

System Operation – Reference Guide

RapiScreen™ Dairy Assay on Innovate

This overview is for reference only and does not supersede any company-specific Standard Operating Procedures (SOPs) established by your company. If your company has SOPs for the operation of this system, please refer to them for guidance in system operation.

Day 1



Sample Prep

- Incubate the sample in its original package at 30°C (or other validated temperature) for a minimum of 48 hours.

Day 2



Reconstitute Reagents

- Remove reagents from the refrigerator.

RapiScreen Dairy 1000

- **Sensilux** (yellow label) – Carefully open a vial of **Sensilux** and a vial of **Dilutor DS** (yellow label). Pour the contents of the **Dilutor DS** into the **Sensilux** vial, swirling gently to mix and pour the total contents into the 50ml PP-vial.
- **Cellsolver DE** (green label) – **Cellsolver DE** is ready for use.
- **ATX** (red label) – Carefully open a vial of **ATX** and a vial of Dilutor.
- **DA** (red label). Pour contents of the **Dilutor DA** into the ATX vial, swirl gently to mix and pour the total contents into the 50ml PP-vial.

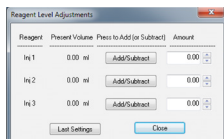
RapiScreen Dairy 5000

- **Sensilux** (yellow label) – Dispense 14ml of Dilutor DS (yellow label) into the Sensilux vial, swirling gently to mix and pour it into the 50ml PP vial. Dispense the second 14ml Dilutor DS directly into the 50ml PP-vial.
- **Cellsolver DE** (green label) – Cellsolver DE is ready for use.
- **ATX** (red label) – Dispense 14ml of Dilutor DA (red label) into the ATX vial, swirl gently to mix and pour total contents into the 50ml PP-vial.
 - Swirl gently, place the reagents in the Innovate reagent holder and leave for 15 minutes before use.

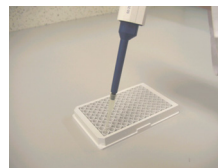
Injector Startup

Washing

- First turn on the instrument and then open the **Innovate software**.
- Select User as username and enter the password **User**.
 1. Select Instrument/Wash on the menu bar.
 2. Wash injectors 1 and 3 with Microwash by following the on-screen instructions.
- Click on **Instrument/Reagent** levels to enter the reagent volumes.
- Select Last Settings in case reagents are left from the previous day.
- Connect the reagents. **ATX** to injector 1 and **Sensilux** to injector 3.
- Cellsolver is already connected to injector 2.
- Click on **Instrument/Prime** to fill the three injectors with reagents.
- Select all three injectors and follow the on-screen instructions.



Day 2 (Cont.)



Daily Control

- It is important to perform daily controls prior to using the system to screen samples. Follow the steps below to perform your daily controls:
 - Leave two wells empty in the microtiterplate for the **InsBlank** measurement.
 - Results must be < 50 RLU before proceeding.
 - Leave two wells empty in the microtiterplate for the **Reagent Blank** measurement.
 - Results must be < 70 RLU before proceeding.
 - Pipette 50 µl of ATP into two wells for the **ATP Positive Control** measurement.
 - Results must be > 40,000 RLU before proceeding.
 - Daily controls can be measured using the **RS_Dairy_Control** protocol.

Samples

Pipette 50 µl of each sample into the wells (column wise). It is important to pipette the sample into the bottom of the well and to avoid splashes against the wall.

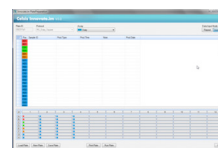


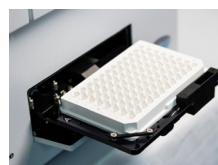
Plate Preparation in Innovate Software

- Protocol selection
 - Click on **PlatePrep** icon.
 - Enter Plate name followed by enter.
 - Select Assay **RS_Dairy** to measure the products.
 - Select **Dairy** with the arrow near the Product Box and in the bottom screen, select the wells containing the product.
- Sample Identification
 - Enter the sample information into the cells in the upper screen.
 - Click on **Run Plate** to measure the plate. The file name will be saved after confirmation.
 - Click on **Save Plate** if you want to define the next microplate before measurement.

Start Measurement

Click Start to start the measurement.

- The Innovate will automatically unload the previous plate outside the instrument.
 - Load plate and click on **OK**. The measurement will automatically start.
- In case of insufficient reagents, you will be automatically prompted to add more reagents. Follow the instructions on the screen.
- Measurement results are automatically saved (C: Program Files/Innovate/Data) and transferred to the **Innovate Software** database.



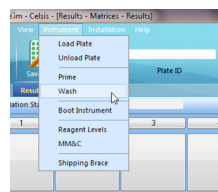
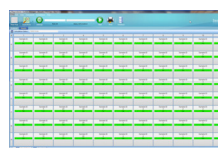
Interpretation

- The system automatically interprets and displays the results based on the criteria established during installations. Typically any sample result greater than 2-3 times the RLU value of non-contaminated sample is positive.

Cleaning the Instrument

The injector system needs to be cleaned at the end of the working day, following the measurement of all samples.

- Connect Microwash to Injector 1 and 3.
- Wash Injector 1 and Injector 3 by selecting **Instrument/Wash**. Follow the on-screen instructions.
- Please refer to the Innovate Operator Manual for more detail.
- Unload the last plate by the **Instrument/Unload Plate** command.
- Close the Innovate Software.
- Leave the reagent in the Innovate reagent holder.
- Turn off the instrument. Make sure the cooling unit of the reagent holder is not switched off.



* Please refer to the Innovate Operator Manual for more details.

Preventive Maintenance

The Innovate system has redefined what microbial screening should be: great instruments designed around customer needs, highly sensitive enzyme reagents and world-class technical support. The recommended preventive maintenance procedures and schedule below will help you optimize the performance of your instrument.

Daily	<ul style="list-style-type: none"> • Clean pipettor daily with alcohol. • Wash injector lines at start-up and shut-down with Microwash solution. • Check waste container and empty contents if more than 2/3 full. • Perform instrument controls to confirm the system is operating within specification before testing any samples: <ul style="list-style-type: none"> – Instrument Blank Control (InsBlank). Negative Control to check instrument interior for light leakages or reagent spillage. – Reagent Blank Control (ReaBlank). Negative Control to ensure there is no contamination of injector lines or reagents. – ATP Positive Control (ATP). Positive Control to ensure that the Sensilux reagent is fully active.
Weekly	<ul style="list-style-type: none"> • Inspect instrument interior for spillage and/or splashed reagents with considerable attention to the plate mask and plate carrier. Clean the interior with Microwash solution and a lint-free towel as appropriate. • Perform a visual inspection of injector tips to ensure tip ends are open and clean • Inspect external injector tubing for kinks and ensure that all connections are tight. • Perform a visual (qualitative) injector volume check using ATP Free Red Dilutor. • Clean/dust reagent holder and cooling block.
Monthly	<p>Clean injector system with the Maintenance and Cleaning Kit (see kit insert for instructions).</p> <ul style="list-style-type: none"> • Perform the (quantitative) Injector Volume Check to ensure that volumes are within +/- 5% of specification.
Annually	<ul style="list-style-type: none"> • Schedule a preventive maintenance visit by a Certified Service Representative to perform a full instrument service.

Certified Service Program

If an instrument requires service or repair, please contact Customer Service and describe problem. Service for all systems can be performed on site or by an authorized service engineer. Instruments cannot be accepted without proper authorization by . Upon system arrival, the Service Department will determine the extent of the repair and fax the customer with details and an estimated cost of repair. A purchase order must be provided with a signed copy of the repair estimate before work will begin.