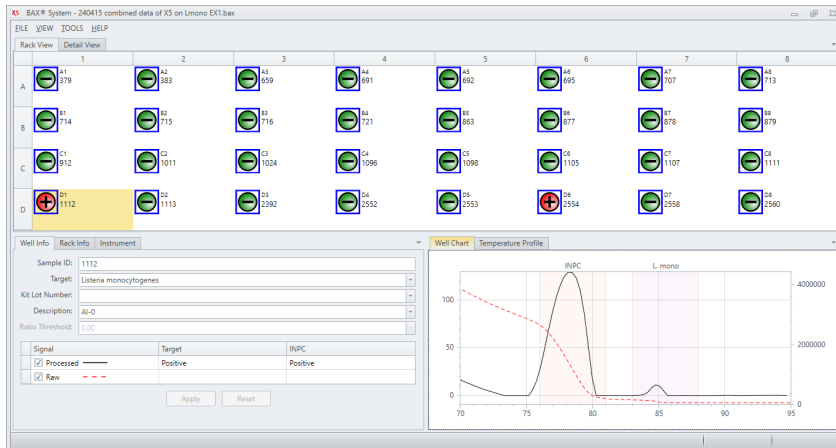


6. Review Results

BAX® System results are displayed as clear “yes” or “no” icons that do not require expert interpretation. Each well has a symbol in the center to illustrate the result.

See the User Guide for more detailed information about reviewing results for each BAX® System X5 assay.



keydiagnostics

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If you have any questions or comments about the BAX® System, please contact your local distributor or representative.

You can also contact support directly by phone at

800.863.6842, 302.695.5300 or by email at diagnostics.support@hygiena.com.

RR-005 Rev 01



BAX® System X5



Be sure you have the following items to use this test method

BAX® System X5 Instrument Package
 with cyclor and setup materials with flight case for transport

BAX® System X5 Computer Package
 with laptop computer pre-loaded with BAX® System X5 software

BAX® System X5 Auxiliary Package
 with Hygiena™ Automated Thermal Block, 32-well cold block, sample carriers capping/de-capping tools, pipettes and consumables

USB memory stick with user documentation, training materials and software

For instructions for unpacking and installing the BAX® System X5 instrument, see the User Guide on the USB memory stick. Please review the Instrument Specifications, Environmental Parameters and Safety Precautions in the User Guide before using the BAX® System X5 instrument.

HOW TO USE THE BAX® SYSTEM METHOD

1. Enrich Samples

Follow the instructions in the BAX® System X5 User Guide to combine samples with enrichment media and incubate at the appropriate time and temperature.

2. Prepare BAX® System Lysis Reagent

For *E. coli* O157:H7 and *Salmonella*

- 150 µL protease + 12 mL lysis buffer
- Cap the bottle and invert to mix

For Genus *Listeria* and *L. monocytogenes*

- 150 µL protease + 200 µL Lysing Agent 2 + 12 mL lysis buffer
- Cap the bottle and invert to mix

3. Perform Sample Lysis

Prepare the Automated Thermal Block

For *E. coli* O157:H7 and *Salmonella*

- Use the Gram Negative program

For Genus *Listeria* and *L. monocytogenes*

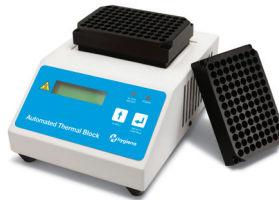
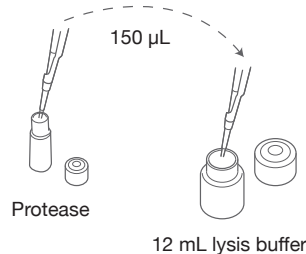
- Use the RT *Listeria* program

Prepare samples in cluster tubes

- Add 200 µL lysis reagent to tubes
- Add 5 µL enriched sample to tubes
- For *E. coli* O157:H7, add 20 µL enriched sample if using BAX® System MP Media
- Cap tubes securely

Place cluster tubes on the Hygiena™ Automated Thermal Block

- Press the SELECT/CONTINUE button
- Lysis is complete when the Hygiena™ Automated Thermal Block beeps and displays the message “Sample PCR Ready”



**Sample PCR Ready
GmNeg 1:01**

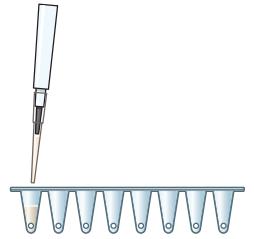
For *E. coli* and *Salmonella* assays

**Sample PCR Ready
RTLis 0:57**

For Genus *Listeria* and
L. monocytogenes assays

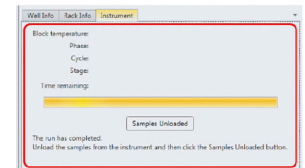
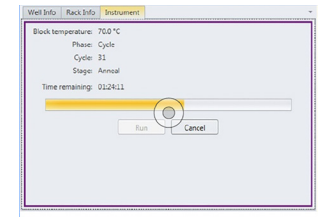
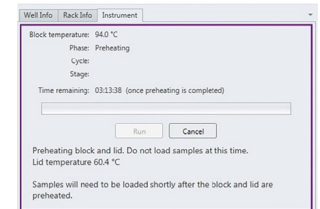
4. Hydrate PCR Tablets

- Place a 32-well sample carrier on a chilled (2-8°C) PCR cooling block.
- Place PCR tubes into the cooling block. Check that each PCR tube contains a PCR tablet
- Transfer 50 µL sample lysate to each PCR tube
- Secure tubes with new flat optical caps using the BAX® System capping/de-capping tool



5. Complete Process Run

- Open the BAX® System X5 software
- In the Instrument tab, click the RUN button. You must load samples within 20 minutes of clicking the RUN button.
- **IMPORTANT** - While the instrument pre-heats, ensure that PCR tubes are clean and no air bubbles are present in the liquid
- After the “Block preheated. Ready to load samples” prompt appears, open the BAX® System X5 instrument lid and insert PCR tubes in a symmetrical, balanced layout
- Close the instrument lid as soon as possible to prevent the instrument from cooling. The process run begins automatically
- After processing is complete, the instrument prompt under the status bar reads “The run has completed”
- Open the instrument lid and remove the PCR tubes from the instrument mount
- Close the instrument lid, then click the SAMPLES UNLOADED button to complete the process run



See the BAX® System X5 User Guide for additional details and troubleshooting information