

K955087

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Attachment 3

SUMMARY OF SAFETY AND EFFECTIVENESS

Hemoglobin A1c (%)

Listed below is a comparison of the performance between the Technicon RA®/opeRA™ Systems Hemoglobin A1c/Total Hemoglobin assays and the similar device assay system that was granted FDA clearance of substantial equivalence (Ames DCA 2000® Hemoglobin method). The information provided in this summary was extracted from the Technicon RA®/opeRA™ Systems Hemoglobin A1c/Total Hemoglobin method sheet and the Ames DCA 2000® Hemoglobin A1c method sheet (Attachments 1 & 2).

INTENDED USE

This *in vitro* diagnostic method is intended to quantitatively measure Hemoglobin A1c (HbA1c) and Total Hemoglobin (Thb) in human blood on the Technicon RA family/opeRA instrument systems. Measurements obtained through this procedure can be used for monitoring the long-term care of persons with diabetes.

METHOD	<u>RA/opeRA HbA1c</u>		<u>DCA 2000 HbA1c</u>	
	<u>Mean %</u>	<u>Total CV%</u>	<u>Mean %</u>	<u>Total CV %</u>
Precision	5.7	3.1	5.2	3.5-5.6
	8.9	2.6	8.2	2.4-4.9
	11.6	2.0	12.0	3.3-4.9

Analytical Range

2.5 - 18%

2.5 - 14.0%

Correlation

$$y = \text{RA/opeRA}$$

$$x = \text{DCA 2000}$$

$$y = 1.09x - 0.39$$

$$n = 154$$

$$r = 0.99$$

$$S_{yx} = 0.36$$

Expected Values

4.4 - 6.0 %

4.5 - 5.7%

updated 5/21/96, gm.

SUMMARY OF SAFETY AND EFFECTIVENESS

Total Hemoglobin (g/dl)

METHOD	<u>RA/opeRA, Thb</u>	<u>NCCLS Reference Method, Thb</u> Document H15 - A2, Vol 14, No. 6, May 1994
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Precision	<u>Mean g/dL</u>	<u>Within-Run CV%</u>
	10.6	0.6
	15.3	0.7
	18.6	0.9

Analytical Range 7 - 23 g/dL

Correlation

y = RA/opeRA	y = 0.96 x 0.13
x = NCCLS method	n = 50
	r = 0.988
	Syx = 0.65

Expected Values 12.3 - 17.9 g/dL

updated 5/21/96, gm.