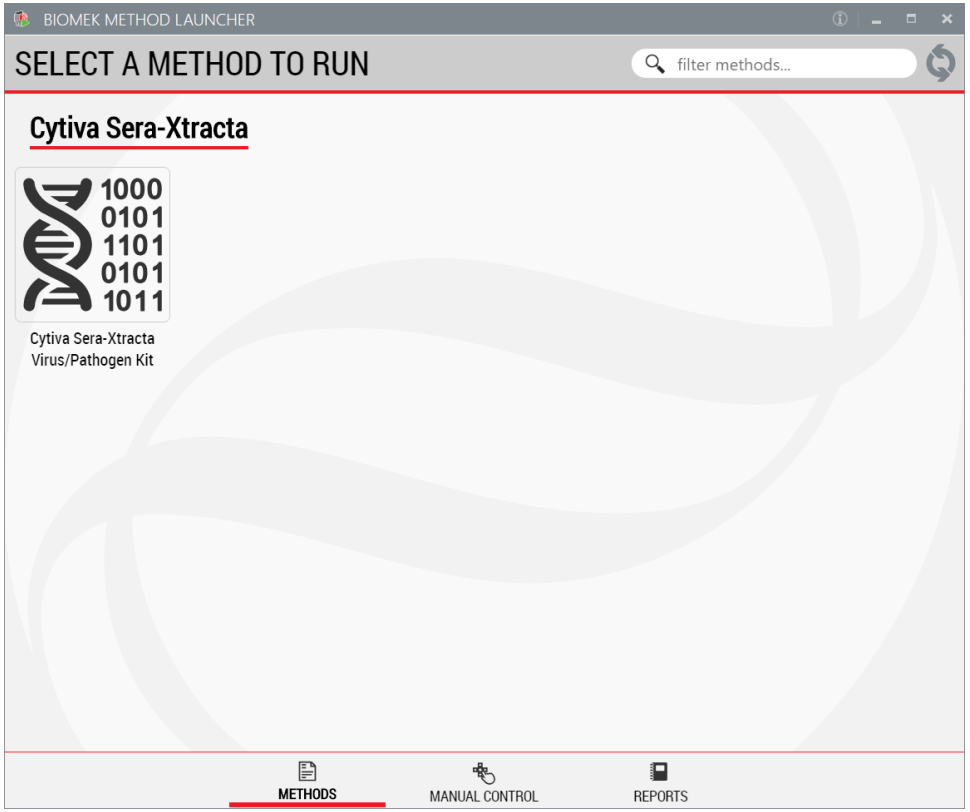

Fig 4. Method selection in the Biomek Method Launcher.

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Demonstrated Method Interface Makes it Easy to Run

Method Option Selector (MOS)
Dynamic, HTML-driven interface allows the user to select a number of options to configure the workflow as desired.

Fig 5. Method Option Selector for the Cytiva Sera-Xtracta Virus/Pathogen kit automated method.

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Demonstrated Method Interface Makes it Easy to Run

MOS options that enable flexibility, reduce errors and provide greater walk-away time

1. **Enter Number of Samples:** The Cytiva™ Sera-Xtracta Virus/Pathogen automated method accepts 8-96 samples in multiples of 8 (one column of the plate).
2. **Specify the sample input volume:** Set the samples' volumes from 100µL to 400µL. The sample volume in each well must be uniform.
3. **Select the desired process for incubating the sample plate during lysis:** Choose from three different incubation options:
    1. *Incubate on-deck:* Integrated Inheco Deep Well Single Plate Incubator
    2. *Incubate on-deck:* An on-deck Inheco Thermoshake AC Peltier
    3. *Incubate off-deck.* Pause the system at the incubation step to allow the user to remove the plate from the deck and manually incubate. The user replaces the plate to the deck after incubation is complete.

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Demonstrated Method Interface Makes it Easy to Run

Guided Labware Setup and Reagent Calculation

- Provides clear instructions for setup
- Reduces setup errors
- GLS diagrams may be printed or saved as a PDF for future reference.

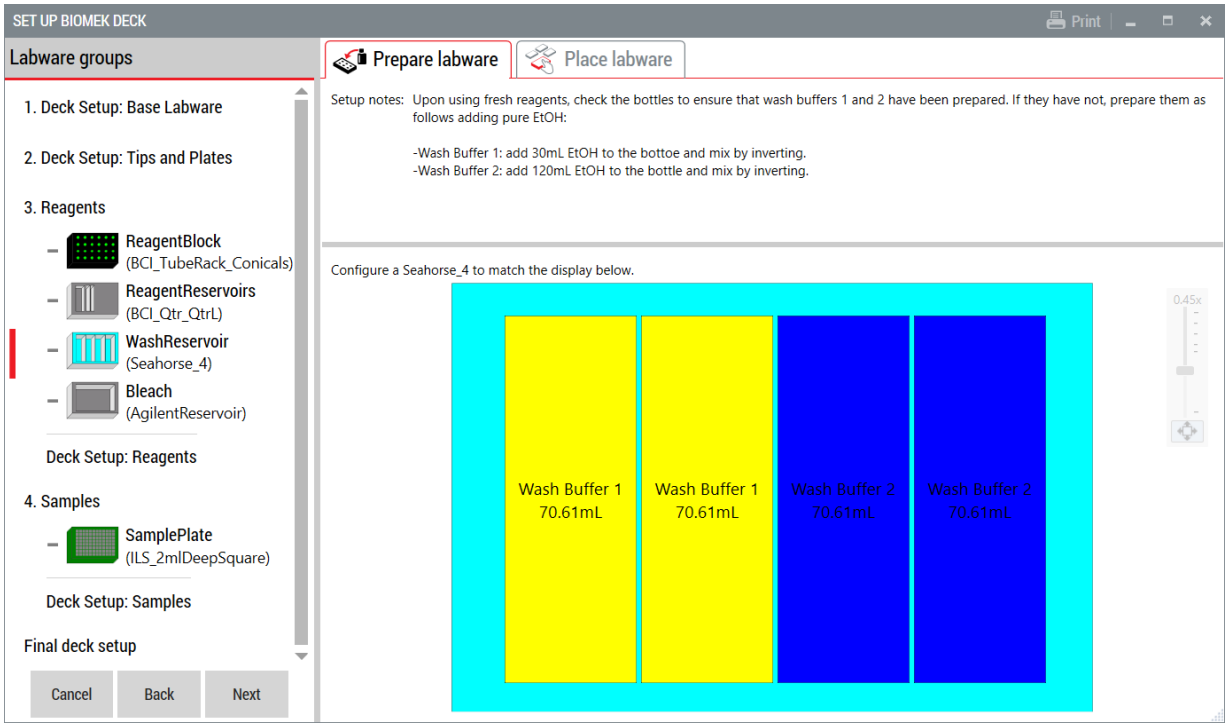

Fig 6. Example of visualized reagent preparation instructions within the Guided Labware Setup steps.

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Experimental Details:
All reagent volumes and preparations were prepared according to the method IFU. Samples of HEK 293 cells in a concentration of $3x10^5$/mL in 200µL of viral transport media were spiked with heat-inactivated SARS-CoV-2 RNA for a finally concentration of 1 copy/µL. The samples were then processed with the same workflow but different incubation methods for 10 min at 60°C for lysate binding; some samples (n=10) were incubated via the integrated Inheco Deep Well Incubator, while other samples (n=15) were incubated via the on-deck Inheco Thermoshake AC Peltier.

Following elution of the extracted nucleic acid the ct scores of each sample were measured by a QuantStuido™ 6 Flex. The samples were prepared with TaqMan Reagents, Bio-Rad 4x Reliance One-Step Master Mix, and IDT 2019-nCoV_N1 primer.

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Samples processed by either the Inheco incubator or the on-deck Peltier both provided Ct means below 40 with minimal deviation.

Samples	Ct mean	St.Dev	Incubation Method
15	35.961	0.652	Peltier
10	36.264	0.462	Inheco Incubator

Table 2. Ct mean and standard deviations and number of samples tested for both incubation methods.

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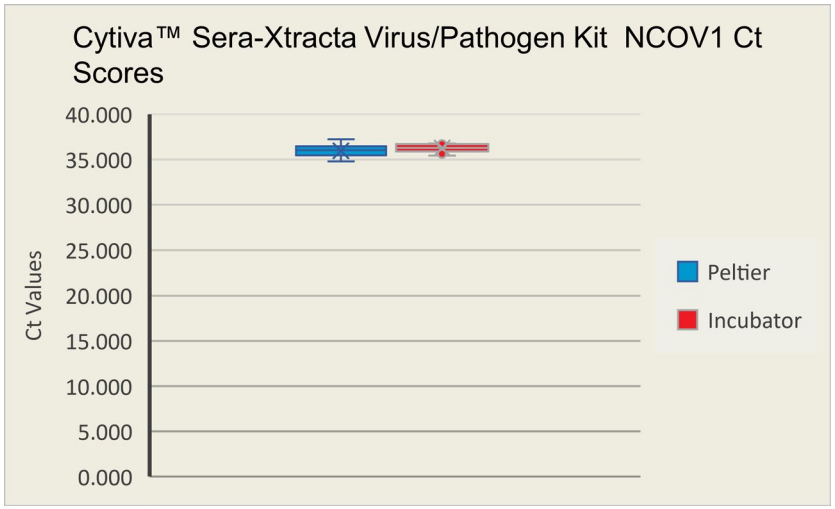

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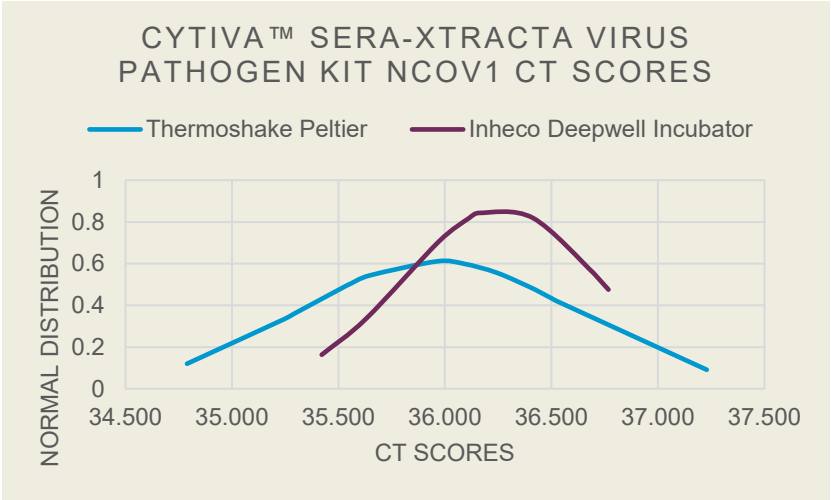

Fig 7. Measured Ct values by incubation method. A .Ct score ranges. B. Ct score normal distributions.

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