DCA 2000®+
Analyzer

Operating Manual

Bayer

Bayer HealthCare LLC
Subsidiary of Bayer Corporation
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CE

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INTRODUCTION

The DCA 2000® System consists of:

- DCA 2000®+ Analyzer
- DCA 2000® Reagent Cartridges, Capillary Holders and Calibration Card
- DCA 2000® Controls
- Optical Test Cartridge

INTENDED USE

The DCA 2000®+ Analyzer quantitatively measures:

- the percent concentration of Hemoglobin A_{1c} in blood
- the concentrations of Microalbumin and Creatinine in urine

FEATURES

- easily calibrated using the bar code card provided with each reagent kit
- stores calibrations for up to two lots of reagent
- stores up to 16 test results
- stores up to 16 control results
- can be connected to a computer and/or printer

SPECIFICATIONS

Power Required:
Instrument Model No. 5031C: 100–240 VAC,
@ 0.4 amps
50/60 Hz

Dimensions/Weight:
Depth 27.2 cm (10.7 in) without power line cord
Width 24.1 cm (9.5 in)
Height 23.9 cm (9.4 in)
Weight 5 kg (11 lbs)

Ambient Operating Temperature:

15°C–32°C (15–32°C)—Hemoglobin A_{1c}

18°C–30°C (18–30°C)—Microalbumin/Creatinine

Relative Humidity Range:
10% – 90% RH (non-condensing)

NOTE: If an instrument I/O port is utilized, the cable used should be 100% shielded to guard against EMI and RFI. There should be continuity between the cable shield and connector shell that mates with the instrument.

Instrument Safety Design
The instument is for professional, IVD *in vitro* diagnostic use and must be used in the manner specified in the Operating Manual in order to provide the safety and standard performance standards specified. The instrument will operate safely in the conditions listed below; however, results will only be correct for the system specifications listed above:
- indoors
- 5°– 40°C (41°– 104°F)
- installation category II (IEC 1010.1)
- safety tested to comply to IEC 1010.1

HAZARDS

To alert you to potential electrical or operational hazards, warning and caution statements are provided where applicable. To ensure your safety, comply with all warning and caution statements.

SAFETY STANDARDS

Underwriters' Laboratories, Inc. (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 3101 and CSA-C22.2, No. 1010.1.

The instrument meets the provisions of the IVD Directive 98/79/EC (Oct./1998), which includes the EMC Directive 89/336 Amendment 92/31/EEC, and the Low Voltage Safety Directive 73/23/EEC.

WARRANTY INFORMATION

Contact your Authorized Bayer Representative for complete warranty information.

SYMBOLS USED

The following symbols are used throughout the product labeling for the DCA 2000® System (Instrument, Instrument Manual, Quick Reference Guide, DCA Reagent Labeling and Instructional inserts and the DCA Control packaging and instructional inserts).

REF Catalog number

IVD *In vitro* diagnostic device

LOT (**LOT**) Batch code

Consult operating instructions

(**EXP**) Use by

Warning/Attention: consult instructions for use

2°C Min. 8°C Max. Temperature limitations

Do not use spray

CONTROL NORMAL Normal control

CONTROL ABNORMAL Abnormal control

CONTROL HIGH High control

CONTROL LOW Low control

RECONSTITUTION FLUID Reconstitution fluid

High temperature part

Fuse

QTY Quantity

REAGENT CARTRIDGE Reagent cartridge

Menu/Next

Increase

Decrease

Enter

Escape

Manufactured by

EC REP Authorized representative

CALIBRATION CARD Calibration card

OPTICAL TEST CARTRIDGE Optical test cartridge

Do not freeze

U.S. PATENTS

6,043,043, 5,822,071, 5,610,073, 5,385,847, 5,372,948, 5,305,093, 5,272,093, 5,258,311, 5,220,161, 5,162,237, 5,151,369, 5,084,397, 4,990,075, 4,970,171, 4,968,472, 4,898,824, 4,847,209, 4,727,036, 4,658,022, 4,647,654, 4,629,692, D400,673.

UNPACKING, GETTING ACQUAINTED AND SET UP

UNPACKING

The DCA 2000® System arrives in one shipping carton.

Inspect the carton for shipping damage.

Unpack the carton.

- Use extreme care when unpacking and handling the instrument. The instrument contains sensitive electronic and optical parts.

Check each item for shipping damage.

- Report shipping damage to the representative of the carrier or to your Bayer HealthCare Sales Representative.

CARTON CONTENTS

*Some instruments will require a separately packed Installation Kit containing language specific instructional materials (Program Card, Operating Manual and Quick Reference Guide), Cleaning Kit, Air Filter Replacement Kit and the appropriate Power Cord.

1 DCA 2000®+ Analyzer

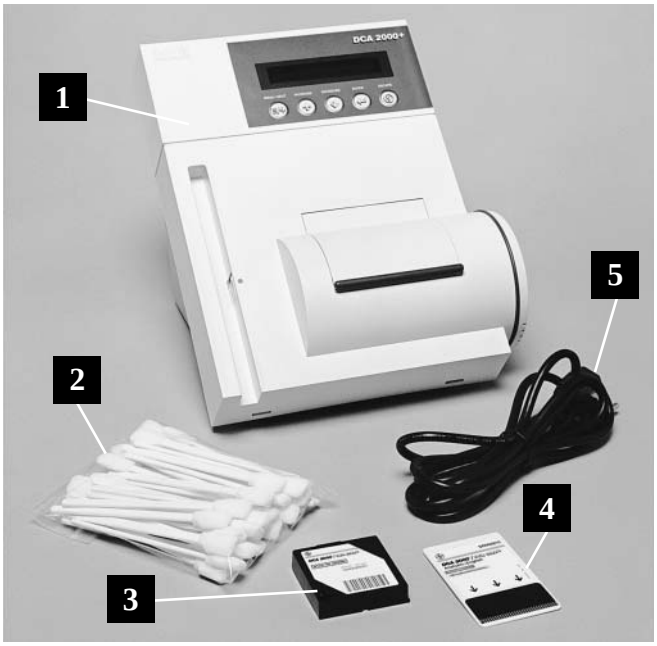
2 Cleaning Kit*

3 Optical Test Cartridge
(in instrument cartridge compartment)

4 Program Card*

5 Power Line Cord*

6 Other (not shown)
- Operating Manual*
- Replacement Fuse (stored in fuse holder located inside the instrument)
- Air Filter Replacement Kit*
- HbA_{1c} Quick Reference Guide*



Missing Items?. . . Contact the nearest Bayer HealthCare office or authorized distributor.

Unlock and then remove the optical test cartridge according to the following instructions.

1. Open the cartridge compartment door.

2. Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.

3. With your left hand, gently push the plastic tab on the cartridge to the right; this action releases (unlocks) cartridge.

4. Pull test cartridge out of compartment.

5. Put test cartridge aside for later use (page 2.17).

6. Make sure the cartridge return spring inside the cartridge compartment is intact (refer to Section 7, page 7.4, for information regarding this spring).

GETTING ACQUAINTED

DCA 2000®+ Analyzer FRONT PANEL

1 **Display**—indicates date, time, error messages, test results, procedural prompts, etc.

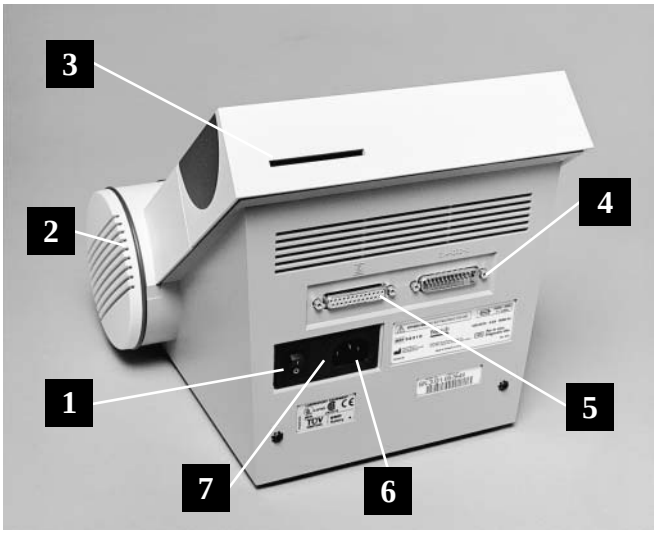
2 **Keys**—allow you to provide input for system set-up, menu items, etc.

3 **Reagent Cartridge Compartment Access Door**—covers and protects the reagent cartridge; closing door starts test timing (after a 5 second delay)

4 **Reagent Cartridge Compartment**—holds one reagent cartridge during sample analysis

5 **Bar Code Reader Window**—covers and protects the bar code reader

6 **Bar Code Track**—area where reagent cartridge, calibration card or control card is placed prior to scanning bar code



BACK PANEL

1 **Power Switch**—turns the power to the instrument ON and OFF

2 **Filter Holder**—contains replaceable air filter that prevents dust contamination

3 **Program Card Connector**—accepts the program card

4 **EIA-232-D Output**—accepts the plug for the computer interface cable

5 **Printer Output**—accepts the plug for the printer cable

6 **Power Cord Connector**—accepts the plug for connecting the power cord to the instrument

7 **Fuse Holder Compartment**—holds two fuses (one fuse is the replacement fuse)

AUDIBLE TONES

Beep—a short audible tone; indicates successful completion of an activity (such as scanning the bar code)

Buzz—a long audible tone; indicates an error condition or reminds you to perform an activity such as removing a reagent cartridge

SCREEN SAVER

When the instrument is not in use for more than 5 minutes, the display will change to a block shaped moving cursor. If the screen saver is on, press any key to return to a normal display before performing any other steps.

BLINKING COLON IN DISPLAYED TIME

The current time is displayed using a “blinking” colon. When the colon does not blink, the time displayed is the time the assay began.

WHEN TO TURN THE POWER OFF

When the instrument is not in use, the power may be turned OFF without loss of stored results. However, when the power is subsequently restored, a warm up period of one to eight minutes is required.

IMPORTANT: If power is turned OFF or interrupted while a test is in progress, the test must be discarded.

Turn the power off when inserting or removing the program card and whenever instructed to do so by the particular procedure (maintenance, etc.) in use.

SET UP

PLACING THE INSTRUMENT/ CONNECTING THE POWER CORD/ INSERTING PROGRAM CARD

IMPORTANT: Do not place the instrument where it would be subjected to extreme temperature variations, direct sunlight, excessive humidity or air current, or excessive particulate matter.

1. **Place** the instrument on a firm, level* surface near a properly grounded electrical outlet.

   *If the surface is not level, the instrument will not function properly.

2. **Set** power switch to OFF (O).

3. **Plug** in program card (contacts facing instrument; label side up).

   IMPORTANT: The program card can be damaged if inserted when the power is ON (I).

4. **Connect** the power cord to the power cord connector on the instrument.

5. **Plug** in power cord to a properly grounded outlet.

6. **Move** the instrument into place on the designated work space.
   - Allow at least 2 inches of air space between the wall (or other surface) and the back and right sides of the instrument (ventilation panels).

CHECKING TO VERIFY INSTRUMENT FUNCTIONS PROPERLY

Set the power switch to ON (I).

- After about 8 seconds, the software version is displayed.

```
SOFTWARE VERSION
E3.11/01.04
```

(displayed for about 8 seconds)

- Copyright information is displayed for 3 seconds.

```
COPYRIGHT 1991-2003
BY BAYER CORPORATION
```

- Then:

```
INITIALIZING
KEEP DOOR CLOSED
```

The instrument is checking internal optics and proper operation of mechanical features.

- Then:

```
INSTRUMENT SETUP
PRESS [←] TO CONTINUE
```

Instrument does not function? Above display(s) fail(s) to appear? . . . Contact the nearest Bayer HealthCare office or authorized distributor. Otherwise, continue with “Viewing Factory Settings” (next).

VIEWING FACTORY SETTINGS—
Upon Receipt of a New or Factory-Serviced Instrument

Only upon receipt of a new or factory-serviced instrument, the following display appears (just after "INITIALIZING / KEEP DOOR CLOSED").

```
   INSTRUMENT SETUP
PRESS [←] TO CONTINUE
```

Before the instrument can analyze samples for the *first* time, it is necessary for you to either accept or change factory settings.

- **To view factory settings, press** ↵.

```
1 1 4 0 0
T D L C P
```

Line 1 shows the factory setting numbers.
Line 2 shows the factory setting options.

The options in Line 2 correspond directly to the number above them in Line 1.

The following chart defines the factory setting *now active* for each available option.

	FACTORY SETTING	
OPTION	**NUMBER**	**DEFINITION**
T (Time)	**1**	AM/PM
D (Date)	**1**	Month/Day/Year
L (Labels displayed with results)	**4**	Time Assay Began; Sequence Number (reset daily, automatically at midnight)
C (Controls)	**0**	Use of DCA 2000 Controls, only
P (Port)	**0**	Computer Port is turned Off (O)

Before deciding to accept factory settings, review the chart under OPTIONS, on the following pages.

**(This page left blank on purpose.
Intended for future use)**

OPTIONS

All available settings are shown in the following chart.

- Review this chart **before** you decide to accept or change the factory setting for each option. An asterisk (*****) marks factory settings.

OPTION	SETTING NUMBER	DEFINITION OF SETTING NUMBER
T (Time Format)	**1***	**AM/PM***
	2	24 hour format
D (Date Format)	**1***	**Month/Day/Year***
	2	Day • Month • Year
	3	Year – Month – Day
L (Labels displayed with results)	0	No labels
	1	Sequence number (reset daily, automatically at midnight)
	2	Sequence number (continuous, 001 – 999)
	3	Time assay began
	4*	**Time assay began; sequence number (reset daily, automatically at midnight)***
	5	Time assay began; sequence number (continuous, 001 – 999)
C (Controls)	**0***	**DCA 2000 Controls, only*** • The control *bar code* card enables the instrument to label the control result. The control result is then stored in the control memory (separate from patient results).
	1	**ANY CONTROL** • If using controls other than DCA 2000 Controls, use the MENU (just prior to *each* control assay) to label the control result. The control result, once labeled, is stored in the control memory. **IMPORTANT: When the MENU is used to label control results, *only* the *next* sample analyzed is labeled (and stored in the control memory).**

OPTION	SETTING NUMBER	DEFINITION OF SETTING NUMBER
P (Computer Port Configuration)	**0***	**OFF*** Computer port is OFF.
	2	ON Computer port is ON. All subsequent results will be transferred to the computer.
NOTE: The options below (baud rate through modem control) are selectable only if the computer port is turned ON.		
B (Baud Rate)	**9***	**9600 bps***
	4	4800 bps
	2	2400 bps
	1	1200 bps
	3	300 bps
U (Data Bits)	**8***	**8 bits***
	7	7 bits
V (Parity)	**0***	**None***
	1	Odd
	2	Even
W (Stop Bits)	**1***	**1***
	2	2
X (Xon—Xoff Protocol)	**0***	**Off***
	1	On
Y (Block Transfer)	0	Off
	1*	**On***
Z (Modem Control)	**0***	**Off***
	1	On

ACCEPTING FACTORY SETTINGS

If the factory setting for each option is acceptable, **press** ↵. If **not,** see below. If acceptable, you are now ready to set the current date and time. Refer to instructions on page 2.14.

CHANGING FACTORY SETTINGS

Before attempting to change factory settings, read the following information on "Keys" and "Cursor."

Keys:

- ≡/→ —*moves* the cursor* (underline) under setting you desire to change
- ↑ ↓ —*cycles* through each setting choice, such as AM/PM or 24 HR for time format
- ↵ —*accepts* all displayed settings (for time, date, labels, controls and computer port) and immediately advances to "SET DATE/TIME" display.

  Important: If you (prematurely) press ↵ before you are finished changing factory settings, refer to Section 3, MENU for instructions on how to access "INSTRUMENT SETUP?"

  HINT: Don't press ↵ until all settings on Line 1 reflect your choices.

****Cursor***

The cursor is the *underline* in the display. The cursor shows you which setting is ready for change.

```
1 1 4 0 0
TIME FORMAT        AM/PM
```

Reminder: If the *underlined* number is acceptable, press ≡/→. The cursor then moves horizontally (right) to the next number on line 1 while line 2 defines the corresponding option and setting choice. *Only when* all numbers shown in Line 1 are acceptable, press ↵.

*The cursor does not move in reverse (left). To change a number to the left of the cursor, repeatedly press ≡/→ until the cursor returns to the desired location.

DISPLAY	WHAT YOU DO
	1. **Press** ≡/→ (places a cursor under factory setting for first option, TIME FORMAT).
	2. **Press** ↑ **and** ↓ to cycle through choices for TIME FORMAT. When the desired choice is displayed, **press** ≡/→ (moves cursor under setting for next option).

DISPLAY

```
1 1 4 0 0
DATE FORMAT   MM/DD/YY
```

```
1 1 4 0 0
LABELS USED TIME/DAILY
```

```
1 1 4 0 0
CONTROLS      DCA 2000
```

```
1 1 4 0 0
COMPUTER PORT OFF
```

WHAT YOU DO

3. **Press ↑ and ↓** to cycle through choices for DATE FORMAT.

   When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).

4. **Press ↑ and ↓** to cycle through choices for LABELS.

   When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).

5. **Press ↑ and ↓** to cycle through choices for CONTROLS.

   When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).

6. **Press ↑ and ↓** to cycle through choices for COMPUTER PORT.

   If you have selected "0" for COMPUTER PORT OFF:

   - Check to make sure *all* numbers on Line 1 reflect your choices.

     Reminder: Options Chart is found on pages 2.8–2.9.
   - **Press** ↵ (accepts all settings and advances display to SET DATE/TIME?)
   - Continue with instructions on page 2.14, "Setting the Date and Time."

   If you have selected "2" for COMPUTER PORT ON:

   - Continue with instructions on page 2.12, "Changing Factory Settings For: Computer Port 'ON' Option."

CHANGING FACTORY SETTINGS FOR: COMPUTER PORT "ON" OPTION

Refer to the chart on page 2.9 for Computer Port Configurations.

NOTE: The first four numbers in each display (below) are factory settings. The display on your instrument may be different for the first four numbers (depending on whether the first four factory settings were accepted or changed).

DISPLAY	WHAT YOU DO
1 1 4 0 2 9801110 COMPUTER PORT ON	1. **Press** ⇆ (places a cursor under factory setting for first computer port option).
1 1 4 0 2 9801010 BAUD RATE 9600	2. **Press** ↑ **and** ↓ to cycle through choices for BAUD RATE. When the desired choice is displayed, **press** ⇆ (moves cursor under setting for next option).
1 1 4 0 2 9801110 DATA BITS EIGHT	3. **Press** ↑ **and** ↓ to cycle through choices for DATA BITS. When the desired choice is displayed, **press** ⇆ (moves cursor under setting for next option).
1 1 4 0 2 9801010 PARITY NONE	4. **Press** ↑ **and** ↓ to cycle through choices for PARITY. When the desired choice is displayed, **press** ⇆ (moves cursor under setting for next option).

DISPLAY	WHAT YOU DO
1 1 4 0 2 9821010 STOP BITS ONE	5. **Press ↑ and ↓** to cycle through choices for STOP BITS. When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).
1 1 4 0 2 9821010 XON/XOFF OFF	6. **Press ↑ and ↓** to cycle through choices for XON/XOFF. When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).
1 1 4 0 2 9821000 BLOCK XFER OFF	7. **Press ↑ and ↓** to cycle through choices for BLOCK TRANSFER. When the desired choice is displayed, **press** ⇥ (moves cursor under setting for next option).
1 1 4 0 2 9801110 MODEM OFF	8. **Press ↑ and ↓** to cycle through choices for MODEM. • **Check** to make sure all numbers on Line 1 represent desired settings. • **Press** ↵ (accepts all settings and advances display to SET DATE/TIME).

SETTING THE DATE AND TIME

Use the following keys:

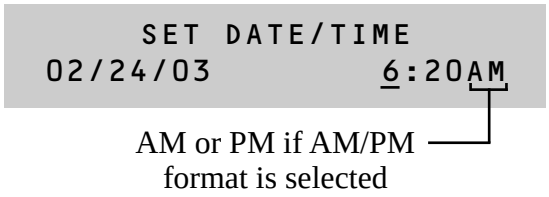
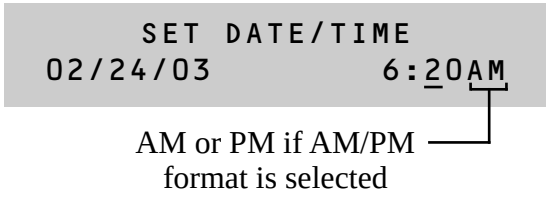
↑ and ↓ To *cycle* through each available *setting* (e.g., digits for day/month/year and time, or AM/PM)

→ To *move cursor under setting you desire to change* (e.g., "2" in display below is marked by cursor and indicates "26" is ready for change)

```
      SET DATE/TIME
02/24/03         6:20AM
```

↵ To *set* the displayed date and time in the instrument

DISPLAY	WHAT YOU DO
	The display on your instrument is displaying the date and time in your chosen format.
	1. **Press ↑ or ↓** until the correct *two* digits are displayed. **Press →**.
	2. **Press ↑ or ↓** until the correct *two* digits are displayed. **Press →**.
	3. **Press ↑ or ↓** until the correct *two* digits are displayed. **Press →**.

DISPLAY	WHAT YOU DO
	4. **Press ↑ or ↓** until the correct *two* digits are displayed. **Press →/≡.**
	5. **Press ↑ or ↓** until the correct *two* digits are displayed. • **If 24 HR format is selected,** press ↵. • **If AM/PM format is selected,** press →/≡. Then press ↑ or ↓ until the correct choice is displayed. Press ↵.

SETTING CREATININE CONCENTRATION UNITS (Microalbumin/Creatinine Assay ONLY)

The concentration units reported for creatinine are selectable between “mg/dL” and “mmol/L”. The factory setting is “mg/dL”.

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM	1. **Press** ⏎.
SET CREATININE UNITS? mg/dL	2. Repeatedly **press** ⏎, until “SET CREATININE UNITS?” is displayed.
SET CREATININE UNITS mg/dL	3. **Press** ↵. This places a cursor below the “m” in “mg/dL”, and the question mark disappears.
SET CREATININE UNITS mmol/L	4. **Press** ↑ **or** ↓ to display “mmol/L” or “mg/dL”.
SET CREATININE UNITS? mmol/L	5. **Press** ↵ to accept desired units.
	6. **Press** ⏎ to exit the MENU.

RUNNING THE OPTICAL TEST CARTRIDGE (Standard 1) —Prior to Analyzing Samples for the First Time

The provided optical test cartridge allows you to monitor the performance of the optical system over time. (The optical test cartridge holds the cartridge return spring in place and also simulates the mass of a reagent test cartridge.)

Before samples are analyzed for the first time, run the optical test cartridge.

IMPORTANT!
Keep a permanent record of the results obtained (i.e., Mean Transmittance, Standard Deviation and Drift).* These initial values will be used for comparison, as in control charting (and also to isolate the cause of an instrument malfunction in conjunction with instructions provided by our Bayer HealthCare Customer Service Department Representative).

*It is recommended that you record the results on the page provided in the appendix of this manual.

After the optical test cartridge is run initially, it is recommended that the optical test cartridge be run:

- quarterly
- after cleaning the cartridge compartment
- after changing the air filter
- when instructed to do so by our Customer Service Representative

NOTE: Refer to Section 7, page 7.6, Instrument Care and Routine Maintenance, for information regarding the comparison of initial values obtained for your instrument with values obtained thereafter.

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM	1. **Locate** the bar code on the optical test cartridge. 2. **Hold** the cartridge so that the bar code faces right. 3. **Insert** the cartridge (above dot on instrument) into the bar code track. 4. **Quickly** (within 1 second) and **smoothly, slide** the cartridge down past the dot. A beep sounds to signal a successful scan. • If no beep sounds, repeat the procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.
RUN STANDARD 1?	5. **Press** ↵.

DISPLAY

```
    STANDARD 1
LOAD, CLOSE DOOR
```

```
 PROCESSING STANDARD
S1   6 MIN    10:02AM
```

6 MIN = total test time

After 1 minute:

```
1.0001 T    0.00012 SD
S1      5 MIN  10:03AM
```

Upon completion of test:

```
1.0001 T 0.00012 SD
S1       0.00387 DRIFT
```

WHAT YOU DO

6. **Open** the cartridge compartment door.
7. **Hold** the optical test cartridge so that the bar code faces right.

   Insert the cartridge into the compartment until a subtle snap is heard/felt.

   HINT: The cartridge is designed to fit only one way into the instrument.
8. **Close** door.
9. **Record** the displayed results in the blanks provided on the last page of this manual (appendix).
10. **Remove** cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the plastic tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull cartridge out of compartment.

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

MENU

The **MENU** consists of up to nine (9) items listed below. Note that item number two and item number nine are optional (may or may not be active—depends upon choices made during "Instrument Setup").

1 RECALL PREVIOUS TESTS?

2 SET SEQUENCE NUMBER? (optional)

3 RECALL CONTROL RESULTS?

4 VIEW CALIBRATION STATUS?

5 SET DATE/TIME?

6 INSTRUMENT SETUP?

7 SET CREATININE UNITS?

8 INSTRUMENT TEST?

9 RUN CONTROL? (optional)

To **access** the MENU (and display the first item):

- Press ⊜

To **display** each additional item:

- Repeatedly press ⊜

To **select** the item displayed:

- Press ↵

To **exit** the MENU:

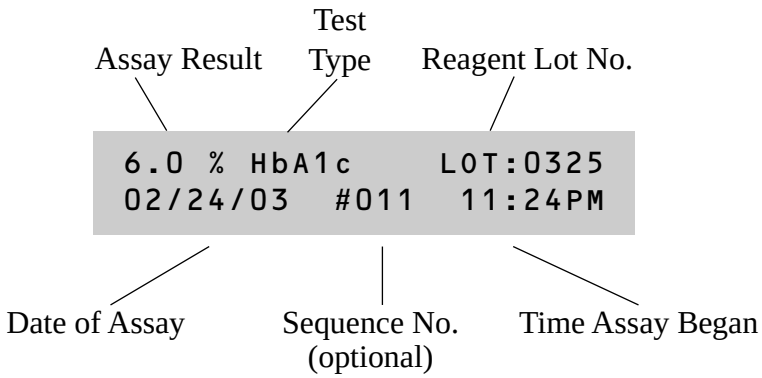
- Press ⊛

Information and instructions for each MENU item are provided in this section.

1 RECALL PREVIOUS TESTS?

- Up to 16 test results can be recalled (and printed if a printer is in use).

Recalled Test Result Format



DISPLAY	WHAT YOU DO
WAIT: WARMING UP 02/24/03 2:09PM	1. Press ⏎.
OR	
READY: SCAN BAR CODE 02/24/03 2:09PM	
OR	
TEST IN PROGRESS #001 6 MIN 10:15AM	(Test in progress is not aborted when MENU is pressed.)

DISPLAY

```
RECALL PREVIOUS TESTS?
```

```
6.0 % HbA1c     LOT:0325
02/24/03  #011   11:24PM
```

(example)

OR

```
A=55.0mg/L      LOT:0325
09/13/02  #010   10:24
```

(example)

OR

```
C=72.1mg/dL     LOT:0325
09/13/02  #010   10:24PM
```

(example)

OR

```
A/C=76          LOT:0325
02/24/03  #010   10:24PM
```

(example)

```
NO MORE RESULTS STORED
    IN INSTRUMENT
```

(after all results are displayed)

WHAT YOU DO

2. Press ↵.
   - The test result for the sample most recently assayed is displayed first.

3. Press ≡/→ to recall up to 16 test results.

NOTES:

- To print the displayed test result, press ↵ (if a printer is in use).
  - –If ↵ is pressed for more than 3 seconds, all stored test results are printed.
- To return display to "RECALL PREVIOUS TESTS?," press ▼ *once* anytime during recall of test results.
- To exit the MENU, press ▼ *twice*.
- Albumin (A), creatinine (C), and the albumin/creatinine ratio (A/C) results for the same specimen are shown sequentially on separate displays, and are labeled with the same sequence number (optional) and date/time.

This display is retained until:

- a calibration card bar code is read
- ≡/→ or ▼ is pressed
  - –≡/→ is pressed, the display returns to the first test result previously recalled (this is the result for the most recent sample assayed).
  - –If ▼ is pressed once, the display returns to "RECALL PREVIOUS TESTS?"
  - –If ▼ is pressed twice, you exit the MENU.

2 SET SEQUENCE NUMBER? (optional)

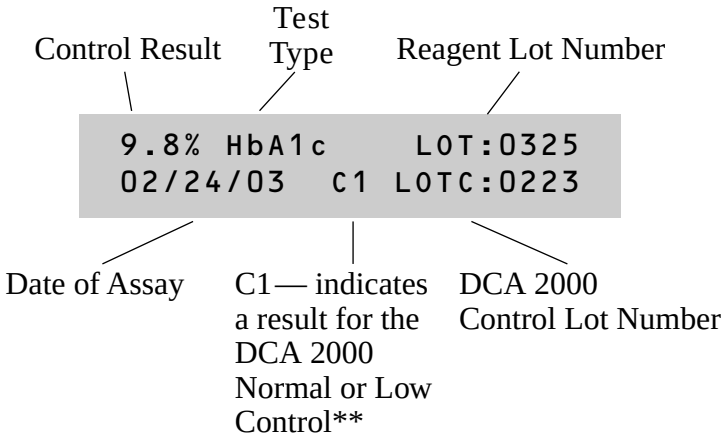
DISPLAY	WHAT YOU DO
WAIT: WARMING UP 02/24/03 2:09PM *OR* READY: SCAN BAR CODE 02/24/03 2:09PM *OR* TEST IN PROGRESS #001 6 MIN 10:15AM	1. Press (≡/→). 2. Press (≡/→). ***NOTE:*** If a sequence number is selected while a test is in progress, the sequence number for the test in progress is changed to the newly selected sequence number.
SET SEQUENCE NUMBER?	3. Press (↵).
SET SEQUENCE NUMBER #009	4. **Press (↑) or (↓)** to select the digit above the cursor. Press (≡/→) to move cursor (right) to next digit. • **Repeat procedure** to select second and third digits. Press (↵).
SET SEQUENCE NUMBER?	5. To exit the MENU, press (▼). To display the next MENU item, press (≡/→).

3 RECALL CONTROL RESULTS?

- Up to 16 control results can be stored and recalled (and also printed if a printer is in use).
- Upper case "C" in display indicates a result for a DCA 2000® Control.
- Lower case "c" in display indicates a result for a control *other than* a DCA 2000 Control*.
- A control lot number is displayed *only* for DCA 2000 Controls.

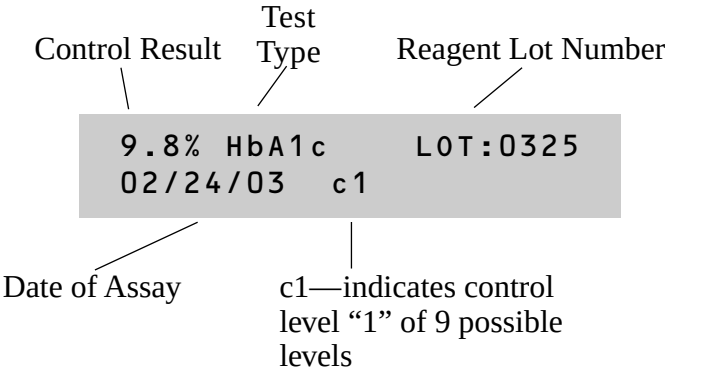
Format for Recalled Results (examples)

DCA 2000 CONTROLS, ONLY



**Cl—is replaced with "C2" for the DCA 2000 Abnormal or High Control and "C1out" or "C2out" for an out-of-range control

ALL CONTROLS EXCEPT DCA 2000 CONTROLS*



*unless a DCA 2000 Control was run without scanning the DCA 2000 Control bar code card provided with the control kit

— continued on next page

Recall Control Results

DISPLAY	WHAT YOU DO
WAIT: WARMING UP 02/24/03 2:09PM	1. Press (≡/→).
OR	2. Repeatedly press (≡/→), until "RECALL CONTROL RESULTS?" is displayed.
READY: SCAN BAR CODE 02/24/03 2:09PM	
OR	
TEST IN PROGRESS #001 6 MIN 10:15AM	(Test in progress is not aborted.)
RECALL CONTROL RESULTS?	3. Press (↵). • The control result for the control most recently assayed is displayed first.

DISPLAY

```
9.8% HbA1c      LOT:0325
02/24/03  C1  LOTC:0223
```

(example)

OR

```
A=24.6mg/L      LOT:0105
02/24/03  C2  LOTC:0345
```

(example)

OR

```
C=54.1mg/dL     LOT:0105
02/24/03  C2  LOTC:0345
```

(example)

Reminder: Upper case "C" indicates result for a DCA 2000® Control

```
NO MORE CONTROLS STORED
     IN INSTRUMENT
```

(after all control results are displayed)

WHAT YOU DO

4. Press ⇶ to recall up to 16 control results.

NOTES:

- To print the control result, press ↵ (if a printer is in use).
  – If ↵ is pressed for more than 3 seconds, all stored control results are printed.
- To return display to "RECALL CONTROL RESULTS," press ▼ *once* anytime during recall of results.
- To exit the MENU, press ▼ twice.
- Albumin (A) and creatinine (C) for the same control are shown sequentially on separate displays, and are labeled with the same date.

This display is retained until:

- a bar code is scanned
- ⇶ or ▼ is pressed
  – If ⇶ is pressed, the display returns to the first control result previously recalled (this is the result for the most recent control assayed).
  – If ▼ is pressed *once*, the display returns to "RECALL CONTROL RESULTS?"
  – If ▼ is pressed *twice*, you exit the MENU.

4 VIEW CALIBRATION STATUS?

The instrument stores up to **two** calibrations for each DCA 2000 Reagent Test. The two calibrations must be for two *different* lot numbers.

DISPLAY	WHAT YOU DO
WAIT: WARMING UP 02/24/03 2:09PM *OR* READY: SCAN BAR CODE 02/24/03 2:09PM *OR* TEST IN PROGRESS #001 6 MIN 10:15AM	1. Press (≡/→). (A test in progress is not aborted.)
	2. Repeatedly press (≡/→), until "VIEW CALIBRATION STATUS?" is displayed.
VIEW CALIBRATION STATUS?	3. Press (↵). • The calibration status for the most recent calibration is displayed first.

DISPLAY

(example)

OR

(example)

(after all stored
calibrations are displayed)

WHAT YOU DO

4. Press (≡/→) to recall status of each calibration stored.

NOTES:

- To return display to "VIEW CALIBRATION STATUS?," press (▼) *once* anytime during calibration status recall.
- To exit the MENU, press (▼) *twice.*

This display is retained until:

- a bar code is scanned
- (≡/→) or (▼) is pressed
  - – If (≡/→) is pressed, the display returns to the first calibration status previously recalled (this is the status for the most recent calibration).
  - – If (▼) is pressed *once*, the display returns to "VIEW CALIBRATION STATUS?"
  - – If (▼) is pressed *twice*, you exit the MENU.

5 SET DATE/TIME?

Use the following keys:

↑ and ↓ To *cycle* through each available *setting* (e.g., digits for day/month/year and time, or AM/PM)

≡/→ To *move cursor under setting you desire to change* (e.g., "2" in display below is marked by cursor and indicates "26" is ready for change)

```
     SET DATE/TIME
02/24/03        6:20AM
```

↵ To *set* the displayed date and time in the instrument

DISPLAY	WHAT YOU DO

`WAIT:WARMING UP`
`02/24/03 2:09PM`
OR
`READY: SCAN BAR CODE`
`02/24/03 2:09PM`
	1. Press ≡/→.
	2. Repeatedly press ≡/→ until "SET DATE/TIME?" is displayed.

`SET DATE/TIME?` `02/24/03 6:19AM`	3. Press ↵.

DISPLAY	WHAT YOU DO
SET DATE/TIME 02/24/03 6:20AM	The display on your instrument is displaying the date and time in your chosen format.
	4. **Press** ↑ **or** ↓ until the correct *two* digits are displayed. **Press** ⇥.
SET DATE/TIME 02/24/03 6:20AM	5. **Press** ↑ **or** ↓ until the correct *two* digits are displayed. **Press** ⇥.
SET DATE/TIME 02/24/03 6:20AM	6. **Press** ↑ **or** ↓ until the correct *two* digits are displayed. **Press** ↵. The cursor will move back to the first digit of the date
	7. **Pres**s ⇥ to advance the cursor to the time setting.
SET DATE/TIME 02/24/03 6:20AM AM or PM if AM/PM format is selected	8. **Pres**s ↑ **or** ↓ until the correct *two* digits are displayed. **Press** ⇥.
SET DATE/TIME 02/24/03 6:20AM AM or PM if AM/PM format is selected	9. **Press** ↑ **or** ↓ until the correct *two* digits are displayed. **Press** ↵.
	10. • **If 24 HR format is selected,** press ⇩. • **If AM/PM format is selected,** press ⇥ to advance cursor to the AM/PM setting. **Press** ↑ or ↓ until the correct choice is displayed. **Press** ↵. **Press** ⇩.

**(This page left blank on purpose.
Intended for future use.)**

6 INSTRUMENT SETUP?

DISPLAY	WHAT YOU DO
WAIT: WARMING UP 02/24/03 2:09PM *OR* READY: SCAN BAR CODE 02/24/03 2:09PM *OR* TEST IN PROGRESS #001 6 MIN 10:15AM	1. Press ⏎/→. 2. Repeatedly press ⏎/→, until "INSTRUMENT SETUP?" is displayed. (Test in progress is not aborted.)
INSTRUMENT SETUP?	3. Press ↵.
1 1 4 0 0 T D L C P If computer port is Off. *OR* 1 1 4 0 2 9801010 T D L C P BUVWXYZ If computer port is On.	4. **Refer** to the chart (pages 2.8 and 2.9) to determine the definition of each number and abbreviated option appearing on your instrument's display. Then continue with step 5 on page 3.14.

INSTRUMENT SETUP DISPLAY OPTIONS/SETTINGS continued

DISPLAY	WHAT YOU DO
1 1 4 0 0 T D L C P If computer port is Off. *OR* 1 1 4 0 2 9801010 T D L C P BUVWXYZ If computer port is On.	5. **Press** ⏎ (places a cursor under the setting for the first option, TIME FORMAT).
1 1 4 0 0 TIME FORMAT AM/PM If computer port is Off. *OR* 1 1 4 0 2 9801010 T D L C P BUVWXYZ If computer port is On.	6. **Press ↑ and ↓** to cycle through choices for TIME FORMAT. When the desired choice is displayed, **press** ⏎ (moves cursor under setting for next option).
1 1 4 0 0 T D L C P If computer port is Off. *OR* 1 1 4 0 2 9801010 T D L C P BUVWXYZ If computer port is On.	7. **Repeat step 6** to change settings for each option as desired.

7 SET CREATININE UNITS

(Microalbumin/Creatinine Assay ONLY)

The concentration units reported for creatinine are selectable between “mg/dL” and “mmol/L”. The factory setting is “mg/dL”.

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM	1. **Press** ⊜.
SET CREATININE UNITS? mg/dL	2. Repeatedly **press** ⊜, until “SET CREATININE UNITS?” is displayed.
SET CREATININE UNITS mg/dL	3. **Press** ↵. This places a cursor below the “m” in “mg/dL”, and the question mark disappears.
SET CREATININE UNITS mmol/L	4. **Press** ↑ **or** ↓ to display “mmol/L” or “mg/dL”.
SET CREATININE UNITS? mmol/L	5. **Press** ↵ to accept desired units.
	6. **Press** ⊙ to exit the MENU.

8 INSTRUMENT TEST?

This menu item is to be used *only* under the guidance of our Bayer HealthCare Customer Service Department Representative.

- Using this menu item allows you and our Customer Service Representative to determine existing problems with the keyboard, display, bar code reader, printer port, memory, and computer port functions.

9 RUN CONTROL? (optional)

- Available only if selected via "INSTRUMENT SETUP" procedure
- Marks the control result with a lower case "c"
  - lower case "c" indicates controls other than DCA 2000 Controls (unless a DCA 2000 Control was analyzed without scanning the control bar code card provided with the control kit)

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM	1. Press (≡/→).
	2. Repeatedly press (≡/→) until "RUN CONTROL?" is displayed.
RUN CONTROL?	3. Press (↵).
SET CONTROL NUMBER c1	4. Press (↑) or (↓) until the desired control number (choices 1–9) is displayed. Press (↵).
SCAN BAR CODE 02/24/03 c1 11:10AM	5. Follow instructions in Section 4, page 4.3, or Section 5, page 5.4, under "Preparing Patient Samples and Controls."

OPERATING INSTRUCTIONS — HEMOGLOBIN A_{1c}

NOTE: The instructions in this section are for use after "INSTRUMENT SETUP" has been performed (a one time requirement upon receipt of a new or factory-serviced instrument).

STEP 1: Turning the Power ON

DISPLAY	WHAT YOU DO
	1. **Set** the power switch to ON. **IMPORTANT: The program card must be inserted or removed only when the power switch is set to OFF. If the card is inserted when the power is ON, the card can be permanently damaged.**

After about 8 seconds:
`SOFTWARE VERSION`
`E3.11/01.04`
(displayed for 8 seconds)	

`COPYRIGHT 1991–2003`
`BY BAYER CORPORATION`
(displayed for 3 seconds)	

`INITIALIZING` `KEEP DOOR CLOSED`	
`WAIT: WARMING UP` `02/24/03 2:09PM`	2. OPTIONAL: While the instrument is warming up (usually 1 – 2 minutes but can take up to 8 minutes), you may access certain MENU items. Refer to Section 3 for instructions. *Reminder:* Current time is denoted by "blinking colon." Time assay began is denoted by stationary colon.

`READY: SCAN BAR CODE`
`02/24/03 2:09PM`
(a beep is heard)	

STEP 2: Calibration

When to Calibrate:
Calibrate the System for each *new lot number* of reagent cartridges.

Materials Required:
- Calibration Card (provided in DCA 2000® Hemoglobin A_{1c} Reagent Kit)

NOTES:
- The instrument stores up to *two* calibrations for the DCA 2000 Hemoglobin A_{1c} Reagent Test. The two calibrations must be for *two different lot numbers.*
- The calibration stored in the instrument *first* is deleted when a calibration card for a third lot number is scanned.

DISPLAY

```
READY: SCAN BAR CODE
02/24/03          2:09PM
```

OR

Any result or menu display
as long as testing is not in progress.

```
CALIBRATION DATA SAVED
LOT:0132          HbA1c
```

(After 5 seconds, the display returns to the display in effect prior to calibration.)

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the calibration card.
3. **Hold** the card so that the bar code faces right.
4. **Insert** the card into the bar code track (above dot). **Hold** card gently against the right side of track.

5. **Quickly** (within 1 sec.) **and smoothly, slide** the card down past the dot.

   A beep sounds to signal a successful scan.
   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.

STEP 3: Preparing Patient Samples and Controls

Materials Required:

- DCA 2000 Hemoglobin A_{1c} Reagent Kit
- Patient Sample, DCA 2000® Hemoglobin A_{1c} Control Kit or other control
- Lint-free tissue
- Clock or timer

OPENING THE FOIL PACKAGE (Containing Reagent Cartridge)

IMPORTANT: Do not use scissors to cut open foil package. Scissors can damage the reagent cartridge, the flexible plastic pull-tab on the cartridge or the sack containing desiccant.

1. Remove one foil package (containing a reagent cartridge) from storage.
2. Refer to "Recommended Procedures for Handling Reagent Cartridges" in the DCA 2000 Hemoglobin A_{1c} Reagent Kit package insert for instructions on how and when to open foil package.

INSPECTING THE CONTENTS OF THE FOIL PACKAGE

The foil package contains:

1. reagent cartridge with flexible pull-tab and bar code label
2. small sack (filled with desiccant)

When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.

Discard the reagent cartridge if:

- the cartridge is damaged
- the flexible pull-tab is loose or missing
- the small sack (desiccant) is missing or open
- loose desiccant particles are found inside the foil package
  (refer to Service Information, Section 9)

CAPILLARY HOLDER

Unused capillary holders may be saved and used with any lot of Hemoglobin A_{1c} reagent cartridges.

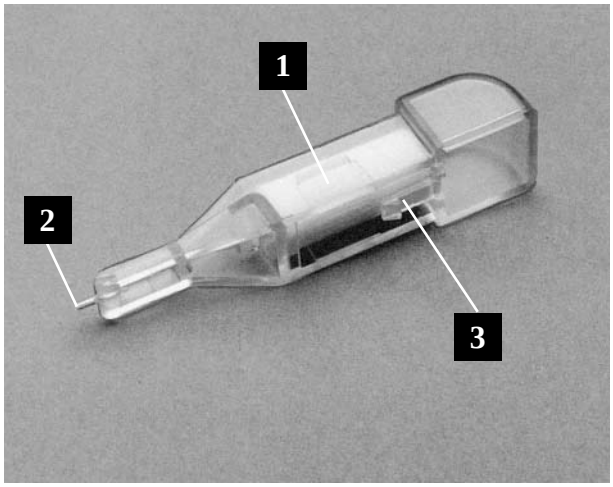
1. Open plastic wrap by tearing wrap at serrated edge.

2. Inspect the capillary holder for the presence of:

   1 absorbent pad

   2 glass capillary

   3 latching mechanism



If the capillary holder is missing any of the above parts, discard the capillary holder (refer to Service Information, Section 9).

FILLING THE CAPILLARY WITH WHOLE BLOOD

(Instructions for filling capillary with *control* sample are found in the DCA 2000 Hemoglobin A_{1c} Control package insert.)

IMPORTANT PLEASE READ CAREFULLY:

Once the capillary is filled with sample, analysis *must begin* within 5 minutes. There is no need to rush. Five minutes allows enough time for proper completion of procedures.

Within 5 minutes *after* filling glass capillary (step 1, next page), complete steps 2-5 (page 4.7) *and* one of the following, whichever applies.

EITHER

- For a Patient Sample or any control other than DCA 2000 Control — Steps 1 through 9 under "WHAT YOU DO" on pages 4.8-4.9

OR

- For DCA 2000 Control — Steps 1 through 14 under "WHAT YOU DO" on pages 4.12-4.13

IMPORTANT: If sample analysis does not begin **within *5 minutes*** after filling glass capillary, discard capillary. If capillary is in the reagent cartridge, discard both capillary and reagent cartridge.

***WARNING!* POTENTIAL BIOHAZARD**

All products or objects which come into contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

The user should follow the recommendations for prevention of blood-borne transmissible diseases in healthcare settings, as recommended for potentially infectious human blood specimens in National Committee for Clinical Laboratory Standards, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissues: Approved Guideline. NCCLS Document M29-A [ISBN 1-56238-339-6] NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 1997. This document has complete information on the topic of user protection and can be used as background material for instruction.

***VAROITUS!* MAHDOLLINEN TARTUNTAVAARA**

Terveydenhoitohenkilökunnan, joka käyttää tätä laitetta useiden ihmisten tutkimiseen, tulee ottaa huomioon, että kaikki tuotteet, jotka joutuvat kosketukseen ihmisveren kanssa, ovat myös puhdistuksen jälkeen mahdollisia viirustartuntalähteitä.

Tartuntojen välttämiseksi suosittelemme laboratorion omien turvallisuusohjeiden ehdotonta noudattamista.

FILLING THE CAPILLARY WITH WHOLE BLOOD—continued

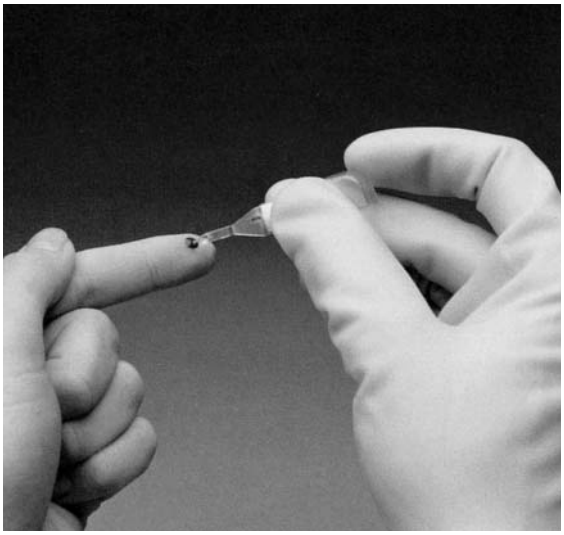
1. Complete step A) **OR** step B) depending upon the blood sample source. Continue with step **2** on the next page.

IMPORTANT: Do not allow blood to contact the plastic part of the capillary holder. Any blood touching the plastic will be transferred into the reaction buffer, along with the blood in the glass capillary. This can cause an invalid HbA_{1c} result or possibly an error message. **If blood contacts the plastic part of the capillary holder, discard capillary holder.**

A) If filling glass capillary with **blood from finger prick:**

1. **Hold** the capillary holder at an angle.

2. **Touch** *only* the tip of the capillary to a *small drop* of blood on the finger until the capillary is filled.



B) If filling glass capillary with **blood obtained by venipuncture:**

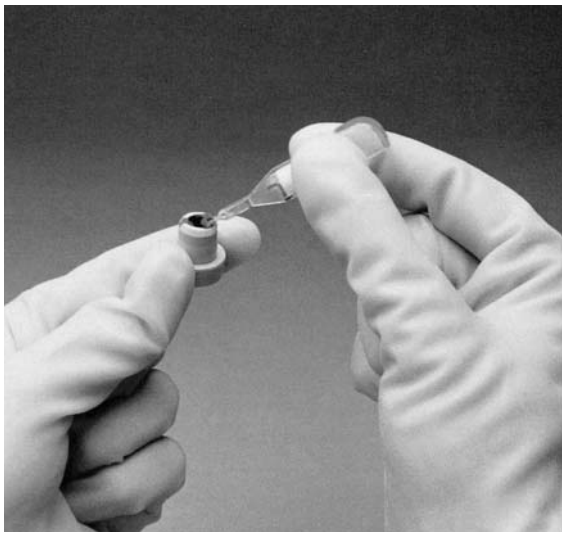
1. **Mix sample well** (by inversion or use of an aliquot mixer) to prevent separation of red blood cells and plasma.

2. **Remove stopper** from blood collection tube in such a way that a small sample of blood remains on stopper.

3. **Hold** the capillary holder at an angle.

4. **Touch** *only* the tip of the capillary to blood sample on stopper.

- **Do not attempt to fill capillary by touching glass capillary to blood in a blood collection tube. Attempting to fill capillary in this manner most often results in blood touching the capillary holder. If blood touches the capillary holder, discard capillary holder.**

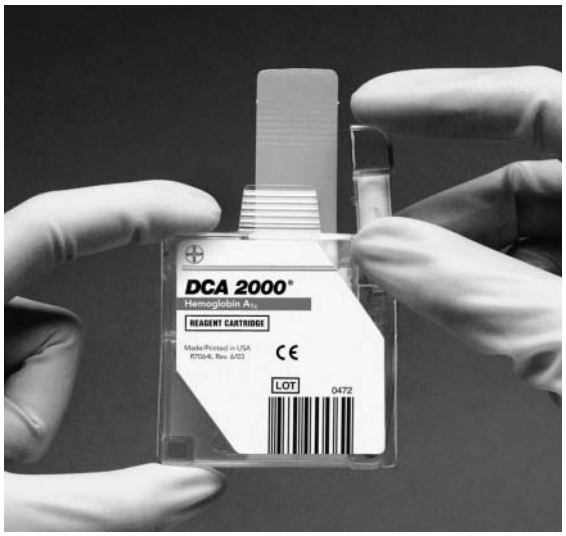


2. Using a lint-free tissue, carefully wipe the outside of the glass capillary.

   Do not allow the tissue to touch the open end of the glass capillary. Contact with the open end of the capillary could result in loss of sample (by wicking into tissue). If sample loss is obvious, discard capillary holder; then repeat procedure using a new capillary holder.

3. **Inspect** the glass capillary for the presence of bubble(s). If bubble(s) are obvious, discard capillary holder; then repeat procedure using a new capillary holder.

4. **Position** the capillary holder in the correct orientation for insertion into the reagent cartridge.



5. **Carefully insert** the capillary holder into the reagent cartridge until the holder **gently snaps** into place.

   IMPORTANT: Avoid harsh insertion of capillary holder. It is important *not to dislodge* sample from glass capillary or erroneous results may occur.

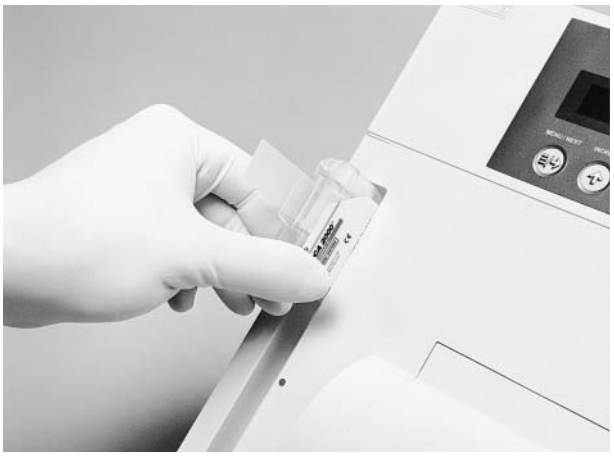
STEP 4: Analyzing the Patient Sample

DISPLAY

```
READY: SCAN BAR CODE
02/24/03          2:09PM
```

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the reagent cartridge.
3. **Hold** the reagent cartridge so that the bar code faces right.
4. **Insert** the reagent cartridge (above dot) into bar code track.



5. **Quickly** (within 1 sec.) **and smoothly,** slide the reagent cartridge down past the dot.

   A beep sounds to signal a successful scan.

   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 5.

DISPLAY

```
LOAD CARTRIDGE
PULL TAB, CLOSE DOOR
```

WHAT YOU DO

6. **Open** the cartridge compartment door.
7. **Hold** the reagent cartridge so that the bar code faces right.

   Insert the reagent cartridge into the cartridge compartment until a subtle snap is heard/felt.

⚠ High temperature part
⚠ Huom. Kuumenee käytettäessä

HINT: The cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument.

8. **Using a smooth, slow, continuous motion, pull flexible pull-tab** completely out of reagent cartridge.
9. **Close** door.
   Dispose of flexible pull-tab.
   - Five (5) seconds after the door is closed, a beep sounds and the assay begins.

     NOTE: If you accidentally close the door before you pull the flexible plastic tab, you have 5 seconds to re-open the door; the display returns to "LOAD CARTRIDGE." You may now pull the tab or correct existing problem(s).

DISPLAY

```
    TEST IN PROGRESS
#001     6 MIN 10:15AM
```

(colon does not blink)

After test is completed:

```
9.8  %HbA1c
     #001 10:21
```

(colon does not blink)

WHAT YOU DO

10. **Record** the displayed result *before* removing the reagent cartridge.

11. **Remove** the reagent cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull the reagent cartridge out of the compartment.
    e) Discard cartridge in proper container, according to your standard laboratory procedures.

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

HINT: If the displayed test result was not recorded, use the MENU to recall up to 16 test results (refer to SECTION 3).

RESULTS:

The displayed test result requires no further calculation. Hemoglobin A_{1c} concentrations in the following range are reported:

2.5% to 14.0%

The test is linear throughout this range.

Result preceded by a less than sign (<):
A less than sign in the display indicates a concentration below the lower limit of the test (under range). Report the result as being less than 2.5% Hemoglobin A_{1c}. This method does not provide for re-assay using a larger sample aliquot. Results less than 2.5% Hemoglobin A_{1c} are rare and may indicate that the sample contains substantial amounts of fetal hemoglobin (does not react in the immunoassay); or that the patient may be suffering from hemolytic anemia or polycythemia (conditions which often result in a significant decrease in the life span of red blood cells).

Result preceded by a greater than sign (>):
A greater than sign in the display indicates a concentration above the upper limit of the test (over range). Report the result as being more than 14.0% Hemoglobin A_{1c}. This method does not provide for re-assay using a diluted sample. To obtain a more quantitative test value at levels greater than 14%, use another test method.

All laboratory tests are subject to random error. If the test result is questionable, or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or confirm the result using another method.

Analyzing DCA 2000® Hemoglobin A_{1c} Controls, ONLY

NOTE: Follow instructions on page 4.8, if analyzing a control other than a DCA 2000 Hemoglobin A_{1c} Control.

Controls are analyzed in the same manner as the patient sample.

- A specially designed control bar code (that enters the control lot number, etc.) is provided with DCA 2000 HbA_{1c} Controls.
- Therefore, when analyzing DCA 2000 Hemoglobin A_{1c} Controls, use instructions that contain steps for scanning the control bar code card found on pages 4.12–4.14.
- If using controls other than DCA 2000 Hemoglobin A_{1c} Controls, refer to Section 3, page 3.17, for information on labeling and storing the control result.

DISPLAY

```
READY: SCAN BAR CODE
02/24/03          2:09PM
```

```
RUN CONTROL C1?
LOTC:1112          HbA1c
```

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the control card.

   NOTE: The control card is double-sided; one side for normal, the other for abnormal. Make sure you are using the correct side of the control card for the particular DCA 2000 Control level in use.

   C1 = CONTROL | NORMAL = Normal

   C2 = CONTROL | ABNORMAL = Abnormal
3. **Hold** the control card so that the bar code faces right.
4. **Insert** the control card into the bar code track (above dot). **Hold** card gently against the right side of track.
5. **Quickly** (within 1 sec.) **and smoothly, slide** the card down past the dot.

   A beep sounds to signal a successful scan.

   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.
6. **Press** ↵.

DISPLAY	WHAT YOU DO
SCAN BAR CODE: HbA1c 02/24/03 C1 11:10AM	7. **Locate** the bar code on the reagent cartridge. 8. **Hold** the reagent cartridge so that the bar code faces right. 9. **Insert** the reagent cartridge (above dot) into bar code track. 10. **Quickly** (within 1 sec.) **and smoothly, slide** the reagent cartridge down past the dot. A beep sounds to signal a successful scan. • If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.
LOAD CONTROL PULL TAB, CLOSE DOOR	11. **Open** the cartridge compartment door. 12. **Hold** the reagent cartridge so that the bar code faces right. **Insert** the reagent cartridge into the cartridge compartment until a subtle snap is heard/felt. **HINT:** The reagent cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument. 13. **Using a smooth, slow continuous motion, pull flexible pull-tab** completely out of reagent cartridge. 14. **Close** door. Dispose of flexible pull-tab. ***NOTE:*** If you accidentally close the door before you pull the tab, you have 5 seconds to re-open the door; the display returns to "LOAD CARTRIDGE." You may now pull the tab or correct existing problem(s).

DISPLAY

```
PROCESSING CONTROL
C1-HbA1c 6 MIN 11:11AM
```

(colon does not blink)

After test is completed:

For a result within the acceptable control range printed in the control package insert

```
5.1   %HbA1c
      C1  10:21AM
```

OR

For a result outside the acceptable control range printed in the control package insert

```
CONTROL OUT OF RANGE
PRESS [ESC] TO PROCEED
```

WHAT YOU DO

15. **NOTE:** If "CONTROL OUT OF RANGE" is displayed, press ⓞ to display value of out-of-range control.

    Record the displayed result *before* removing the reagent cartridge.

16. **Remove** the reagent cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull the reagent cartridge out of the compartment.
    e) Discard cartridge in proper container, according to your standard laboratory procedures.

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

CANCELLING A TEST

You may cancel a test anytime.

Important: If a test in progress is cancelled, the test must be discarded.

DISPLAY	WHAT YOU DO
LOAD CARTRIDGE PULL TAB, CLOSE DOOR	1. Press ⓞ.
OR	
TEST IN PROGRESS #001 6 MIN 10:15AM (colon does not blink)	
CANCEL TEST? PRESS [←] TO CONFIRM (an error buzz sounds)	2. Press ↵ *within 15 seconds.* ***NOTE:*** After pressing ↵, "PLEASE WAIT" is displayed until the cartridge returns to original loading position. If ↵ is not pressed within 15 seconds: • the display returns to the original display (i.e., either display shown in Step 1). • the test in progress continues without interruption

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM – displayed if the test is cancelled after the bar code is scanned but before the cartridge compartment door is opened – a beep is heard	3. The test is cancelled. • Scan bar code
OR	*OR*
CANCELLED: DISCARD TEST 02/24/03 10:18AM – displayed if the test is cancelled during sample analysis (cartridge is in instrument) – an error buzz is heard	• Open cartridge compartment door and remove cartridge.

OPERATING INSTRUCTIONS — MICROALBUMIN/CREATININE

NOTE: The instructions in this section are for use after "INSTRUMENT SETUP" has been performed (a one time requirement upon receipt of a new or factory-serviced instrument).

STEP 1: Turning the Power ON

DISPLAY	WHAT YOU DO
	1. **Turn** the power switch to ON. **IMPORTANT: The program card must be inserted or removed only when the power switch is set to OFF. If the card is inserted when the power is ON, the card can be permanently damaged.**

After about 8 seconds:
`SOFTWARE VERSION`
`E3.11/01.04`
(displayed for 8 seconds)	

`COPYRIGHT 1991-2003`
`BY BAYER CORPORATION`
(displayed for 3 seconds)	

`INITIALIZING` `KEEP DOOR CLOSED`	
`WAIT: WARMING UP` `02/24/03 2:09PM`	2. OPTIONAL: While the instrument is warming up (usually 1 – 2 minutes but can take up to 8 minutes), you may access certain MENU items. Refer to Section 3 for instructions. *Reminder:* Current time is denoted by "blinking colon." Time assay began is denoted by stationary colon.

`READY: SCAN BAR CODE`
`02/24/03 2:09PM`
(a beep is heard)	

STEP 2: Calibration

When To Calibrate:
Calibrate the System for each *new lot number* of reagent cartridges.

Materials Required:
- Calibration Card (provided in DCA 2000® Microalbumin/Creatinine Reagent Kit)

NOTES:
- The calibration card has two bar codes, one on each side of the card. Side 1 and Side 2 are identified on the card. Either side may be scanned first. After the first scan, the display will indicate the next side to be scanned. Side 1 is Malb/C; Side 2 is Malb-2.
- It is necessary to scan **both** bar codes to calibrate the system for *each new lot* of reagent cartridges.
- The instrument stores up to *two* calibrations for the DCA 2000 Microalbumin/Creatinine Reagent Test. The two calibrations must be for *two different lot numbers.*
- The calibration stored in the instrument *first* is deleted when a calibration card for a third lot number is scanned.

DISPLAY

```
READY: SCAN BAR CODE
02/24/03        2:09PM
```

OR

Any result or menu display
as long as testing is not in progress.

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the calibration card.
3. **Hold** the card so that the bar code faces right.
4. **Insert** the card into the bar code track (above dot). **Hold** card gently against the right side of track.

DISPLAY

```
CALIBRATION DATA SAVED
LOT:0432          Malb/C
```

After 5 seconds, the instrument then sounds a 2 second beep and displays:

```
SCAN CALIBRATION CARD
LOT:0432          Malb-2
```

```
CALIBRATION DATA SAVED
LOT:0432          Malb-2
```

WHAT YOU DO

5. **Quickly** (within 1 sec.) **and smoothly, slide** the card down past the dot.

   A beep sounds to signal a successful scan.

   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.

6. **Repeat** Steps 1–5 above using the other side of the card.

   If the second bar code is not scanned within 5 minutes:

   - the display returns to the original display and the calibration process must start over. (See previous page.)

STEP 3: Preparing Patient Samples and Controls

Materials Required:

- DCA 2000 Microalbumin/Creatinine Reagent Kit
- Patient Sample, DCA 2000® Microalbumin/ Creatinine Control Kit or other control
- Lint-free tissue

OPENING THE FOIL PACKAGE (Containing Reagent Cartridge)

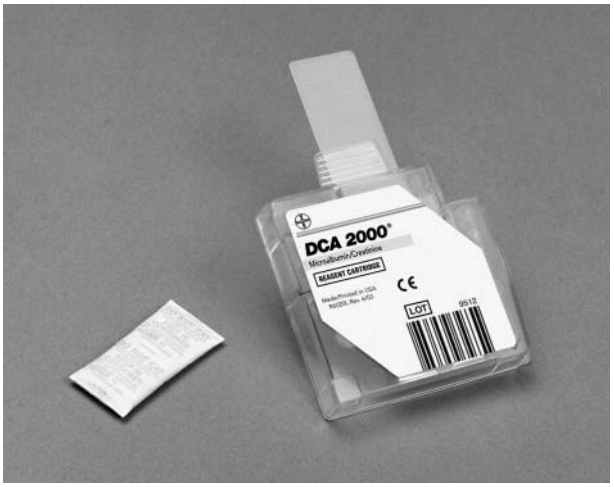
IMPORTANT: Do not use scissors to cut open foil package. Scissors can damage the reagent cartridge, the flexible pull-tab on the cartridge or the sack containing desiccant.

1. Remove one foil package (containing a reagent cartridge) from storage.
2. Refer to "Recommended Procedures for Handling Reagent Cartridges" in the DCA 2000 Microalbumin/Creatinine Reagent Kit package insert for instructions on how and when to open foil package.

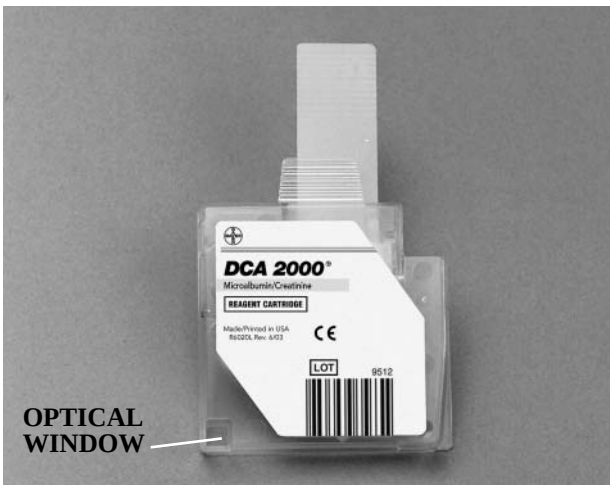
INSPECTING THE CONTENTS OF THE FOIL PACKAGE

The foil package contains:

1. reagent cartridge with flexible pull-tab and bar code label
2. small sack (filled with desiccant)



When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.



Discard the reagent cartridge if:

- the cartridge is damaged
- the flexible pull-tab is loose or missing
- the small sack (desiccant) is missing or open
- loose desiccant particles are found inside the foil package
  (refer to Service Information, Section 9)

CAPILLARY HOLDER AND PLUNGER

Unused capillary holders may be saved and used with any lot of microalbumin/creatinine reagent cartridges.

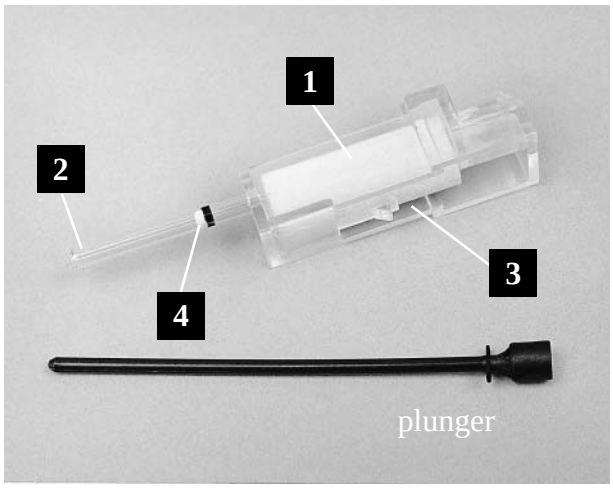
1. Remove a capillary holder and plunger from plastic bag.
2. Inspect the capillary holder for the presence of:

   1 absorbent pad

   2 glass capillary

   3 latching mechanism

   4 starch plug



3. If the capillary holder is missing any of the above parts, discard the capillary holder; also discard if the starch plug is at the bottom of the capillary tube **2** (refer to Service Information, Section 9).

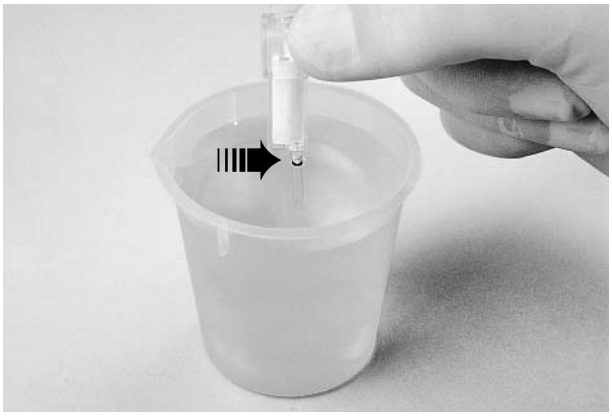
FILLING THE CAPILLARY WITH URINE

1. Complete step A) **OR** step B) depending upon the volume of urine specimen available. Continue with Step **2** on the next page.

IMPORTANT: Do not allow urine to contact either the plastic part of the capillary holder or the adsorbent material in the capillary holder. Any urine touching the plastic will be transferred into the reaction buffer, along with the urine in the glass capillary. This can cause an invalid microalbumin/creatinine result or possibly an error message. **If urine contacts the plastic part of the capillary holder, discard capillary holder.**

A) If filling capillary tube with urine from a container with a **large** sample volume:

1. **Immerse** the tip of the capillary tube in the urine specimen to a level just above the plug in the capillary.



2. **Allow** enough time for the urine specimen to flow into the capillary tube and come in contact with the starch plug, approximately 5 seconds. Wetting the starch plug seals the capillary tube and keeps the urine within the tube.

3. **Remove** the capillary tube from the urine specimen. If the urine flows back down the tube, re-immerse the capillary tube in the urine specimen again, allowing enough time to ensure that the starch plug becomes saturated.

(Instructions for filling capillary with *control* sample are found in the DCA 2000 Microalbumin/Creatinine Control package insert.)

B) If filling capillary tube with urine from a container with a **small** sample volume:

1. **Immerse** the tip of the capillary tube in the urine specimen. Tilt sample container and capillary holder to a more horizontal position to increase the rate of flow into the capillary. Take care not to spill the urine specimen.

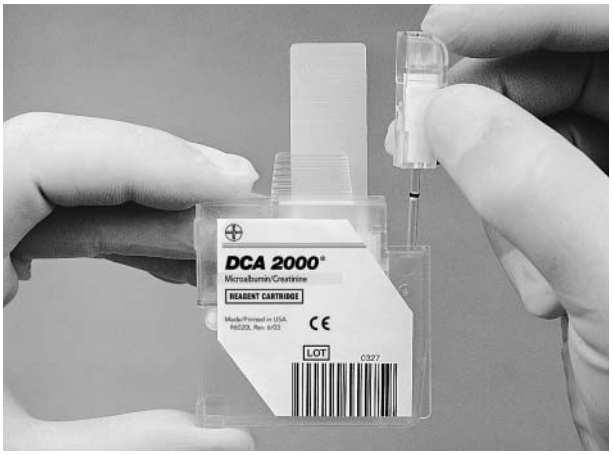
2. **Allow** enough time for the urine specimen to flow into the capillary tube and come in contact with the starch plug. Wetting the starch plug seals the capillary tube and keeps the urine within the tube.

3. **Remove** the capillary tube from the urine specimen. If the urine flows back down the tube, re-immerse the capillary tube in the urine specimen again, allowing enough time to ensure that the starch plug becomes saturated.

2. Using a lint-free tissue, carefully wipe the outside of the glass capillary tube. **Do not allow the tissue to touch the open end of the glass capillary.** Contact with the open end of the capillary tube could result in loss of sample (by wicking into tissue). If sample loss is obvious, discard the capillary holder; then repeat procedure using a new capillary holder.

3. **Inspect** the glass capillary tube for the presence of bubble(s). If bubbles are obvious, discard the capillary holder; then repeat procedure using a new capillary holder.

4. **Position** the capillary holder in the correct orientation for insertion into the reagent cartridge.



5. **Carefully insert** the capillary holder into the reagent cartridge until the holder **gently snaps** into place.

IMPORTANT: Avoid harsh insertion of the capillary holder. It is important *not to dislodge* sample from the capillary tube, or erroneous results may occur.

STEP 4: Analyzing the Patient Sample

DISPLAY

```
READY: SCAN BAR CODE
02/24/03          2:09PM
```

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the reagent cartridge.
3. **Hold** the reagent cartridge so that the bar code faces right.
4. **Insert** the reagent cartridge (above dot) into bar code track.

5. **Quickly** (within 1 sec.) **and smoothly,** slide the reagent cartridge down past the dot.

   A beep sounds to signal a successful scan.

   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.

DISPLAY	WHAT YOU DO
LOAD CARTRIDGE, INSERT PLUNGER, PRESS [←]	6. **Open** the reagent cartridge compartment door. 7. **Hold** the reagent cartridge so that the bar code faces right. **Insert** the reagent cartridge into the cartridge compartment until a subtle snap is heard/felt. **HINT:** The cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument. 8. **Insert** plunger into hole in top of capillary holder. **Depress plunger** into capillary holder fully. Plunger will lock into the capillary holder. Press ↵.
	⚠ High temperature part ⚠ Huom. Kuumenee käytettäessä
	
PULL TAB, CLOSE DOOR	9. **Using a smooth, slow, continuous motion, pull flexible pull-tab** completely out of reagent cartridge. 10. **Close** door. Dispose of flexible pull-tab. • Five (5) seconds after the door is closed, a beep sounds and the assay begins. ***NOTE:*** If you accidentally close the door before you pull the flexible tab, you have 5 seconds to re-open the door; the display returns to "LOAD CARTRIDGE." You may now pull the tab or correct existing problem(s).

—continued on next page

DISPLAY

```
    TEST IN PROGRESS
#001     6 MIN 10:15AM
```

(colon does not blink)

After test is completed:

```
A=102mg/L      C=141mg/dL
A/C=72      #001  10:17AM
```

(colon does not blink)

WHAT YOU DO

11. **Record** the displayed result *before* removing cartridge.

    NOTE: If creatinine units are mg/dL, then the Albumin/Creatinine (A/C) ratio is reported as mg/g. If the creatinine units are mmol/L, then the Albumin/Creatinine (A/C) ratio is reported as mg/mmol.

12. **Remove** cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull cartridge out of compartment.
    e) Discard cartridge in proper container, according to your standard laboratory procedures.

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

HINT: If the displayed test result was not recorded, use the MENU to recall up to 16 test results (refer to SECTION 3).

RESULTS:

Albumin: The displayed test result requires no further calculation. Albumin concentrations in the following range are reported: 5 to 300 mg/L. The test is linear throughout this range.

Creatinine: The displayed test result requires no further calculation. Creatinine concentrations in the following range are reported: 15 to 500 mg/dL or 1.3 to 44.2 mmol/L. The test is linear throughout this range.

Albumin/Creatinine Ratio: The displayed test result requires no further calculation. Albumin/ Creatinine ratios can be reported in the following range: 1 to 2,000 mg/g or 0.11 to 226 mg/mmol.

Albumin or creatinine result preceded by a less than sign (<): A less than sign in the display indicates a concentration below the lower limit of the test (under range). This method does not provide for re-assay using a larger sample.

Albumin or creatinine result preceded by a greater than sign (>): A greater than sign in the display indicates a concentration above the upper limit of the test (over range). This method does not provide for re-assay using a diluted sample. To obtain a more quantitative test value, use another test method.

Ratio result preceded by a less than (<) sign or greater than (>) sign or (---): If the albumin and/or creatinine result is under or over range, the ratio will also be reported as under or over range. In certain cases, no ratio will be reported (---).

Example 1: If the albumin result is >300 mg/L and the creatinine result is 100 mg/dL (8.84 mmol/L), then the ratio will be reported as >300 mg/g (>26.5 mg/mmol).

Example 2: If the albumin result is 75 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), then the ratio will be reported as >500 mg/g (>56.4 mg/mmol).

Example 3: If the albumin result is >300 mg/L and the creatinine result is >500 mg/dL (>44.2 mmol/L), then no ratio will be reported (---).

Example 4: If the albumin result is <5 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), then no ratio will be reported (---).

All laboratory tests are subject to random error. If the test result is questionable, or if clinical signs and symptoms appear inconsistent with the test results, re-assay the sample or confirm the result using another method.

Analyzing DCA 2000® Microalbumin / Creatinine Controls, ONLY

NOTE: Follow instructions on page 5.8, if analyzing a recommended control other than a DCA 2000 Microalbumin/Creatinine Control.

Controls are analyzed in the same manner as the patient sample.

- A specially designed control bar code (that enters the control lot number, etc.) is provided with DCA 2000 Microalbumin/Creatinine Controls.
- Therefore, when analyzing DCA 2000 Microalbumin/Creatinine Controls, use instructions that contain steps for scanning the control bar code card found on pages 5.12–5.14.
- If using controls other than DCA 2000 Microalbumin/Creatinine Controls, refer to Section 3, page 3.17, for information on labeling and storing the control result.

DISPLAY

```
READY: SCAN BAR CODE
02/24/03        2:09PM
```

```
RUN CONTROL C1?
LOTC:1112        Malb/C
```

WHAT YOU DO

1. **Locate** the dot (on the instrument) next to the bar code track.
2. **Locate** the bar code on the control card.

   NOTE: The control card is double-sided; one side for Low, the other for High. Make sure you are using the correct side of the control card for the particular DCA 2000 Control level in use.

   C1 = CONTROL LOW = Low

   C2 = CONTROL HIGH = High
3. **Hold** the control card so that the bar code faces right.
4. **Insert** the control card into the bar code track (above dot). **Hold** card gently against the right side of track.
5. **Quickly** (within 1 sec.) **and smoothly, slide** the card down past the dot.

   A beep sounds to signal a successful scan.

   - If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.
6. **Press** ↵.

DISPLAY	WHAT YOU DO
SCAN BAR CODE Malb/C 02/24/03 C1 11:10AM	7. **Locate** the bar code on the reagent cartridge. 8. **Hold** the cartridge so that the bar code faces right. 9. **Insert** the cartridge (above dot) into bar code track. 10. **Quickly** (within 1 sec.) **and smoothly, slide** the cartridge down past the dot. A beep sounds to signal a successful scan. • If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6. 11. **Open** the cartridge compartment door.
LOAD CARTRIDGE, INSERT PLUNGER, PRESS [←]	12. **Hold** the reagent cartridge so that the bar code faces right. **Insert** the cartridge into the cartridge compartment until a subtle snap is heard/felt. **HINT:** The cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument. 13. **Insert** plunger into hole in top of capillary holder. **Depress plunger** into capillary holder fully. Plunger will lock into the capillary holder. Press ↵.
PULL TAB, CLOSE DOOR	14. **Using smooth, slow continuous motion, pull flexible pull-tab** completely out of reagent cartridge. 15. **Close** door. Dispose of flexible pull-tab. ***NOTE:*** If you accidentally close the door before you pull the tab, you have 5 seconds to re-open the door; the display returns to "LOAD CARTRIDGE." You may now pull the tab or correct existing problem(s).

— continued on next page

DISPLAY

```
   PROCESSING CONTROL
C1-Malb/C 7 MIN 11:11AM
```

(colon does not blink)

After test is completed:

For a result within the acceptable control range printed in the control package insert

```
A=102mg/L     C=141 mg/dL
              C1  11:11AM
```

NOTE: The albumin/creatinine ratio is not calculated for controls.

OR

For a result outside the acceptable control range printed in the control package insert

```
  CONTROL OUT OF RANGE
PRESS [ESC] TO PROCEED
```

WHAT YOU DO

16. **NOTE:** If "CONTROL OUT OF RANGE" is displayed, press ◎ to display value of out-of-range control.

    Record the displayed result *before* removing cartridge.

17. **Remove** cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the flexible tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull cartridge out of compartment.
    e) Discard cartridge in proper container, according to your standard laboratory procedures.

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

CANCELLING A TEST

You may cancel a test anytime.

Important: If a test in progress is cancelled, the test must be discarded.

DISPLAY	WHAT YOU DO
LOAD CARTRIDGE, INSERT PLUNGER, PRESS [←] *OR* PULL TAB, CLOSE DOOR *OR* TEST IN PROGRESS #001 6 MIN 10:15AM (colon does not blink)	1. Press ⓞ.
CANCEL TEST? PRESS [←] TO CONFIRM (an error buzz sounds)	2. Press ↵ *within 15 seconds.* ***NOTE:*** After pressing ↵, "PLEASE WAIT" is displayed until the cartridge returns to original loading position. If ↵ is not pressed within 15 seconds: • the display returns to original display (i.e., either display shown in Step 1). • the test in progress continues without interruption

— continued on next page

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM – displayed if the test is cancelled after the bar code is scanned but before the cartridge compartment door is opened – a beep is heard	3. The test is cancelled. • Scan bar code
OR	*OR*
CANCELLED: DISCARD TEST 02/24/03 10:18AM – displayed if the test is cancelled during sample analysis (cartridge is in instrument) – an error buzz is heard	• Open cartridge compartment door and remove cartridge.

ERROR AND WARNING MESSAGES, ERROR CODES AND TROUBLESHOOTING

Use the chart below to quickly find the correct page for the desired error and warning message, error code, or troubleshooting information.

ERROR AND WARNING MESSAGES

Error and warning messages are provided in alphabetical order.

ERROR CODES

TROUBLESHOOTING

ERROR AND WARNING MESSAGES

ERROR OR WARNING	CAUSE	SOLUTION
CANCELLED: DISCARD TEST 02/24/03 10:18AM	The cartridge compartment door was opened while testing was in progress. The door was then closed and "PLEASE WAIT" was displayed prior to "CANCELLED: DISCARD TEST." *OR* ◎ was pressed in response to "SEE OPERATING MANUAL/ (any system error) "	Open the cartridge compartment door. Remove and discard the reagent cartridge. Repeat the test. • If the error message "SEE OPERATING MANUAL/(any system error)" is displayed again, refer to Section 9, for instructions on "How to Report the Problem."
DOOR OPEN ERROR CLOSE DOOR	The cartridge compartment door was opened while testing was in progress.	Close door. Wait for next display "PLEASE WAIT."
OUT OF DATE CONTROL LOTC:1154 HbA1c (displayed for 15 seconds) Control lot number and test name above are examples, only.	The bar code for an out-of-date control (past expiration date) has been read.	Discard out-of-date control(s).
OUT OF DATE REAGENT LOT:1154 HbA1c (displayed for 15 seconds) Reagent lot number and test name above are examples, only.	The bar code for an out-of-date (past expiration date) reagent cartridge has been read.	Discard out-of-date reagent cartridge(s).
PLEASE WAIT	The cartridge compartment door was opened while testing was in progress. Then the door was closed. *OR* A System Error was detected and ◎ was pressed.	Wait until cartridge is in correct position for removal (until "CANCELLED: DISCARD TEST" is displayed).
SCAN CALIBRATION CARD LOT:1154 HbA1c Lot number and test name above are examples, only	The calibration card for the reagent cartridge in use has not been scanned.	Scan the correct calibration card. • Check name and lot number of cartridge in use.
SEE OPERATING MANUAL COMPUTER PORT ERROR–E51	The computer port is ON and/or: • the instrument buffer is full of untransmitted results • the computer will not accept results	1. Check to make sure cable is securely connected to both instrument and computer. 2. If the problem persists, refer to Section 9, for instructions on "How to Report the Problem." **HINT:** To facilitate testing (without transmitting results to a computer) turn off the computer port (refer to Section 3, MENU).

ERROR OR WARNING	CAUSE	SOLUTION
SEE OPERATING MANUAL ERROR 90–RAM MEMORY	When the power was turned ON (I), a failure was detected in the non-volatile memory.	Press ⓞ key. "INSTRUMENT SETUP/PRESS [←] TO CONTINUE" is displayed. **All factory settings (defaults) are now active.** • Turn to Section 2 and follow the instructions beginning with "Viewing Factory Settings." You must now, once again, either accept or change factory settings.
SEE OPERATING MANUAL TEST ERROR 115 ERROR—101 TO 116 for HbA_{1c} ERROR—301 to 316 for Microalbumin/Creatining	An error relating to a test measurement parameter has been detected (e.g., abnormal hemoglobin levels, high C.V.'s, out of range hemoglobin transmission, etc.).	1. Discard the test. 2. See pages 6.6, 6.7, 6.8, and 6.9. 3. Repeat the test using a new reagent cartridge and sample. 4. If the problem persists, record the test error identification number; then refer to Section 8, for instructions on "How to Report the Problem."
SEE OPERATING MANUAL ERROR 11–MOTOR **OR:* ERROR 2x—OPTICAL ERROR 3x—TEMPERATURE ERROR 4x—BAR CODE ERROR 9x—INTERNAL	* The instrument has detected an instrument error (motor or optical failure, temperature, etc.).	• If testing is in progress, press ⓞ. Follow instructions under error message "CANCELLED: DISCARD TEST." • If testing is not in progress, turn the power OFF, then ON. If the problem persists, record the error message. Then refer to Section 9, for instructions on "How to Report the Problem."
SEE OPERATING MANUAL LOT:2234 TEST: UNKNOWN	The instrument does not recognize the reagent test in use.	Contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
WRONG CARD (displayed for 5 seconds—then "SCAN CALIBRATION CARD" appears)	In response to "SCAN CALIBRATION CARD," the wrong calibration card is scanned. Both sides of the calibration card must be scanned to enter the calibration for Microalbumin / Creatinine.	Scan correct calibration card. • Check name and lot number of cartridge in use. • Repeat calibration process making certain to scan both sides of the calibration card.

ERROR CODES

ERROR CODE	CAUSE	SOLUTION
E1	An internal system error has been detected.	Contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
E2	When the power switch was set to ON (I), the instrument detected an error in the system's non-volatile memory.	Set the power switch to OFF (O). Contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
E3	1. The wrong program card is plugged into the instrument.	1. Set the power switch to OFF (O). Remove the wrong program card. Plug the correct program card completely into the instrument. Set the power switch to ON (I).
	2. No program card is plugged into the instrument.	2. Set the power switch to OFF (O). Plug the correct program card completely into the instrument. Set the power switch to ON (I).
	3. The correct program card is correctly plugged into the instrument but the contacts on the program card need cleaning or are defective.	3. Set the power switch to OFF (O). Use a pencil eraser to gently clean the contacts on the program card. Use a lint-free tissue to wipe particles from the contacts. Correctly insert the program card. Set the power switch to ON (I). • If the problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.

ERROR CODE	CAUSE	SOLUTION
E4	1. The wrong program card is plugged into the instrument.	1. Set the power switch to OFF (O). Plug the correct program card completely into the instrument. Set the power switch to ON (I).
	2. The correct program card is not *completely* plugged into the instrument.	2. Refer to step 1.
	3. The contacts on the correct program card need to be cleaned or are defective.	3. Set the power switch to OFF (O). Remove the program card. Use a pencil eraser to gently clean the contacts on the program card. Use a lint-free tissue to wipe particles from contact. Correctly insert the program card. Set the power switch to ON (I). If the problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
E5	When the power switch was set to ON (I), the instrument detected use of a defective program card.	1. Set the power switch to OFF (O). 2. Remove the program card. 3. Plug a replacement program card into the instrument. (Refer to Section 9, SERVICE INFORMATION, for instructions on where to order replacement program card.) 4. Set the power switch to ON (I). If the problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
E6	When the power switch was set to ON (I), the instrument detected an error in system timing.	Set the power switch to OFF (O). Contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.

ERROR CODE	CAUSE	SOLUTION
101 Buffer Reading Out of Limits — High	No cartridge present. Optical alignment problem.	Repeat test with cartridge in place. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
102 Buffer Reading Out of Limits — Low	Condensation on cartridge — cartridge not allowed to warm up Cartridge not located properly in instrument. Buffer tab not pulled. Buffer tab removed before cartridge inserted. Cartridge defect in optical window. Cartridge optical window blocked or dirty.	Allow at least 10 minutes after cartridge is removed from refrigerator before starting test. Ensure that cartridge is inserted completely into instrument. Pull buffer tab after inserting cartridge into holder. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
103 High Variation in Readings for Buffer	Condensation on cartridge — cartridge not allowed to warm up Rare. Particulate contamination.	Allow at least 10 minutes after cartridge is removed from refrigerator before starting test. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
104 **106** Reading for Hemoglobin Value — Low	No or low blood in reaction — capillary underfill or air bubble — blood dried in capillary — no capillary holder inserted — improper reconstitution of controls or use of non-DCA 2000 controls Hemoglobin < 7 g/dL — anemic patient, abnormally low hemoglobin Buffer tab not pulled or buffer not released from tray.	Ensure that capillary is completely filled with no air bubbles. Wait no more than 5 minutes after filling capillary before starting test. Repeat test with capillary holder in place. Review procedure for reconstitution of DCA 2000 controls. Perform test by another method. Pull buffer tab before closing door.
105 **107** Reading for Hemoglobin Value — High	Excess blood on capillary holder. Blood not lysing — cartridge not allowed to warm up — irregularity in patient red blood cells (rare) Hemoglobin > 24 g/dL — patient has abnormally high hemoglobin — very high triglycerides	Take care in sampling the blood to avoid excess blood on capillary holder. Ensure that capillary is wiped before inserting into cartridge. Allow at least 10 minutes after cartridge is removed from refrigerator before starting test. Freeze/thaw specimen before use, or perform test by another method. Perform test by another method. See reagent kit insert under Limitations.

ERROR CODE	CAUSE	SOLUTION
108 High Variation in Readings for Hemoglobin	Rare. Particulate contamination.	If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
109 110 111 112 Readings for Glycated Hemoglobin Out of Limits	Cartridge exposed to excessive temperature and/or humidity.	Ensure proper storage of reagent kits. Open foil package just prior to use of cartridge.
113 114 116 Irregular Reaction Kinetics for Glycated Hemoglobin	Cartridge exposed to excessive temperature and/or humidity. Particulate contamination.	Ensure proper storage of reagent kits. Open foil package just prior to use of cartridge. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
115 Final Hemoglobin Reading Greater Than Reading at Earlier Checkpoint	Blood left too long in capillary.	Wait no more than 5 minutes after filling capillary before starting test.

ERROR CODE	CAUSE	SOLUTION
301 Buffer Mean Out of Limits — Low Absorbance	No cartridge present. Optical alignment problem.	Repeat test with cartridge in place. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
302 Buffer Mean Out of Limits — High Absorbance	Condensation on cartridge — cartridge not allowed to warm up Cartridge not located properly in instrument. Buffer tab not pulled. Buffer tab removed before cartridge inserted. Cartridge defect in optical window. Cartridge optical window blocked or dirty.	Allow at least 15 minutes after cartridge is removed from refrigerator before starting test. Ensure that cartridge is inserted completely into instrument. Pull buffer tab after inserting cartridge into holder. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
303 High Variation in Readings for Buffer	Rare. Particulate contamination.	If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
304 Sample Blank Mean Out of Limits — Low	Particulate contamination.	Repeat test. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
305 Sample Blank Mean Out of Limits — High	Urine sample is turbid or highly pigmented.	Centrifuge sample before assaying if sample is very turbid or cloudy. If sample contains visible amounts of blood, or is highly pigmented, obtain a fresh sample. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
306 High Variation in Readings for Sample Blank	Rare. Particulate contamination.	Repeat test. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
307 **308** Readings for Albumin Out of Limits	Rare. Cartridge exposed to excessive temperature and/or humidity.	Ensure proper storage of reagent kits. Open foil package just prior to use of cartridge.

ERROR CODE	CAUSE	SOLUTION
309 High Variation in Albumin Readings	Rare. Particulate contamination.	Repeat test. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
310 **311** Readings for Creatinine Out of Limits	Rare. Cartridge exposed to excessive temperature and/or humidity.	Ensure proper storage of reagent kits. Open foil package just prior to use of cartridge.
313 Irregular Reaction Kinetics for Creatinine	Cartridge exposed to excessive temperature and/or humidity. Particulate contamination.	Ensure proper storage of reagent kits. Open foil package just prior to use of cartridge. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
315 Normalization Factor has not been set	Instrument has not been adjusted to run the Microalbumin/Creatinine assay.	Contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.
316 Normalization Factor outside allowable range	Normalization Cartridge is not located properly in instrument. Normalization Cartridge is dirty or defective.	Ensure that cartridge is inserted completely into instrument. If problem persists, contact Bayer HealthCare Customer Service Department. See Section 9, Service Information.

TROUBLESHOOTING

PROBLEM	SOLUTION
Beep repeatedly fails to sound after scanning a bar code.	1. Insert the cartridge or expanded bottom of card (whichever applies) into the bar code track **below** the dot. 2. Quickly (within 1 second) and smoothly, slide the card or cartridge **up** past the dot. If a beep continually fails to sound, refer to Section 8 for instructions on "How to Report the Problem."
Capillary will not fill completely with sample.	Discard capillary holder.
Flexible tab tears off before it is pulled completely out of reagent cartridge.	Discard the reagent cartridge. • Refer to Section 9 for instructions on "How to Report the Problem."

INSTRUMENT CARE AND ROUTINE MAINTENANCE

INSTRUMENT CARE

The DCA 2000®+ Analyzer contains sensitive electronics and optics.

- **IMPORTANT! Do not use sprays.** Sprays will permanently damage the optical system.
- Handle the instrument with extreme care. Severe mechanical shocks can damage and/or dislodge internal parts and connections.
- Do not block the ventilation panels found on the back and right sides of the instrument. Allow at least two inches of air space between the wall (or other surface) and the back and right sides of the instrument.
- Do not operate the instrument beyond the recommended maximum ambient operating temperature or relative humidity ranges listed below.

  Maximum Ambient Operating Temperature:

  (15–32°C)—Hemoglobin A_{1c}

  (18–30°C)—Microalbumin/Creatinine

  Relative Humidity: 10% – 90% RH

- Do not place the instrument where it would be exposed to direct sunlight, extreme temperature variations, particulate matter, excessive humidity or air currents.
- Do not smoke in the room where you have placed the instrument. Smoke may cause a film to form on the internal optical surfaces affecting the optical transmission qualities of the instrument.

ROUTINE MAINTENANCE CHART

Weekly	Quarterly	As Required (by spillage, troubleshooting or contamination)
Exterior Bar Code Window	Cartridge Compartment Change Air Filter Run Optical Test Cartridge	Exterior Change Air Filter Cartridge Compartment Bar Code Window Run Optical Test Cartridge

NOTE: Maintenance requirements for each laboratory must be assessed individually. Use the above chart as a guide. It is good laboratory practice to properly maintain your instrument.

EXTERIOR OF THE INSTRUMENT AND BAR CODE WINDOW

WARNING: Turn off the power and unplug the power cord before cleaning exterior of instrument.

VAROITUS: Kytke virta pois ja irrota virtajohto ennen kuin alat puhdistaa laitteen ulkopintoja.

Do not allow water or other cleaning fluid to drip inside instrument (bar code window area, program card area and key pad are especially vulnerable).

1. **Clean** the exterior of the instrument, including the display panel and bar code window with a lint-free cloth dampened with water. A cloth dampened with ethanol may also be used.

   If you desire to **disinfect** the **exterior** of the instrument, **expose** the surface to either of the following for **10 minutes**.[1] Remove liquid blood (as much as possible) prior to disinfection.

   a. 0.5% sodium hypochlorite (see household bleach, below)

   b. 2% glutaraldehyde

   [1]This is as referenced in the National Committee for Clinical Laboratory Standards, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissues: Approved Guideline. NCCLS Document M29-A [ISBN 1-56238-339-6].

2. After the exterior is clean and dry, **attach** and **plug-in** power cord.

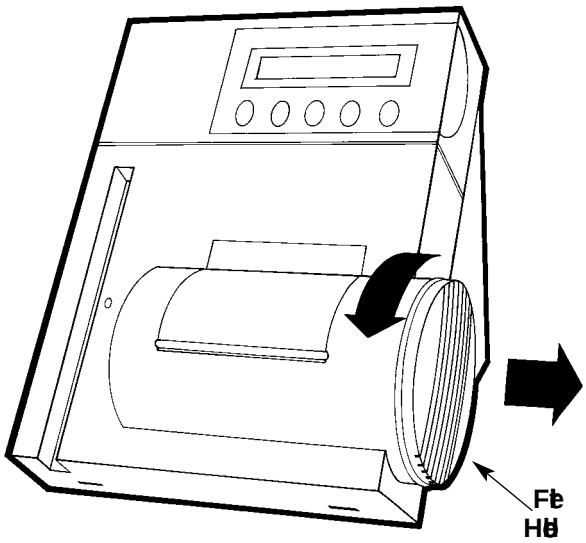
Most household bleach is (approx.) a 5% solution of sodium hypochlorite (read the label).

Dilute household bleach containing (approx.) 5% sodium hypochlorite as follows to obtain (approx.) a 0.5% solution of sodium hypochlorite.

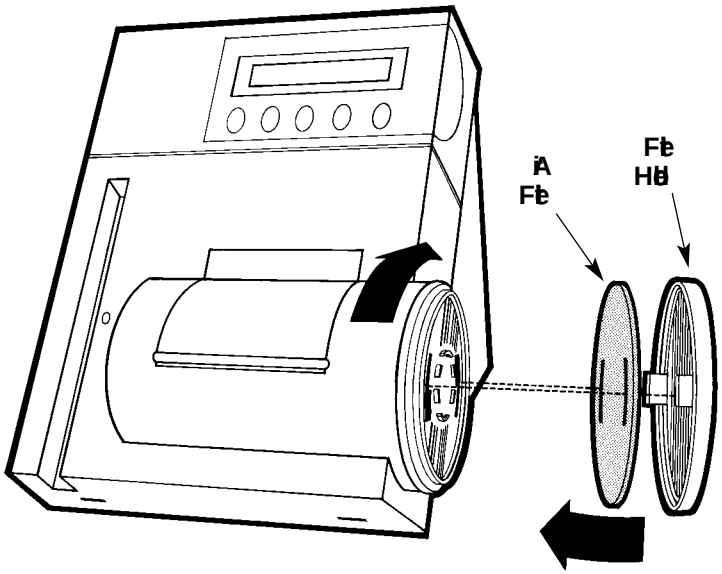
- 10 mL of household bleach + 90 mL of water or alternatively:
- 1 part household bleach + 9 parts water

CHANGING THE AIR FILTER

1. Remove the filter holder from the right side of the instrument by rotating the holder counter-clockwise (until it stops) and pulling it off.



2. Dispose of the old air filter.
3. Place a new air filter into the filter holder.
4. Place the filter holder back on the instrument and rotate the holder clockwise (until it stops).



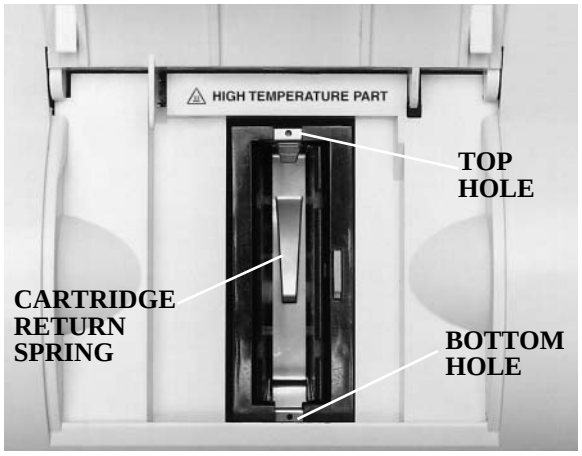
CARTRIDGE COMPARTMENT

WARNING: Turn off the power and unplug the power cord before cleaning the cartridge compartment.

VAROITUS: Kytke virta pois ja irrota virtajohto, ennen kuin puhdistat kasettipesän.

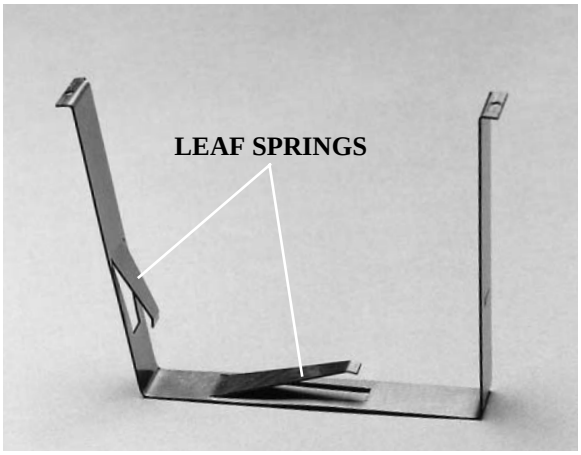
Do not allow liquid to drip into instrument. If liquid drips into instrument, optics can be destroyed.

1. **Open** the cartridge compartment door as far as possible.
2. Using a lint-free cloth dampened with water or ethanol, **wipe** the inside surface of the compartment door and surfaces on both sides of the cartridge holder.
   - **Dry** surfaces using a clean, dry, lint-free cloth.
3. **Locate** the cartridge return spring inside the cartridge holder. Note top and bottom holes.



4. **Insert** the tip of a straightened paper clip (or other like device) into the top hole on the spring.
   - Gently, pull metal end toward center of cartridge compartment to release one side of the spring from the cartridge holder.
   - Repeat procedure to release other side of spring from cartridge holder.
5. **Pull** cartridge return spring completely out of instrument.
6. **Clean** cartridge return spring using any of the following:
   - warm solution of mild detergent and water (you may immerse cartridge return spring)
   - lint-free cloth dampened in water or ethanol

   IMPORTANT: Make sure the leaf springs are not bent or damaged while cleaning. Damaged leaf springs will not function properly.



7. **Dry** cartridge return spring with a clean, lint-free cloth. Set spring aside.

8. Using a clean, dry, *sponge* swab (provided in "Cleaning Kit," Part No. 95001901) **remove** spilled liquid from the cartridge holder.

   IMPORTANT: Do not use a cotton swab. Cotton fibers may be left on surface and interfere with instrument optical system.

   With compartment door partially closed, rotate the cartridge holder as shown to locate and remove any additional liquid.

   NOTE: Cartridge holder cannot be rotated if compartment door is completely open.

9. **Dampen** (do not soak) a sponge swab with water or ethanol. **Clean** cartridge holder (rotating cartridge holder as necessary).

   IMPORTANT: Do not allow liquid to drip off sponge swab into instrument. If liquid drips into instrument, optics can be destroyed.

10. **Look** inside the cartridge compartment and **locate** the vertical grooves (tracks). Next, **locate** the front and back slots (found near the top lip of the compartment).

11. **Locate** the leaf spring on one side of the cartridge return spring.

12. With the leaf spring orientated toward the back of the instrument, lower the leaf spring into the instrument as follows:

    a. **Hold onto** both sides of the cartridge return spring (near the holes).

    b. **Pinch** the sides together (push toward each other) and lower the spring into instrument by sliding the sides of the spring between the vertical grooves (tracks) in the compartment. **Release** (let go of) spring.

       NOTE: When "step b," above, has been properly completed, the return spring should be free to slide up and down within the cartridge compartment. If not, repeat "step b" above.

       IMPORTANT: Never force the spring into the cartridge compartment! Forcing the spring into the compartment will damage the spring.

    c. **Gently and carefully, push down** on edge of cartridge return spring (with hole) and insert edge into slot.

       Repeat "step c" to attach opposite side of cartridge return spring to cartridge compartment.

       IMPORTANT: When the cartridge return spring is placed back into the instrument, the leaf spring **must** be orientated toward the back of the instrument and cartridge return spring **must** be securely attached via the grooves (tracks) and slots.

       IMPORTANT: Failure to properly replace return spring can result in erroneous test results.

13. **Run** optical test cartridge according to instructions that follow.

    (Allows you to verify that the optical system was not damaged or contaminated by dust, etc., during this maintenance procedure.)

RUNNING THE OPTICAL TEST CARTRIDGE (Standard 1)

The provided optical test cartridge allows you to monitor the performance of the optical system over time.

IMPORTANT! Keep a permanent record of the results obtained (i.e., Mean Transmittance, Standard Deviation and Drift).*

*It is recommended that you record the results on the page provided in the appendix of this manual.

Comparing New Values With Initial Values

Compare the new values obtained with the results recorded initially for your instrument (see appendix). The mean Transmittance should be within the range of 0.9500 to 1.0500, and should not have varied by more than ± 0.0100. The Standard Deviation should be less than 0.00150 and the Drift should be less than 0.01400.

DISPLAY	WHAT YOU DO
READY: SCAN BAR CODE 02/24/03 2:09PM	1. **Locate** the bar code on the optical test cartridge. 2. **Hold** the cartridge so that the bar code faces right. 3. **Insert** the cartridge (above dot on instrument) into the bar code track. 4. **Quickly** (within 1 second) **and smoothly, slide** the cartridge down past the dot. A beep sounds to signal a successful scan. • If no beep sounds, repeat the procedure. If a beep repeatedly fails to sound, refer to Troubleshooting, Section 6.
RUN STANDARD 1?	5. **Press** ↵.

DISPLAY

```
      STANDARD 1
  LOAD, CLOSE DOOR
```

WHAT YOU DO

6. **Open** the cartridge compartment door.
7. **Hold** the optical test cartridge so that the bar code faces right.

   Insert the cartridge into the compartment until a subtle snap is heard/felt.

   HINT: The cartridge is designed to fit only one way into the instrument.
8. **Close** door.

```
  PROCESSING STANDARD
S1     6 MIN     10:02AM
```

6 MIN = total test time

After 1 minute:

```
1.0001   T   0.00012 SD
S1    5 MIN      10:03AM
```

DISPLAY

Upon completion of test:

```
1.0001 T  0.00012 SD
S1       0.00387 DRIFT
```

WHAT YOU DO

9. **Record** the displayed results in the blanks provided on the last page of this manual (appendix).

10. **Remove** cartridge.
    a) Open cartridge compartment door.*
    b) Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c) With your left hand, gently push the plastic tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d) Pull cartridge out of compartment.

11. **Compare** the results obtained with results obtained initially.

    If the results are not within the limits found on page 7.6 and in the appendix, refer to Section 9 for information on "How to Report the Problem."

*If the door *is* opened (within 15 minutes after assay completion), the test result is displayed for only 30 seconds.

If the door *is not* opened, the test result will remain displayed for 15 minutes.

At 15 minutes, an audible tone (error buzz) sounds and the display changes to "READY: REMOVE TEST."

MINOR REPAIR

You can:

- replace the fuse

If your instrument requires any other type of repair, refer to Section 9, Service Information.

How to Replace the Fuse

Tool Required: Screwdriver

Fuse Required:
250 V, T-1.25A (Instrument Model No. 5031C)

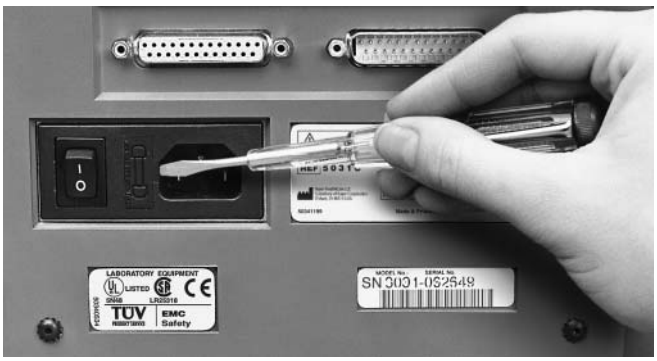
One replacement fuse is stored in the fuse holder. The fuse holder is located on the back panel of the instrument between ON/OFF switch and power cord connector.

1. **WARNING: Set the power switch to OFF. Unplug power cord from wall outlet. Unplug power cord from instrument.**

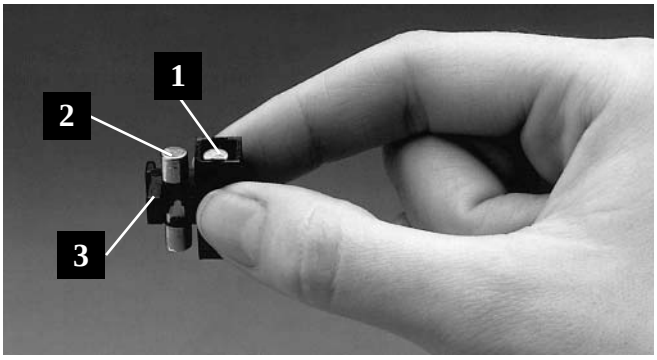
   VAROITUS: Kytke virta pois (off -asento). Irrota virtajohto seinäpistokkesta. Irrota virtajohto laitteesta.

2. **Locate** the groove on the side of the fuse holder that faces power cord connector.

3. **Insert** the tip of a screwdriver into the groove. Then, exert pressure to unsnap fuse holder from instrument.



4. **Remove** the fuse holder from instrument.



1 replacement fuse

2 blown fuse

3 fuse block

5. **Remove and dispose** of blown fuse.

6. **Push** the replacement fuse out of the black box using the tip of a screwdriver or similar device.

7. **Insert** replacement fuse onto fuse block.

   WARNING: For continued protection against fire hazard, replace only with the indicated type and rating of fuse.

   VAROITUS: Paloturvallisuussyistä, käytä vain suositeltuja sulakkeita.

8. **Re-insert** fuse holder into instrument (snap gently into place.)

SERVICE INFORMATION

When you have a problem with the System

- Refer to Troubleshooting, Section 6, of this Manual

If Section 6 cannot assist you in solving the problem, answer all of the following questions before contacting us for help. The requested information will help identify the cause of the particular problem.

How to Report the Problem

First

Record the following information.

Instrument Serial Number _____

Installation Date_____

Test Type _____

Reagent Cartridge Lot Number _____

Control Lot Number _____

Control Results _____

Optical Test Cartridge Results:

	Initial	Current
Mean Transmittance	_____	_____
Standard Deviation	_____	_____
Drift	_____	_____

Second

Complete the following "Preservice Questionnaire."

1. Has Section 6, Trouble-shooting been reviewed? ☐ YES ☐ NO
2. Have you performed the required maintenance procedures (Section 7)? ☐ YES ☐ NO
3. Set the power switch to OFF. Make sure the program card is securely plugged in. Set the power switch to ON. Are the following displayed? ☐ YES ☐ NO

```
SOFTWARE VERSION
E3.11/01.04
```

```
COPYRIGHT 1991-2003
BY BAYER CORPORATION
```

```
INITIALIZING
KEEP DOOR CLOSED
```

```
WAIT: WARMING UP
02/24/03        2:09PM
```

(if instrument is not within operating temperature range)

```
READY: SCAN BAR CODE
02/24/03        2:09PM
```

4. If displays do not appear:
   - is the instrument plugged into a live, AC electrical outlet? ☐ YES ☐ NO
   - Is the line fuse defective? Refer to Section 7, Minor Repair. ☐ YES ☐ NO
5. Do any characters on the display appear partially defective? ☐ YES ☐ NO

SERVICE INFORMATION

6. If your instrument is connected to a printer or computer, are all cables securely attached? ☐ YES ☐ NO

7. List error messages that have appeared. _____

   _____

   _____

   _____

   _____

   _____

8. Record the exact sequence of events that took place when the failure occurred and any results obtained.

9. Be prepared to perform a complete test procedure when you call for assistance.

Third

Contact the nearest Bayer Diagnostics office or authorized distributor.

ACCESSORY ITEMS

Part Number	Description
Hemoglobin A_{1c}	
5035C	DCA 2000® Reagent Kit
5068A	DCA 2000® Normal & Abnormal Control Kit
Microalbumin/Creatinine	
6011A	DCA 2000® Reagent Kit
6012A	DCA 2000® Low & High Control Kit

NOTE: Part numbers are subject to change without notice.

REPLACEMENT PARTS

Part Number	Description
SR002810	Program Card for Instrument English
40330028	N.A. Power Cord for Instrument
40330046	Euro Power Cord for Instrument
40330050	U.K. Power Cord for Instrument
50214149	Filter Holder
50546216	Cartridge Return Spring
625-0127-01	Fuse: T-1.25A, Slow Blow; 250V
95001901	Cleaning Kit
95002911	Optical Test Cartridge
95002117	Air Filter (8) Replacement Kit
95002836	Operating Manual

NOTE: Part numbers are subject to change without notice.

TO ORDER:

Contact the nearest Bayer HealthCare office or authorized distributor.

Distributed by:

Bayer HealthCare LLC
Elkhart, IN 46515 USA

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Strawberry Hill
Newbury, Berkshire
RG14 1JA UK

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Diagnostics Division
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Pymble NSW 2073
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Bayer (South East Asia), Pte Ltd
No.9 Benoi Sector
Singapore 629844
Tel: (65) 6261 3389
Fax: (65) 6266 3376

APPENDIX

OPTICAL TEST CARTRIDGE RESULTS

Initial Values

Date _____

Mean Transmittance _____

Standard Deviation _____

Drift _____

Comparing New Values With Initial Values

Compare the new values obtained with the initial values. The Mean Transmittance should be within the range of 0.9500 to 1.0500, and should not have varied by more than ±0.0100. The Standard Deviation should be less than 0.00150 and Drift should be less than 0.01400.

DATE	MEAN TRANSMITTANCE	STANDARD DEVIATION	DRIFT

INDEX

S

T

U

V

W