

# Multiprobe Temperature Verification Kit

for use with  $\mathsf{Veriti}^\mathsf{\scriptscriptstyle TM} \mathsf{Dx} \mathsf{Thermal} \mathsf{Cycler}$ 

User Guide

The Multiprobe Temperature Verification Kit has been qualified for use as a service tool for the Veriti™ Dx Thermal Cycler (IVD), when used by trained service personnel according to the procedures defined in this document.

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The Applied Biosystems Multiprobe Temperature Verification Kit is covered by U.S. Patent No. 5,224,778.

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### About this Guide

#### Safety information

**Note:** For general safety information, see this Preface and Appendix B, "Safety" on page 51. When a hazard symbol and hazard type appear by a chemical name or instrument hazard, see the "Safety" Appendix for the complete alert on the chemical or instrument.

## Safety alert words

Four safety alert words appear in Applied Biosystems user documentation at points in the document where you need to be aware of relevant hazards. Each alert word—IMPORTANT, CAUTION, WARNING, DANGER—implies a particular level of observation or action, as defined below:

**IMPORTANT!** – Indicates information that is necessary for proper instrument operation, accurate chemistry kit use, or safe use of a chemical.



**CAUTION!** – Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.



**WARNING!** – Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.



**DANGER!** – Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.

Except for IMPORTANTs, each safety alert word in an Applied Biosystems document appears with an open triangle figure that contains a hazard symbol.

## Temperature Verification Kit Overview

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#### Overview

The Multiprobe Temperature Verification Kits (TVKs) are for use with the Veriti<sup>TM</sup> Dx Thermal Cycler, as described in the *Veriti*<sup>TM</sup> Dx *Thermal Cycler User Guide* (PN 4453697).

The Multiprobe TVKs verify the temperature accuracy and non-uniformity of Applied Biosystems thermal cyclers. The Multiprobe TVKs must be used only by operators trained in laboratory techniques and procedures.

The customer is responsible for validation of assays and compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

#### About this Guide

This guide describes how to assemble and use the Multiprobe TVKs and how to ensure availability of hardcopy documentation. After using the Veriti<sup>TM</sup> Dx Thermal Cycler, we recommend that the customer prints the results for regulatory purposes. The requirements for creating and maintaining TVK hardcopy documentation should be specified by the customer's Quality system and procedures.

#### **About the Multiprobe Temperature Verification Kits**

#### Components

A Multiprobe TVK consists of:

- A multiprobe module, 0.1-mL, 0.2-mL, or 0.02-mL size with ribbon cable
- A digital thermometer, Model 4690 with 9 V battery installed, and communication cable
- Light mineral oil
- · Cotton swabs

#### Recalibration

Applied Biosystems recommends that you have the digital thermometer and multiprobe module calibrated once a year. See Appendix A for decontamination and shipping instructions.

#### Annual Temperature Verification Tests

Use the TVK on the sample block(s) to perform the following tests at least once a year:

- **Temperature Verification Test** Checks the temperature of the sample blocks against specifications for temperature accuracy.
- **Temperature Non-Uniformity Test (TNU)** Checks the temperature uniformity of the sample blocks.
- **Heated Cover Test** Checks the heated cover temperature accuracy.

## Testing Frequency

Applied Biosystems recommends that you perform each of the three tests at least once a year, then as frequently as necessary, depending on the type of work your laboratory performs.

Based on customer application, the Veriti<sup>TM</sup> Dx Thermal Cycler may require more frequent temperature testing. The customer is responsible for determining the needed testing frequency.

## TVK Specifications

Parameter	Specification
Accuracy	Accuracy of well probes:
	• ±0.1 °C (35 °C to 96 °C)
	• ±0.2 °C (0 °C to 100 °C)
	Accuracy of heated cover probes:
	• ±1.0 °C (100 °C to 110 °C)
	• ±1.5 °C (35 °C to 125 °C)
Resolution	±0.01 °C
Range	
Well probes, location 1 to 8	• 0.00 °C to 100 °C
Cover probe location 9	• 35.0 °C to 115.0 °C
Environmental conditions	
Temperature	• 18 °C to 28 °C
Relative humidity	• 0 to 75%
Storage	
Temperature	• 10 to 40 °C
Relative humidity	• 0 to 70%
Reading rate	1 per 1.2 sec

#### **Multiprobe Modules**

**IMPORTANT!** Use only the multiprobe module that is designed for the sample block you are testing. See pages 10 and 11 for the TVKs and multiprobe module part numbers.

Each multiprobe module consists of 8 temperature probes that measure the temperature of 8 sample wells. Position 9 measures the heated cover temperature.

**IMPORTANT!** Applied Biosystems recommends that you use the multiprobe module and digital thermometer to perform only the Temperature Verification Test, Temperature Non-Uniformity Test, and the Heated Cover Test.

Multiprobe Modules for the Veriti<sup>™</sup> Dx 96-Well Sample Blocks

To test the	Use the	Kit PN
96-Well Fast Thermal Cycler, with 0.1-mL sample wells	9-Channel Temperature Verification Kit for VeriFlex <sup>™</sup> 0.1- mL 96-Well Sample Blocks	4373997
	0.1-mL Multiprobe Module Upgrade Kit for 96-Well Sample Blocks (probe module only)	4375938
96-Well Thermal Cycler with 0.2-mL sample wells	9-Channel Temperature Verification Kit for VeriFlex <sup>™</sup> 0.2- mL 96-Well Sample Blocks	4377669
	0.2-mL Multiprobe Module Upgrade Kit for 96-Well Sample Blocks (probe module only)	4377670

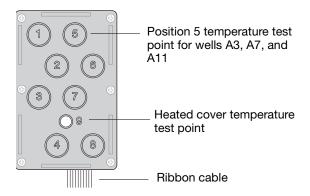


Figure 1 Multiprobe module for the Veriti<sup>™</sup> Dx 96-well sample blocks, showing the probe locations

Multiprobe Modules for Veriti<sup>™</sup> Dx 384-Well Sample Blocks

To test the	Use the	Kit PN
384-Well Thermal Cycler with 0.02-mL sample wells	9-Channel Temperature Verification Kit for 0.02-mL 384-Well Sample Block	4385338
	0.02-mL Multiprobe Module Upgrade Kit for 384-Well Sample Block (probe module only)	4385339

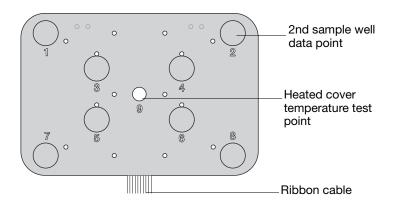


Figure 2 Multiprobe module for Veriti<sup>™</sup> Dx 384-well sample blocks, showing the probe locations

### **Digital Thermometer**

**Front View** For additional information, see "TVK Specifications" on page 9.

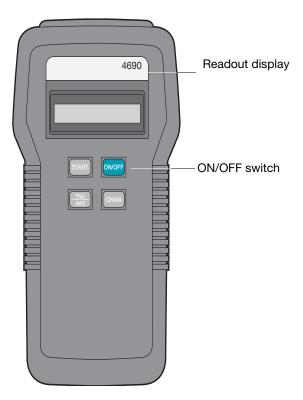


Figure 3 Handheld digital thermometer

**IMPORTANT!** Do not try to calibrate or perform any service on the digital thermometer. The only user-serviceable component is the battery.

#### **Keypad Buttons**

Button	Function	
START	Begins continuous temperature measurements (after being stopped by either the TNU/AVG or CHAN button).	
ON/OFF	Powers on or powers off the digital thermometer.  During power on, the thermometer model number, firmware version, low-battery condition, out-of-range indicator, probe calibration date, and probe serial number are displayed.	
TNU/AVG	Displays temperature in degrees Celsius:  TNU = Temperature Non-Uniformity (maxReading — minReading) for channels 1 to 8  AVG = Average for channels 1 to 8  Channel 9 = °C Heated cover	
CHAN	Displays the individual channel temperature of each tested well (channels 1 through 8) and of the heated cover (channel 9).	

#### **Top View**

The top view shows the ports for cable connections:



Adapter port (Adapter not included)

Ribbon cable input connector port

Communication cable port

## Operating Guidelines

When you use the digital thermometer to perform the tests in this guide:

• Ensure that the multiprobe module is connected by the ribbon cable to the input connector at the top of the thermometer.

**IMPORTANT!** Use only the multiprobe module that is designed for the sample block(s) you are testing. See pages 10 and 11 for the TVKs and multiprobe module part numbers.

- Power on the thermometer by pressing the **ON/OFF** switch on its front panel.
- The average temperature measured by the multiprobe module is shown on the readout display in degrees Celsius.
- When you complete a test, press the **ON/OFF** switch to power off the thermometer.

#### Displayed Temperatures

During heating and cooling transitions, the temperature displayed on the digital thermometer differs from the temperature displayed on the thermal cycler. The difference occurs because the digital thermometer measures block temperature, but the thermal cycler reports sample temperatures. The sample temperature displayed by the thermal cycler depends on the tube type and the reaction volume.

#### This chapter covers:

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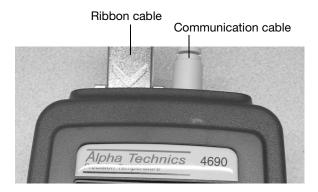
#### Before You Run 96-Well Instrument Tests

#### WARNING PHYSICAL INJURY HAZARD. Hot Surface.

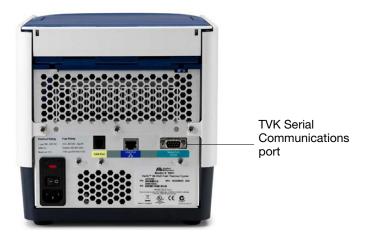
Use care when working around the heated cover and sample blocks to avoid being burned.

#### Connect the Digital Thermometer

- 1. Connect the free end of the ribbon cable (from the multiprobe module) to the input connector port on the digital thermometer.
  - **IMPORTANT!** Use only the multiprobe module that is designed for the sample block(s) you are testing. See pages 10 and 11 for the TVKs and multiprobe module part numbers.
- 2. Connect the round 8-pin DIN receptacle end of the communication cable to the thermometer communication port.

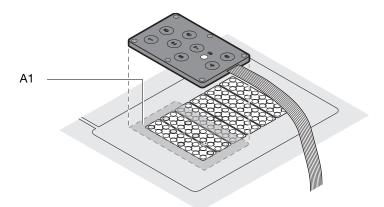


3. Connect the other end of the communication cable (9-pin) to the communication port of the instrument.



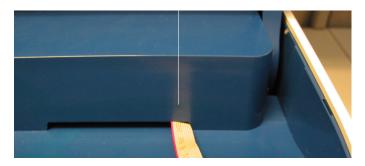
## Set up the Multiprobe Module

- 1. If the heated cover is closed, lift the lever and place the heated cover in the fully opened position.
- 2. Place the multiprobe module so that tip #1 sits in well A1.



3. Ensure that the ribbon cable leads straight out from the module, lies flat, and is under the thermal cycler cutout.

#### Ribbon cable placed under thermal cycler cutout



4. Close the heated cover, then pull down the lever.

**IMPORTANT!** Do not crush the multiprobe module ribbon cable when the heated cover is closed.

#### 96-Well Temperature Verification Test

This test determines the temperature accuracy of a thermal cycler by measuring sample well temperatures at two set points, 45 °C and 85 °C.

To pass the test, the six sample blocks must be within  $\pm 0.25$  degrees Celsius of the set points.

WARNING PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample blocks to avoid being burned.

#### Test Pattern of 96-Well Sample Blocks

The test wells (gray) are in the six sample blocks. Each sample block consists of two columns.

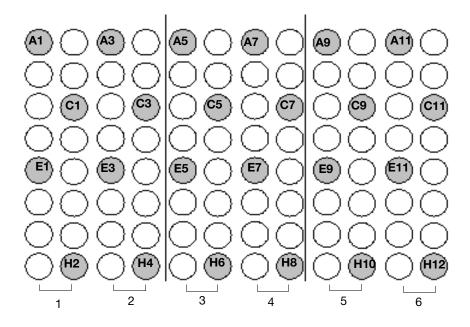
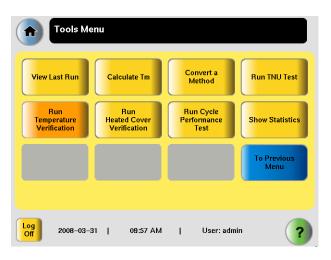


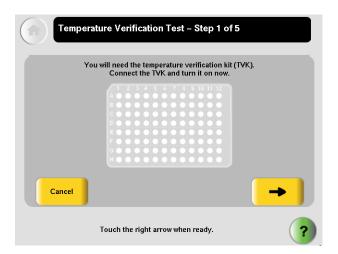
Figure 4 Sample blocks test pattern

#### Run the Test

- 1. See "Before You Run 96-Well Instrument Tests" on page 16.
- 2. Power on the thermal cycler, then power on the digital thermometer.
- 3. Touch Main Menu ➤ Tools Menu ➤ Run Temperature Verification.



The first screen opens.

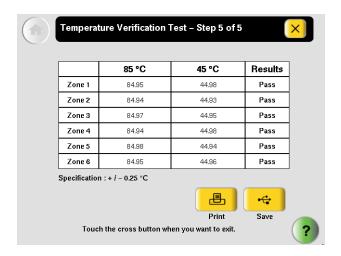


4. Follow the prompts in the touchscreen, making sure the multiprobe module is aligned in the well locations shown on page 19 and indicated below. The thermal cycler prompts you to move the probes 3 times during the test.

Testing Zones (Sample Blocks)	Well Position of Probe Tip #1
1 and 2	A1
3 and 4	A5
5 and 6	A9

**Note:** The test wizard refers to each sample block as a "zone." "Zone 1" refers to Sample Block 1, "Zone 2" refers to Sample Block 2, and so on.

At the end of the test, the results are displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the *Veriti*<sup>TM</sup> *Dx Thermal Cycler User Guide*.

Press **Print** to print results.

#### **Save Test Results**

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file bcalevents.txt. Test results are not stored on the thermal cycler.

**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

## Repeat the Test (Optional)

#### If the test fails:

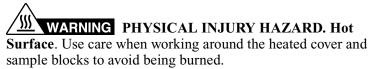
- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
  - Probe tips are not cracked or damaged.
- 2. Dispense 2 to 3 drops of mineral oil onto a cotton swab. Use the swab to apply a thin film of oil to the cone surface of each probe to improve heat transfer.
- 3. Repeat the steps in "Before You Run 96-Well Instrument Tests" on page 16.
- 4. Verify that the:
  - Probes are seated securely in the appropriate test wells.
  - Cables are connected securely to the ports.

- Ribbon cable lies flat under the thermal cutout and is not crimped.
- Heated cover is closed and locked down.
- 5. Repeat the steps in "Run the Test" on page 20.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

- 1. Follow the prompts to exit the test.
- 2. Wait for the sample blocks to reach room temperature (~25 °C), then remove the multiprobe module from the sample blocks.



- 3. Power off the digital thermometer.
- 4. Clean the oil off the multiprobe and sample blocks if you retested the system with oil.

#### 96-Well Temperature Non-Uniformity Test

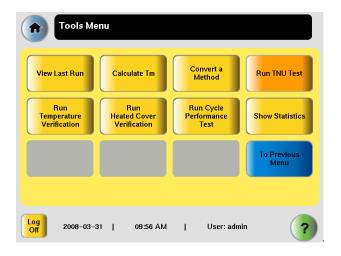
This test determines the temperature uniformity of the thermal cycler by measuring temperatures at 24 well locations.

To pass the test, all six sample blocks must be within  $\pm 0.5$  degrees Celsius of each set point temperature (95 °C and 60 °C) no later than 30 seconds after the set point temperature is changed.

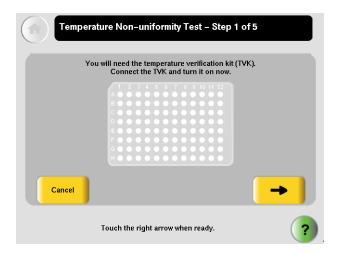
WARNING PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample blocks to avoid being burned.

#### Run the Test

- 1. See "Before You Run 96-Well Instrument Tests" on page 16.
- 2. Power on the thermal cycler, then power on the digital thermometer.
- 3. Touch Tools Menu ▶ Run TNU Test.



The first screen opens.

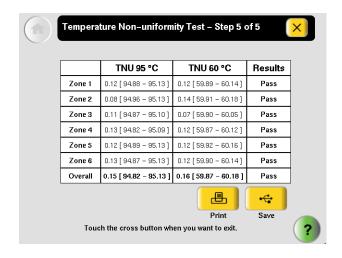


4. Follow the prompts in the touchscreen, making sure the multiprobe module is aligned in the well locations shown on page 19, and as indicated below:

Testing Zones (Sample Blocks)	Well Position of Probe Tip #1
1 and 2	A1
3 and 4	A5
5 and 6	А9

**Note:** The test wizard refers to each sample block as a "zone." "Zone 1" refers to Sample Block 1, "Zone 2" refers to Sample Block 2, and so on.

At the end of the test, the results are displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the *Veriti*<sup>TM</sup> *Dx Thermal Cycler User Guide*.

Press Print to print results.

#### Save Test Results

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file tnuEvents.txt. Test results are not stored on the thermal cycler.

**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

## Repeat the Test (Optional)

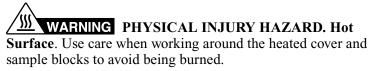
#### If the test fails:

- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
  - Probe tips are not cracked or damaged.
- 2. Dispense 2 to 3 drops of mineral oil onto a cotton swab. Use the swab to apply a thin film of oil to the cone surface of each probe to improve heat transfer.
- 3. Repeat the steps in "Before You Run 96-Well Instrument Tests" on page 16.
- 4. Verify that the:
  - Probes are seated securely in the appropriate test wells.
  - Cables are connected securely to the ports.
  - Ribbon cable lies flat under the thermal cutout and is not crimped.
  - Heated cover is closed and locked down.
- 5. Repeat the steps in "Run the Test" on page 24.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

1. Follow the prompts to exit the test.



- 2. Wait for the sample blocks to reach room temperature ( $\sim$ 25 °C), then remove the multiprobe module from the sample blocks.
- 3. Power off the digital thermometer.
- 4. Clean the oil off the multiprobe and sample blocks if you retested the system with oil.

#### 96-Well Heated Cover Verification Test

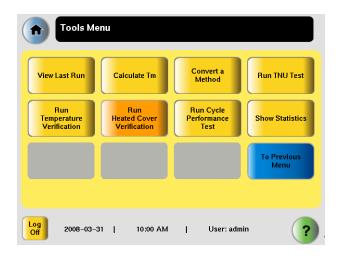
This test determines if the heated cover holds temperature at  $105 \pm 3$  °C.



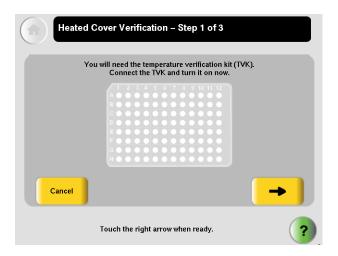
avoid being burned.

#### Run the Test

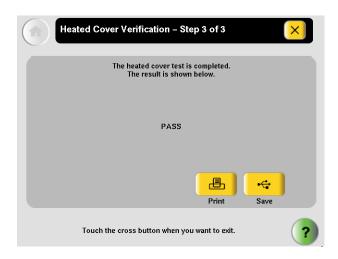
- 1. See "Before You Run 96-Well Instrument Tests" on page 16.
- 2. Power on the thermal cycler, then power on the digital thermometer.
- 3. Touch Tools Menu > Heated Cover Verification.



The first screen opens.



- 4. Verify that the:
  - Probes are seated securely in the appropriate test wells in zones 3 and 4.
  - Cables are connected securely to the ports.
  - Ribbon cable lies flat under the thermal cutout and is not crimped.
  - · Heated cover is closed and locked down.
- 5. Follow the prompts in the touchscreen. When the test is finished, PASS or FAIL is displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the  $Veriti^{TM} Dx Thermal Cycler User Guide$ .

Press **Print** to print results.

#### Save Test Results

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file heatedCover.txt. Test results are not stored on the thermal cycler.

**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

## Repeat the Test (Optional)

#### If the test fails:

- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
  - Probe tips are not cracked or damaged.
  - Multiprobe module is seated securely in zones 3 and 4.

- Cables are connected securely to the ports.
- Ribbon cable lies flat under the thermal cutout and is not crimped.
- · Heated cover is closed and locked down.
- 2. Repeat the steps in "Run the Test" on page 29.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

- 1. Power off the digital thermometer.
- 2. Wait for the sample blocks to reach room temperature ( $\sim$ 25 °C), then remove the multiprobe module from the sample blocks.

WARNING PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample blocks to avoid being burned.

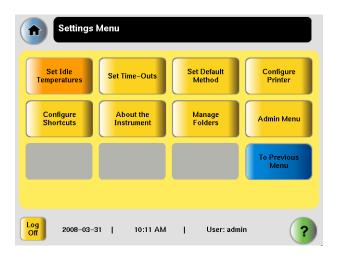
#### Before You Run 384-Well Instrument Tests

WARNING PHYSICAL INJURY HAZARD. Hot Surface.

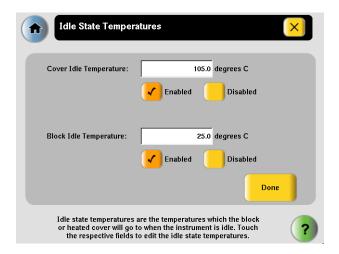
Use care when working around the heated cover and sample blocks to avoid being burned.

#### Set the Idle Temperature

- 1. Power on the instrument.
- 2. Touch Main Menu ▶ Settings Menu ▶ Set Idle Temperatures.



3. Enter **25.0** in the Block Idle Temperature field.



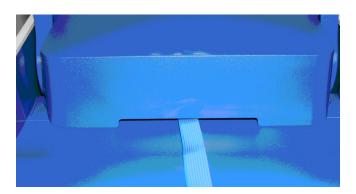
## Set Up the Multiprobe Module

- 1. Connect the multiprobe module to the digital thermometer. See page 16 for instructions.
- 2. If the heated cover is closed, lift the lever and place the heated cover in the fully opened position.
- 3. Place the multiprobe module so that tip #7 sits in well P1.



- 4. Make sure that the ribbon cable leads straight out, lies flat, and is under the thermal cycler cutout.
- 5. Slide the heated cover forward, then pull down the lever.

**IMPORTANT!** Do not crush the multiprobe module ribbon cable when the heated cover is closed.



#### 384-Well Temperature Verification Test

This test determines the temperature accuracy of a thermal cycler by measuring sample well temperatures at two set points, 45  $^{\circ}$ C and 85  $^{\circ}$ C.

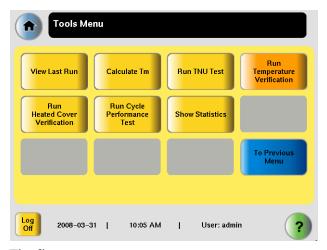
To pass the test, the left and right zones of the sample block must stabilize within  $\pm 0.25$  degrees Celsius of the set points.

WARNING PHYSICAL INJURY HAZARD. Hot Surface.

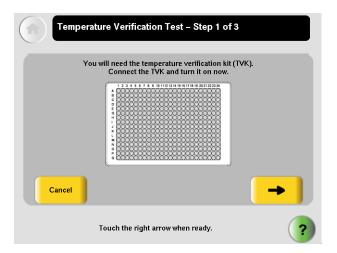
Use care when working around the heated cover and sample block to avoid being burned.

#### Run the Test

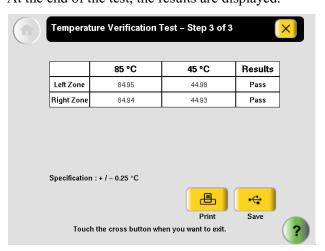
- 1. Power on the thermal cycler, then power on the digital thermometer.
- 2. Touch Main Menu ➤ Tools Menu ➤ Run Temperature Verification.



The first screen opens.



Follow the prompts in the touchscreen.At the end of the test, the results are displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the  $Veriti^{TM} Dx Thermal Cycler User Guide$ .

Press Print to print results.

#### Save Test Results

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file bcalevents.txt. Test results are not stored on the thermal cycler.

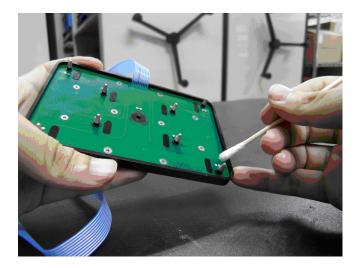
**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

# Repeat the Test (Optional)

#### If the test fails:

- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
  - Probe tips are not cracked or damaged.
- 2. Dispense 2 to 3 drops of mineral oil onto a cotton swab. Use the swab to apply a thin film of oil to the cone surface of each probe to improve heat transfer.

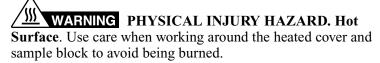


- 3. Repeat the steps in "Before You Run 384-Well Instrument Tests" on page 33.
- 4. Verify that the:
  - Probes are seated securely in the appropriate test wells.
  - Cables are connected securely to the ports.
  - Ribbon cable lies flat under the thermal cutout and is not crimped.
  - Heated cover is closed and locked down.
- 5. Repeat the steps in "Run the Test" on page 35.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

- 1. Follow the prompts to exit the test.
- 2. Wait for the sample block to reach room temperature (~25 °C), then remove the multiprobe module from the sample blocks.



- 3. Power off the digital thermometer.
- 4. Clean the oil off the multiprobe and sample blocks if you retested the system with oil.

### 384-Well Temperature Non-Uniformity Test

This test determines the overall temperature uniformity of the thermal cycler.

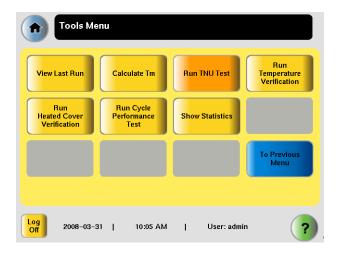
To pass the test, the overall temperature must be within  $\pm 0.5$  degrees Celsius of each set point temperature (95 °C and 60 °C) no later than 30 seconds after the set point temperature is changed.

WARNING PHYSICAL INJURY HAZARD. Hot Surface.

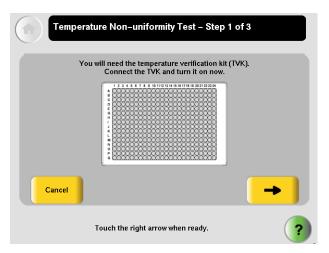
Use care when working around the heated cover and sample block to avoid being burned.

#### Run the Test

- 1. See "Before You Run 384-Well Instrument Tests" on page 33.
- 2. Power on the thermal cycler, then power on the digital thermometer.
- 3. Touch Tools Menu ▶ Run TNU Test.

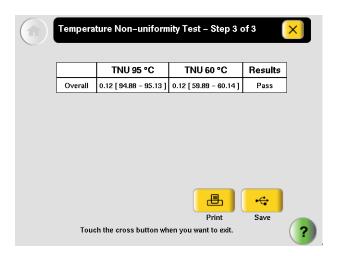


The first screen opens.



4. Follow the prompts in the touchscreen.

At the end of the TNU test, the results are displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the  $Veriti^{TM}$  Dx Thermal Cycler User Guide.

Press Print to print results.

#### Save Test Results

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file tnuEvents.txt. Test results are not stored on the thermal cycler.

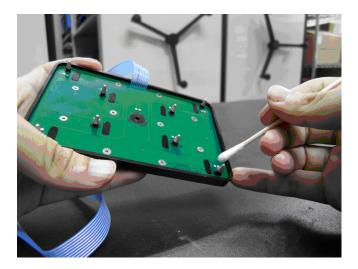
**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

# Repeat the Test (Optional)

#### If the test fails:

- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
  - Probe tips are not cracked or damaged.
- 2. Dispense 2 to 3 drops of mineral oil onto a cotton swab. Use the swab to apply a thin film of oil to the cone surface of each probe to improve heat transfer.

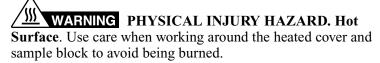


- 3. Repeat the steps in "Before You Run 384-Well Instrument Tests" on page 33.
- 4. Verify that the:
  - Probes are seated securely in the appropriate test wells.
  - Cables are connected securely to the ports.
  - Ribbon cable lies flat under the thermal cutout and is not crimped.
  - Heated cover is closed and locked down.
- 5. Repeat the steps in "Run the Test" on page 39.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

- 1. Follow the prompts to exit the test.
- 2. Wait for the sample block to reach room temperature (~25 °C), then remove the multiprobe module from the sample block.



- 3. Power off the digital thermometer.
- 4. Clean the oil off the multiprobe and sample blocks if you retested the system with oil.

#### 384-Well Heated Cover Verification Test

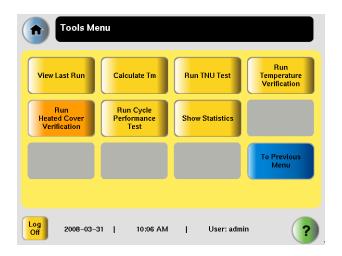
This test determines if the heated cover holds temperature at  $105 \pm 3$  °C.



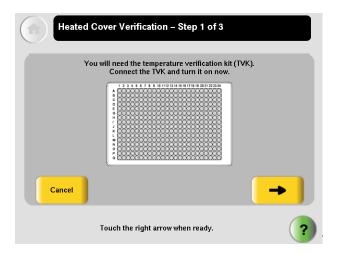
Use care when working around the heated cover and sample block to avoid being burned.

#### **Run the Test**

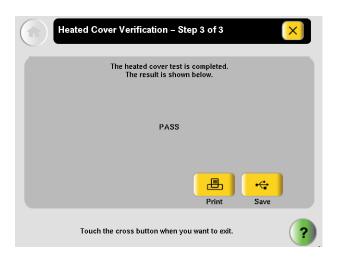
- 1. See "Before You Run 384-Well Instrument Tests" on page 33.
- 2. Power on the thermal cycler, then power on the digital thermometer.
- 3. Touch Tools Menu > Run Heated Cover Verification.



The first screen opens.



4. Follow the prompts in the touchscreen. When the test is finished, PASS or FAIL is displayed.



#### **Print Test Results**

You must have a printer connected and configured as described in the  $Veriti^{TM} Dx Thermal Cycler User Guide$ .

Press Print to print results.

#### Save Test Results

1. Connect your USB memory stick to the USB port on the front of the thermal cycler.



2. Touch **Save** to save the results to the USB drive.

**Note:** Results are saved on the USB only. The results are saved to the file heatedCover.txt. Test results are not stored on the thermal cycler.

**Note:** A USB drive may be necessary if you intend to save the results to document compliance and do not have a printer connected. Please follow your internal quality systems requirements.

3. Connect the USB memory stick to the USB port of the computer to transfer the test data.

# Repeat the Test (Optional)

#### If the test fails:

- 1. Verify that the:
  - Calibration of the TVK is up-to-date.
    - Probe tips are not cracked or damaged.
    - Cables are connected securely to the ports.
    - Ribbon cable lies flat under the thermal cutout and is not crimped.
    - Heated cover is closed and locked down.

2. Repeat the steps in "Run the Test" on page 43.

**IMPORTANT!** If the test fails again, contact Applied Biosystems (see "Obtaining support" on page 53).

#### **End the Test**

- 1. Power off the digital thermometer.
- 2. Wait for the sample block to reach room temperature (~25 °C), then remove the multiprobe module from the sample block.

WARNING PHYSICAL INJURY HAZARD. Hot Surface. Use care when working around the heated cover and sample block to avoid being burned.

## Maintaining the TVK



Applied Biosystems recommends that you have Alpha Technics recalibrate the Model 4690 digital thermometer and multiprobe module once a year.

The last calibration date is displayed:

- On the recalibration label on the back of the unit
- In the Report of Calibration, which came with your TVK
- In the display readout after you press ON

Before shipping the TVK for calibration, you must decontaminate the thermometer and multiprobe module, and complete a certificate of decontamination.

#### This appendix covers:

Maintain the TVK Components	48
Complete a Certificate of Decontamination	49
Recalibration Services	49

### Maintain the TVK Components

CAUTION

**CAUTION** Do not submerge the digital thermometer in



**CAUTION** Do not autoclave the thermometer or multiprobe

## Decontaminate the Thermometer

#### To decontaminate the digital thermometer:

- 1. Dampen a soft cloth with a diluted bleach solution (10% bleach, 90% water).
- 2. Wipe the outside surfaces of the thermometer. Avoid getting liquid onto the cable connection ports.

#### Decontaminate the Multiprobe Module

- 1. Gently wipe the probe tips with a cotton swab that has been moistened with bleach solution (10% bleach, 90% water).
  - **IMPORTANT!** Do not submerge the probe in bleach solution. Do not disassemble the multiprobe module.
- 2. Complete a Decontamination Certificate (see page 49) to prepare for recalibration.

#### Clean the LCD Lens

Use only a commercially available plastic-compatible lens cleaner.

Chemicals such as alcohol, acetone, and lacquer thinner damage the lens, the case, and the rubber key pad.

#### Replace the Battery

Battery life is ~20 hours when not connected to an instrument and ~15 hours when connected to an instrument communication port (RS-232 interface).

#### To replace the battery:

- 1. Place the thermometer front side down.
- 2. Remove the battery door at the bottom of the back side.

- 3. Remove the battery using your thumb or forefinger.
- 4. Install a new 9 V alkaline battery, such as Duracell MN1604 or equivalent.

### Complete a Certificate of Decontamination

A completed copy of the Certificate of Decontamination must be attached to the TVK and to the outside of the packing container in which you ship the TVK for calibration.

**Note:** Please complete a Certificate of Decontamination form by contacting Applied Biosystems (see "Obtaining support" on page 53).

#### **Recalibration Services**

#### TVK Support

A temperature verification kit is available for use to complete a customer-performed installation qualification protocol or annual user maintenance activities. Applied Biosystems recommends that you have the digital thermometer and multiprobe module calibrated once a year.

### To send the temperature verification kit equipment for recalibration:

- 1. Use the address or Fax information below to request a quote from Alpha Technics for a recalibration order:
  - Mail: Alpha Technics 17151 Gillette Avenue Irvine, CA 92614-5602 USA
  - Fax: (949)-271-2300
- 2. Ensure that the probe assembly has been decontaminated (see "Decontaminate the Multiprobe Module" on page 48).
- 3. Pack the digital thermometer and the probe assembly in the black case.
- 4. Create a shipping package with:

- Black case containing the digital thermometer and probe assembly
- Completed copy of the Certificate of Instrument Decontamination
- Payment for shipping/handling in one of the following forms:
  - Purchase order
  - Company letterhead with the words "verbal purchase order"
  - Visa/MasterCard credit card information
- Your address and contact information:
  - Billing address
  - Return shipping address
  - Name and phone number of a contact (person most familiar with the thermometer)

**Note:** If payment is not included with the package, Alpha Technics may bill for calibration fee plus an administrative fee. Please contact Alpha Technics directly for current rates.

5. Send the package freight prepaid to Alpha Technics at the address in step 1.

Safety

# B

### Instrumentation safety

### Symbols on instruments

# Environmental symbols on instruments

The following symbol applies to all Applied Biosystems electrical and electronic products placed on the European market after August 13, 2005.

Symbol	Description
	Do not dispose of this product as unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE).
	European Union customers: Call your local Applied Biosystems Customer Service office for equipment pick-up and recycling. See www.appliedbiosystems.com for a list of customer service offices in the European Union.

### General instrument safety



**WARNING!** PHYSICAL INJURY HAZARD. Using the instrument in a manner not specified by Applied Biosystems may result in personal injury or damage to the instrument.

# Operating the instrument

Ensure that anyone who operates the instrument has:

- Received instructions in both general safety practices for laboratories and specific safety practices for the instrument.
- Read and understood all applicable Safety Data Sheets (SDSs).

# Cleaning or decontaminating the instrument



**CAUTION!** Before using a cleaning or decontamination method other than those recommended by the manufacturer, verify with the manufacturer that the proposed method will not damage the equipment.

## Documentation and Support

#### Related documentation

Instruments that use the Multiprobe Temperature Verification Kits covered in this guide are supported by the following documents:

Instrument	Document Part Number
Veriti <sup>™</sup> Dx Thermal Cycler User Guide	4453697

### Obtaining support

#### Support information

For the latest services and support information for all locations, go to **www.appliedbiosystems.com**, then click the link for **Support**.

At the Support page, you can:

- Access worldwide telephone and fax numbers to contact Applied Biosystems Technical Support and Sales facilities.
- Search through frequently asked questions (FAQs)
- Submit a question directly to Technical Support
- Order Applied Biosystems user documents, SDSs (Safety Data Sheets), certificates of analysis, and other related documents
- · Download PDF documents
- · Obtain information about customer training

# Recalibration Information

See "Recalibration Services" on page 49 for information on recalibration of the Temperature Verification Kit.

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**Technical Resources and Support** 

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