



## Suggested Product Storage Conditions

CardioChek® brand products are designed to be conveniently stored at room temperature. These storage conditions and analyzer operating ranges are stated in the respective package insert as shown in the table below (Column A).

It is well established that chemistry based IVDD products are best maintained at controlled room temperature which is 20-26°C. This controlled range helps to maintain long term product stability. In addition, avoidance of extreme temperatures during operation of the analyzer is preferred, thus within the range 20-27°C which is up to 80°F. These values are shown in Column B.

<b>A</b>		<b>B</b>	
Acceptable Conditions <sup>1</sup>		Optimal Conditions	
Test Strip Storage	Analyzer Operating Range	Test Strip Storage	Analyzer Operating Range
20-30°C 68-86°F	18-35°C 64-95°F	20-26°C 68-79°F	20-27°C 68-80°F
<sup>1</sup> See respective package insert			

Current operating and storage specifications consider the broad application of our products in various health care settings. The acceptable ranges may continue to be used for all products and will yield reliable and accurate results which meet performance claims. The recommended optimal operating and storage temperatures listed in column B provide added assurance of performance reliability and long term product stability.

It is our constant mission at Polymer Technology Systems, Inc. to ensure that our customers and their patients receive the most reliable and accurate results possible. In doing so, we have determined the defined new optimal operating and storage temperature ranges.

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## Customer Bulletin

### **Assignment of Ranges for PTS Panels<sup>®</sup> Multi-Chemistry Controls (Cat. No./REF 721) and PTS Panels<sup>®</sup> HDL Cholesterol Controls (Cat. No./REF 722)**

#### **Background:**

PTS Panels Multi-Chemistry Controls and PTS Panels HDL Cholesterol Controls are provided as assayed controls intended for use with CardioChek<sup>®</sup> brand analyzers PTS Panels test strips. Currently, assay ranges are set based upon selected multiple lots of test strips and multiple analyzers. The effect of this commonly accepted industry practice of setting control ranges may yield ranges that may be larger than desired by an individual laboratory. Control ranges set specifically for the combination of the analyzer, test strip lot and control lot numbers in use, are typically narrower. PTS, Inc. has received numerous questions regarding appropriate methods to set specific ranges for controls based on the combination of products in use at each facility.

#### **Summary:**

While control materials are universally used to monitor the performance of laboratory systems, controls have some characteristics that produce a wider range than whole blood when multiple lots of test strips are used. There exists a variability of response across the different lots of test strips and thus the best method of quality control is a lot specific range. For this reason and others, this control material, while helpful for qualitative analysis of the precision of CardioChek analyzer results, does not have exactly the same response as human whole blood.

#### **Why are we sending you this bulletin?**

A review of the acceptance ranges currently assigned to the control material illustrates an acceptance range derived by testing a large number (at least 4 to 6 different lots) of test strips with each control lot. The ranges established are reflective of a large and specific sub-population of all the available lots of test strips, and not all available assay lots. As a result of this limited testing, the ranges of different control material lots are wider than anticipated for a single lot of test strips, but still not always representative of the entire universe of test strips. The two reasons we are sending this bulletin are:

1. We are making a change in how we set control ranges to better represent the response of all current test strip lots. The change we are making provides a universal range that should encompass all available lots of test strips and controls. Ranges are separate for single analyte and multi-analyte test strips.
2. We are providing a procedure to assist you in establishing your own specific control range based on the combination of analyzer, test strip lot and control lot you are using.

#### **What does this mean to the User?**

Control ranges will be provided in each package of controls on a range card, as is done currently. These ranges will represent the entire control range for all lots of test strips and controls. This is the range the customer should be able to attain when testing with any combination of PTS Panels test strips and controls. Examples of range cards are provided in Attachment 1. A procedure in Attachment 2 (with a blank form and examples of completed forms and QC chart) specifies how a user can test their own materials to generate a system-specific range (by analyzer S/N, control and test strips lot numbers). Once established, this represents the customer acceptance range which will be used to run routine quality control.

#### **Questions/Comments?**

Please call Customer Service at +1-317-870-5610 (Direct) or +1-877-870-5610 (Toll-free inside USA).

**ATTACHMENT 1: Examples of PTS, Inc. Control Value Range Cards**

PTS Panels <sup>®</sup> Multi-Chemistry Control* Ranges	Level 1		Level 2	
	mg/dL	mmol/L	mg/dL	mmol/L
<b>Single-analyte test strips</b>				
Cholesterol	≤100 - 220	≤2.59 – 5.70	115 - 320	2.98 – 8.29
Triglycerides	105 - 275	1.19 – 3.11	105 - 400	1.19 – 4.52
Glucose	45 - 140	2.50 – 7.77	70 - 290	3.89 – 16.10
Ketone	3 - 15	0.29 – 1.44	30 - 75	2.88 – 7.21
LDL Cholesterol	≤ 50 - 95	≤1.30 – 2.46	65-175	1.68 – 4.53
<b>Multi-analyte test strips</b>				
Cholesterol	≤100 - 220	≤2.59 – 5.70	105 - 360	2.72 – 9.32
Triglycerides	70 - 255	0.79 – 2.88	130 - 355	1.47 – 4.01
Glucose	40 - 140	2.22 – 7.77	100 - 290	5.55 – 16.10
<p>*HDL Cholesterol requires a separate HDL Cholesterol Control (Cat. No. 722).                      For assistance contact PTS, Inc. Customer Service at                      +1-877-870-5610 (Toll-free inside USA); +1-317-870-5610 (Direct)                      or +1-317-870-5608 (Fax).                      . Email: <a href="mailto:inforequest@cardiochek.com">inforequest@cardiochek.com</a></p>				

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PTS Panels <sup>®</sup> HDL Cholesterol Control Ranges	Level 1		Level 2	
	mg/dL	mmol/L	mg/dL	mmol/L
<b>Single-analyte test strips</b>				
HDL Cholesterol	≤25 - 65	≤0.65 - 1.68	40 - ≥85	1.04 – ≥2.20
<b>Multi-analyte test strips</b>				
HDL Cholesterol	≤15 - 65	≤0.39 - 1.68	40 - ≥100	1.04- ≥2.59
<p>For assistance contact PTS, Inc. Customer Service at                      +1-877-870-5610 (Toll-free inside USA); +1-317-870-5610 (Direct)                      or +1-317-870-5608 (Fax).                      . Email: <a href="mailto:inforequest@cardiochek.com">inforequest@cardiochek.com</a></p>				

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**Attachment 2: Procedure for Establishing Quality Control (QC) Ranges Using PTS Panels® Multi-Chemistry Controls and PTS Panels® HDL Cholesterol Controls**

**Background:** Quality control testing is important in confirming that any test system is functioning properly. Various materials are suitable for quality control testing. PTS, Inc. provides assayed controls specifically designed to be used with CardioChek® brand analyzers. These are **PTS Panels® Multi-Chemistry Controls and PTS Panels® HDL Cholesterol Controls.** PTS, Inc. establishes the assay values for each lot of controls using multiple lots of reagents and a large number of analyzers. Due to some non-human components in the control material and this method of initial testing, control ranges may be wider than desirable for an individual institution. This procedure provides a means to define control ranges that are specific to the system in use (control lot no., test strip lot no., analyzers). The resulting lot-specific ranges are usually narrower than the ranges in the package insert, and offer a means for each site to apply tighter control limits in routine testing.

**Materials Needed:**

- CardioChek brand analyzer(s)
- PTS Panels test strips from each lot number for which the range is to be determined
- Pipet or capillary blood collector
- Two levels of a single lot of controls (PTS Panels® Multi-Chemistry Controls and/or PTS Panels® HDL Cholesterol Controls)

Note: If multiple control lots are to be used, values need to be assigned to each lot of control using each lot of test strips. Results for a selected lot number of control may not be pooled if results are from multiple test strip lots.

**Procedure:**

1. Run a gray optical check strip on each CardioChek analyzer to be used and make sure the check strip passes.
2. Run each level of control test at least ten times (e.g., 2 runs/day for 5 days). If you have multiple analyzers, you may use several analyzers.
  - a. Make sure the MEMO chip installed in each CardioChek analyzer matches the lot of test strip used.
  - b. Insert the test strip into the CardioChek analyzer as far as it will go.
  - c. Turn the analyzer ON by pressing one of the buttons.
  - d. Pipet a fixed volume of control or add a drop from the bottle onto the test strip blood application window. (A fixed volume is between 10 and 15 µL for single analyte test strips and 25µL for multi-analyte test strips, such as Lipid Panel test strips) \*
  - e. Record results using the form attached. KEEP EACH LOT OF CONTROL WITH EACH LOT OF TEST STRIPS SEPARATE. DO NOT MIX RESULTS FROM

DIFFERENT LOTS. PAIR EACH TEST STRIP LOT WITH A CONTROL LOT.

- f. Repeat until you have recorded ten results.
- g. Calculate the average and standard deviation for the test results.
- h. The following is an example of how to report the control range you established.

Report the range as:

Control Range for combination of Lot HXXX HDL Cholesterol and Level 1 control Lot abcd =

(Average – 3X Standard Deviation) to (Average + 3XStandard Deviation) \*\*.

NOTE: Results such as “>85” or “<25” should be used as “85” and “25” respectively in calculations, unless an error is suspected. If you suspect an error in running the control test, repeat test.

See User Guide for additional instructions on how to run controls.

**\* Use either a fixed volume of control or use a drop from the bottle. Make sure when you test controls that you use the same fixed volume of control (or drop) as you used to determine the range.**

\*\*The control range only applies to the combination of a single control lot number with a single test strip lot number. All ranges are for lot-specific combination of control and test strip. The range established should fall within the manufacturer’s published control range.

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**Control Value Range Determination Datasheet**    Sample volume \_\_\_\_\_  $\mu\text{L}$

	Control Level 1	Control Level 2	PTS Panels <sup>®</sup> test strips
Brand Name or Description	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol test strips</b>
Cat. No.			
Lot No.			
Exp. Date			

Run / Date	Control Level 1 HDL Result in mg/dL	Control Level 2 HDL Result in mg/dL	Tested by:
CardioChek <sup>®</sup> S/N			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
n			
Average			
Standard Deviation (SD)			
2*SD			
3*SD			
Average - 3*SD			
Average + 3*SD			
Control Range			

Control Ranges for Lot \_\_\_\_\_ of PTS Panels HDL Cholesterol test strips:

\_\_\_\_\_ Lot \_\_\_\_\_:

\_\_\_\_\_ Lot \_\_\_\_\_:

**Control Value Range Determination Datasheet**      Sample volume \_\_\_\_\_  $\mu\text{L}$

	Control Level 1	Control Level 2	PTS Panels <sup>®</sup> test strips
Brand Name or Description	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol test strips</b>
Cat. No./REF	<b>721</b>	<b>721</b>	<b>H904</b>
Lot No.	<b>30680A</b>	<b>30680B</b>	
Exp. Date	<b>2009-07-05</b>	<b>2009-07-05</b>	

Run / Date	Control Level 1 HDL Result in mg/dL	Control Level 2 HDL Result in mg/dL	Tested by:
CardioChek <sup>®</sup> S/N			
1	52	>85.00	
2	49	84.56	
3	49	78.90	
4	51	>85.00	
5	48	75.18	
6	55	>85.00	
7	51	84.21	
8	51	>85.00	
9	62	>85.00	
10	56	>85.00	
n	10	10	
Average	52.4	83.3	
Standard Deviation (SD)	4.22	3.47	
2*SD	8.44	6.93	
3*SD	12.66	10.40	
Average - 3*SD	40	73	
Average + 3*SD	65	94	
Control Range	<b>40 – 65 mg/dL</b>	<b>73-94 mg/dL</b>	

Control Ranges for Lot H904 of PTS Panels HDL Cholesterol test strips:

PTS Panels HDL Cholesterol Controls Level 1 Lot 30680A:

40-65 mg/dL

PTS Panels HDL Cholesterol Controls Level 1 Lot 30680B:

73-94 mg/dL

**Control Value Range Determination Datasheet**    Sample volume \_\_\_\_\_  $\mu\text{L}$

	Control Level 1	Control Level 2	PTS Panels <sup>®</sup> test strips
Brand Name or Description	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol Controls</b>	<b>PTS Panels HDL Cholesterol test strips</b>
Cat. No./REF	<b>721</b>	<b>721</b>	<b>H904</b>
Lot No.	<b>30680A</b>	<b>30680B</b>	
Exp. Date	<b>2009-07-05</b>	<b>2009-07-05</b>	

Run / Date	Control Level 1 HDL Result in mmol/L	Control Level 2 HDL Result in mmol/L	Tested by:
CardioChek <sup>®</sup> S/N			
1	1.35	2.20	
2	1.27	2.20	
3	1.27	2.05	
4	1.32	2.20	
5	1.24	1.94	
6	1.42	2.20	
7	1.32	2.18	
8	1.32	2.20	
9	1.61	2.20	
10	1.45	2.20	
n	10	10	
Average	1.36	2.16	
Standard Deviation (SD)	0.11	0.09	
2*SD	0.22	0.18	
3*SD	0.33	0.27	
Average - 3*SD	1.03	1.89	
Average + 3*SD	1.69	2.43	
Control Range	<b>1.03 – 1.69 mmol/L</b>	<b>1.89 – 2.43 mmol/L</b>	

Control Ranges for Lot H904 \_\_\_\_\_ of PTS Panels HDL Cholesterol test strips:

PTS Panels HDL Cholesterol Controls Level 1 Lot 30680A:

1.03 – 1.69 mmol/L
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PTS Panels HDL Cholesterol Controls Level 1 Lot 30680B:

1.89 – 2.43 mmol/L
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QC Chart PTS Panels HDL Cholesterol Test Strips Lot H904 using HDL Cholesterol Control  
Lot 30680 A Level 1

