**HM-JACKarc Procedure Summary**

**Fully Automated Quantitative FIT system**

The HM-JACKarc system combines the qualities of a state-of-the-art automated analyser, a bespoke faecal sample tube and sensitive, latex agglutination reagents.

This combination provides a high throughput solution for the detection of Faecal Occult Blood.

**Key features:**

- Sensitivity: 7 ng/mL
- Easy to use sample collection device
- Fully automated
- No prozone effect up to 300,000 ng/mL
- High speed performance: 200 samples per hour

**HM-JACKarc**

Kyowa Medex
Handling of Reagents and Samples

**Latex Reagent**
- Return to room temperature (15~25°C) before use, at least 20 minutes
- Gently mix by repeated inversion before setting in position on analyser
- Never top-up one bottle from another
- Always calibrate when changing between lots
- Return to storage at 2~8°C immediately after use

*When changing between lots, read the barcode from the Master Curve Card provided with the reagent.*

**Buffer Reagent**
- Return to room temperature (15~25°C) before use, at least 20 minutes
- This reagent may be stored on the analyser once opened (up to 1 month)
- Before a long period of inactivity, replace buffer with dH₂O and perform 2-3 WASH primes
- Unopened bottles should be stored at 2~8°C for long-term storage

**Calibrator (Standards)**
- Bring to room temperature (15~25°C) before use, at least 20 minutes
- Add 1.0 mL of dH₂O, leave to stand for at least 30 minutes, then mix by gently rolling, making sure no bubbles remain
- This reagent is stable for one week at 2~8°C after reconstituted
- Frozen storage in 200 µL aliquots is recommended (-30°C, for up to one month)

*When changing between lots, read the barcode from the Calibrator Card provided with the reagent.*
Control

- Bring to room temperature (15~25°C) before use, at least 20 minutes
- Add 1.0 mL of dH₂O, leave to stand for at least 30 minutes, then mix by gently rolling, making sure no bubbles remain
- This reagent is stable for one week at 2~8°C after reconstituted
- Frozen storage in 200 µL aliquots is recommended (-30°C or below, for up to one month)

Samples

- Mix sample collection devices by repeated inversion before placing them on the HM-JACKarc

* Read the insert documentation before handling reagents

Registration of Latex Reagent Master Curves and Calibration Data

1. Have the latex reagent Master Curve Card and the Calibration Card ready.
2. Touch [Calibration Curve] on the Main Menu.
4. Use the handheld barcode reader provided to read the barcodes on the Master Curve Card, top to bottom.

5. Touch [OK] to save new Master Curve.

6. Next, read the barcodes from the Calibrator Card.

7. Touch [OK] to save the new Calibration Curve.

8. Once all registrations are complete, touch [RETURN] to go back to the Main Menu.
Adding New Buffer and Control Lot Numbers, Expiry Dates and Control Ranges

1. From the Main Menu, touch the [Calibration Curve] icon.
2. Next, touch the [Master] icon, then on the next screen touch the [M/C Edit] icon.
3. Touch the [Buffer/Cont] icon, this screen will then allow for the Buffer and Control information to be modified.
4. Touch the area to modify and this will open an input screen with an alphanumeric keyboard. Only the month and year is required, e.g. (MM/YY).
5. Input the new lot number, control ranges and expiry dates.

Cell Setting Operation Procedure

1. Touch [Cell Set] icon on the Main Menu.
2. Cells can be set on the reaction table using the [ALL Changes], [Selective Change] and [ALL OK].

<table>
<thead>
<tr>
<th>Display</th>
<th>Cell status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OK</td>
<td>Cell present (unused)</td>
</tr>
<tr>
<td>MS</td>
<td>Cell present (measurement in progress)</td>
</tr>
<tr>
<td>NG</td>
<td>Cell replacement error or aborted</td>
</tr>
<tr>
<td>? ?</td>
<td>Cell not checked</td>
</tr>
<tr>
<td>(Blank)</td>
<td>No cell present</td>
</tr>
</tbody>
</table>

Setting the start position for picking up the cells in the Cell Cassette

1. Touch [Cell Cassette].

2. Touch the numbers of the cells you want to remove on the diagrams of the left and right cell cassettes.

3. The highlighted number displayed is the “Start Position”, cells are picked up starting from this position.
System Start-up

Turn on HM-JACKarc and wait for up to an hour before measurement.

While waiting, perform the following:

**Consumables Check**
- Check the WASH volume in the pure water tank (0.1% cleaning fluid - full tank = 5mL WASH fluid : 5 litres dH2O)
- Check the WASTE tank level
- Check the Cell Trash box
- Check the number of cells left in the cell cassette

**Reagent Check**
- Latex and Buffer must be at room temperature before measurement
- Mix Latex Reagent gently (DO NOT INVERT OR SHAKE)
- Remove the cap of Latex and set in position on the instrument
- Set Buffer in position on the instrument

**Sample Rack Trays Check**
- Check both are seated correctly
- Remove all processed (analysed) racks

Measurement

The Main Menu is displayed when the screen is touched.

1. Touch [WASH] to perform priming.

*Run [WASH] program 3 - 4 times if replacing from dH2O to Buffer*
Prepare Calibration [STD] and Control [CTL]

Reconstitute each vial with 1.0 mL of dH₂O and allow them to stand for 20 mins.

Disperse 200µl each of Calibrator and Control into sample cups and set them in the specified positions, as shown above.

2. Run "Calibration" and "Control"

- Set the Racks in the sample compartment
- Touch [Analysis] on the Main Menu
- The Sample Order screen is displayed
- Check how many tests the latex/buffer reagent is sufficient for
- If too low, replace reagent and touch the box to input new bottle volume, to reset available tests (18mL for Latex, 205mL for Buffer)
- Touch [Start] to start analysis.

3. Analyse Samples

- Set sample collection picker on the "Sample Rack" and place on In Tray
- All barcodes should be facing front
- Touch [Start] to begin analysis
Shutdown Operation

1. Touch [Wash] to perform priming.

* Before an extended period of inactivity, replace the Buffer Reagent with dH2O and then perform the [WASH] at least 2 times

2. Once priming is complete, touch [Sleep Mode] in the lower left of the screen.

Sleep Mode Screen

- The machine will start up at the displayed date and time.
- Check that the date is that of the next working day. Touch the date to change it. Enter a time at least one hour before the scheduled start of analysis.
- After checking the above, touch [Sleep Mode NOW].
- The screen blanks and enters Standby Mode.
- To restart, touch the screen and touch [Yes] to display the initial screen.

Shutdown Inspection

Consumables Check

- Check the remaining volume in the WASH tank (0.1% WASH Liquid) and top-up if required
- Check the volume in the WASTE tank and discard if required
- Discard waste cells from the Cell Trash Box
- Refill the cell cassette if necessary

Reagent Check

- Store the Latex reagent at 2~8°C immediately

Sample Rack Trays Check

- Remove any racks from the Output Tray
- Set the Input/Output trays correctly in position
### Alarm Displays on the Analysis Monitor

![Analysis Monitor with sensor and sample images]

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Barcode error</td>
</tr>
<tr>
<td>Q</td>
<td>Order confirmation error</td>
</tr>
<tr>
<td>N</td>
<td>During automatic analysis</td>
</tr>
<tr>
<td></td>
<td>During manual order analysis</td>
</tr>
<tr>
<td>F</td>
<td>During manual order analysis</td>
</tr>
<tr>
<td>T</td>
<td>Feed error</td>
</tr>
</tbody>
</table>

- **Barcode error**: Sample barcode is illegible
- **Order confirmation error**: No order, or no response to order
- **Sample sensor Off**: There is an order, but the sample sensor is Off
- **Sample sensor On**: There is no order, but the sample sensor is On
- **Feed error**: There is a feed error

### Barcode Read Messages

When a sample barcode has been set, the following barcode read message is printed together with the results printout:

<table>
<thead>
<tr>
<th>Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of 1-16 digits</td>
<td>Normal</td>
</tr>
<tr>
<td>No reading</td>
<td>There is a sample, but reading is not required</td>
</tr>
<tr>
<td>No Sample</td>
<td>There is no sample</td>
</tr>
<tr>
<td>Barcode Error xxx</td>
<td>Barcode reading resulted in an error</td>
</tr>
<tr>
<td></td>
<td>xxx is the error message reference</td>
</tr>
</tbody>
</table>
Faecal Immunochemical Testing
Operation Guide

Ordering Information

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>058093</td>
<td>EXTEL HEMO AUTO HS Latex</td>
<td>4 x 18ml</td>
</tr>
<tr>
<td>058094</td>
<td>EXTEL HEMO AUTO HS Calibrator</td>
<td>8 x 1 ml</td>
</tr>
<tr>
<td>058095</td>
<td>EXTEL HEMO AUTO HS Control</td>
<td>8 x 1 ml</td>
</tr>
<tr>
<td>052352</td>
<td>EXTEL HEMO AUTO Buffer</td>
<td>1 x 250ml</td>
</tr>
<tr>
<td>058198</td>
<td>EXTEL HEMO AUTO MC Collection Picker</td>
<td>200 pieces</td>
</tr>
<tr>
<td>061397</td>
<td>EXTEL HEMO AUTO MC Collection Picker</td>
<td>400 pieces</td>
</tr>
<tr>
<td>053150</td>
<td>HM-JACK Reaction Cell</td>
<td>1000 pieces</td>
</tr>
<tr>
<td>053151</td>
<td>HM-JACK Sample Cup</td>
<td>500 pieces</td>
</tr>
<tr>
<td>057848</td>
<td>HM-JACK Print Paper A</td>
<td>2 rolls</td>
</tr>
<tr>
<td>052404</td>
<td>Wash Liquid (Auto Detergent H)</td>
<td>1 x 200ml</td>
</tr>
</tbody>
</table>

Additional Consumables

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIC-01000-01</td>
<td>Picos 50-1000µl 1-Channel Pipette</td>
<td>Each</td>
</tr>
<tr>
<td>791002</td>
<td>10-1000µl Biohit Tip Refill Pack Non Sterile</td>
<td>100x96</td>
</tr>
<tr>
<td>791003</td>
<td>10-1000µl Biohit Tip Refill Pack Sterile</td>
<td>100x96</td>
</tr>
<tr>
<td>791001</td>
<td>10-1000µl Biohit Tip Single Tray Sterile</td>
<td>100x96</td>
</tr>
<tr>
<td>721006</td>
<td>Pipette tip cone filter set, 1000µl</td>
<td>50</td>
</tr>
<tr>
<td>730981</td>
<td>Charging Stand</td>
<td>Each</td>
</tr>
</tbody>
</table>

Service Hotline: 02380 487239
Chris Scoble - Service Manager: 078318 85526
Matthew Davis - Senior Product Manager: 02380 487204
All other enquiries: 02380 487252

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