



## Method Comparison Evaluation Report

<b>Location:</b>	Changsha, China	<b># Within 5% Pass 36</b>	<b>34 No</b>
<b>Manufacturer:</b>	Changsha Sinocare, Inc.		
<b>Test Method (Y):</b>	HbA1c on PCH-100		
<b>Comparative Method (X):</b>	ASRL#3 D-100		
<b>Units of Measurement:</b>	% HbA1c		
<b>Certification Type:</b>	Manufacturer		

### Bias Estimation Data

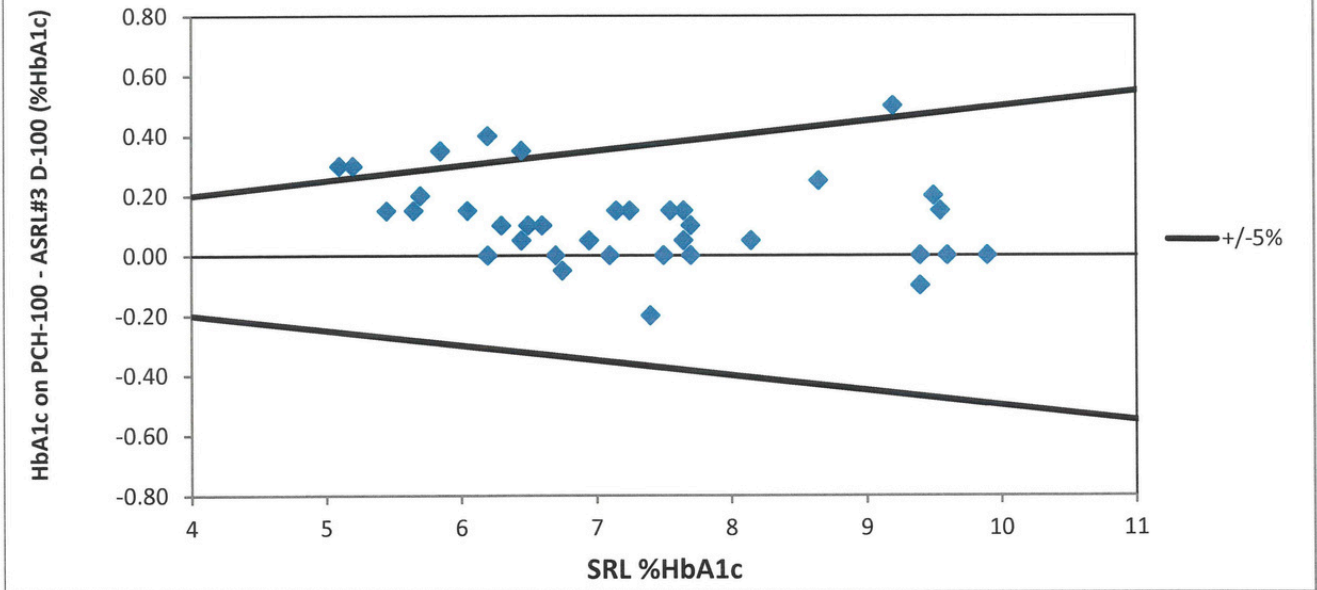
Test Method		0	Comparative Method	
Sample ID	Analysis Date	Y1	X1	X2
C4341	20220905	8.20	8.10	8.20
C4342	20220905	7.70	7.60	7.80
C4343	20220905	5.60	5.40	5.50
C4344	20220905	7.00	6.90	7.00
C4345	20220905	6.60	6.20	6.20
C4346	20220905	9.70	9.50	9.50
C4347	20220905	5.80	5.70	5.60
C4348	20220905	6.80	6.50	6.40
C4349	20220906	7.70	7.60	7.70
C4350	20220906	9.30	9.40	9.40
C4351	20220906	7.80	7.60	7.80
C4352	20220906	6.60	6.50	6.50
C4353	20220906	6.70	6.80	6.70
C4354	20220906	6.20	6.20	6.20
C4355	20220906	7.40	7.20	7.30
C4356	20220906	5.40	5.10	5.10
C4357	20220907	5.60	5.40	5.50
C4358	20220907	7.10	7.20	7.00
C4359	20220907	8.90	8.70	8.60
C4360	20220907	9.70	9.50	9.60
C4361	20220907	7.30	7.10	7.20
C4362	20220907	7.20	7.40	7.40
C4363	20220907	6.40	6.30	6.30
C4364	20220907	6.20	5.90	5.80
C4365	20220908	7.80	7.70	7.60
C4366	20220908	9.40	9.50	9.30
C4367	20220908	9.60	9.70	9.50
C4368	20220908	6.70	6.70	6.50
C4369	20220908	6.70	6.80	6.60
C4370	20220908	5.50	5.30	5.10
C4371	20220908	7.50	7.60	7.40
C4372	20220908	5.90	5.80	5.60
C4373	20220909	7.70	7.80	7.60
C4374	20220909	5.80	5.70	5.60
C4375	20220909	6.50	6.50	6.40
C4376	20220909	9.70	9.20	9.20
C4377	20220909	9.90	9.90	9.90
C4378	20220909	7.70	7.50	7.60
C4379	20220909	7.00	6.90	7.00
C4380	20220909	6.20	6.10	6.00

SRL Mean	Y	% Diff	Within 5%
8.15	8.20	0.61%	Y
7.70	7.70	0.00%	Y
5.45	5.60	2.75%	Y
6.95	7.00	0.72%	Y
6.20	6.60	6.45%	N
9.50	9.70	2.11%	Y
5.65	5.80	2.65%	Y
6.45	6.80	5.43%	N
7.65	7.70	0.65%	Y
9.40	9.30	-1.06%	Y
7.70	7.80	1.30%	Y
6.50	6.60	1.54%	Y
6.75	6.70	-0.74%	Y
6.20	6.20	0.00%	Y
7.25	7.40	2.07%	Y
5.10	5.40	5.88%	N
5.45	5.60	2.75%	Y
7.10	7.10	0.00%	Y
8.65	8.90	2.89%	Y
9.55	9.70	1.57%	Y
7.15	7.30	2.10%	Y
7.40	7.20	-2.70%	Y
6.30	6.40	1.59%	Y
5.85	6.20	5.98%	N
7.65	7.80	1.96%	Y
9.40	9.40	0.00%	Y
9.60	9.60	0.00%	Y
6.60	6.70	1.52%	Y
6.70	6.70	0.00%	Y
5.20	5.50	5.77%	N
7.50	7.50	0.00%	Y
5.70	5.90	3.51%	Y
7.70	7.70	0.00%	Y
5.65	5.80	2.65%	Y
6.45	6.50	0.78%	Y
9.20	9.70	5.43%	N
9.90	9.90	0.00%	Y
7.55	7.70	1.99%	Y
6.95	7.00	0.72%	Y
6.05	6.20	2.48%	Y



## Method Comparison Evaluation Report

### Bias Plot: HbA1c on PCH-100 vs. ASRL#3 D-100





## Method Comparison Evaluation Between Method Outlier Report (For Investigational Use Only)

**Manufacturer:** Changsha Sinocare, Inc.      **Certification Type:** Manufacturer  
**Test Method (Y):** HbA1c on PCH-100  
**Comparative Method (X):** ASRL#3 D-100      **Report Date:** 09/20/22

Sample ID	Assay Date	Mean X	Y	Between Method Differences	Between Method
				Y-Mean X	Outliers
C4341	20220905	8.15	8.20	0.05	
C4342	20220905	7.70	7.70	0.00	
C4343	20220905	5.45	5.60	0.15	
C4344	20220905	6.95	7.00	0.05	
C4345	20220905	6.20	6.60	0.40	
C4346	20220905	9.50	9.70	0.20	
C4347	20220905	5.65	5.80	0.15	
C4348	20220905	6.45	6.80	0.35	
C4349	20220906	7.65	7.70	0.05	
C4350	20220906	9.40	9.30	-0.10	
C4351	20220906	7.70	7.80	0.10	
C4352	20220906	6.50	6.60	0.10	
C4353	20220906	6.75	6.70	-0.05	
C4354	20220906	6.20	6.20	0.00	
C4355	20220906	7.25	7.40	0.15	
C4356	20220906	5.10	5.40	0.30	
C4357	20220907	5.45	5.60	0.15	
C4358	20220907	7.10	7.10	0.00	
C4359	20220907	8.65	8.90	0.25	
C4360	20220907	9.55	9.70	0.15	
C4361	20220907	7.15	7.30	0.15	
C4362	20220907	7.40	7.20	-0.20	
C4363	20220907	6.30	6.40	0.10	
C4364	20220907	5.85	6.20	0.35	
C4365	20220908	7.65	7.80	0.15	
C4366	20220908	9.40	9.40	0.00	
C4367	20220908	9.60	9.60	0.00	
C4368	20220908	6.60	6.70	0.10	
C4369	20220908	6.70	6.70	0.00	
C4370	20220908	5.20	5.50	0.30	
C4371	20220908	7.50	7.50	0.00	
C4372	20220908	5.70	5.90	0.20	
C4373	20220909	7.70	7.70	0.00	
C4374	20220909	5.65	5.80	0.15	
C4375	20220909	6.45	6.50	0.05	
C4376	20220909	9.20	9.70	0.50	
C4377	20220909	9.90	9.90	0.00	
C4378	20220909	7.55	7.70	0.15	
C4379	20220909	6.95	7.00	0.05	
C4380	20220909	6.05	6.20	0.15	

	n=	Mean	sd	3sd	Upper Limit	Lower Limit	Outliers
<b>Between Method</b>	40	0.116	0.140	0.421	0.537	-0.304	0

**Explanation:**  
 Between-method outliers exceed the mean +/- 3sd of the differences between methods.



# Scatter Plot

Changsha Sinocare, Inc. HbA1c on PCH-100

