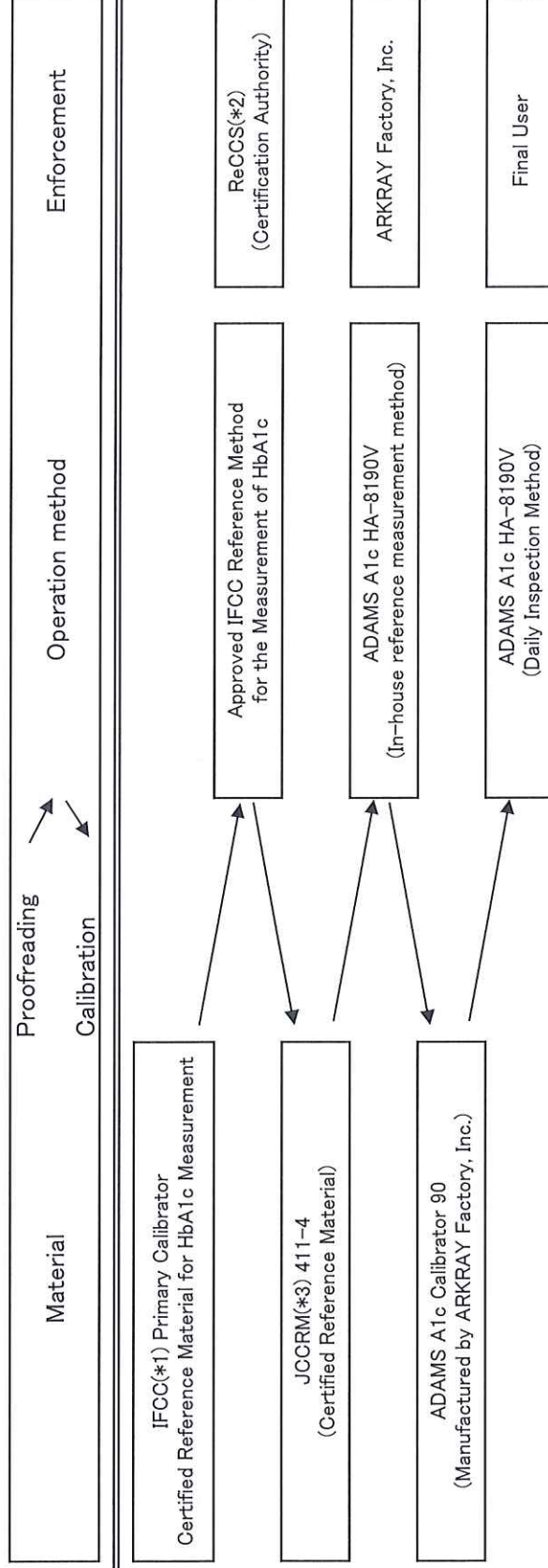


Traceability Chart

Item: ADAMS A1c HA-8190V



- (*1) IFCC: International Federation of Clinical Chemistry and Laboratory Medicine
 (*2) ReCCS : Reference Material Institute for Clinical Chemistry Standards
 (*3) JCCRM : Japanese Clinical Laboratory Use certified Reference Materials

Sep 2, 2020

Ryuichi Sasaki

Ryuichi Sasaki
 Quality Assurance Team Leader
 Quality Assurance Team, Quality Dept.
 ARKRAY Factory, Inc.

Report of Traceability and Uncertainty

Manufacturer Name	ARKRAY Factory, Inc.
Item name	HbA1c
Reagent name	None
Name of Instrument	ADAMS A1c HA-8190V
Manufacturer's product Calibrator (Product Calibrator)	ADAMS A1c Calibrator 90
Accuracy Control Substance (Product Control)	

	Reference Substance	Measurement Method	Stability	Uncertainty
First Calibrator	JCCRM 411-4		to expiry date	
Second Standard Measurement Procedure		None		
Second Calibrator	None		None	
Manufacturer's Standard Measurement Procedure		In-house Standard (HPLC Method)		
Manufacturer's Standard Substance	JCCRM 411-4		to expiry date	
Manufacturer's product Calibrator (Product Calibrator)	Calibrator 90 dedicated for ADAMS A1c	Routine Testing (HPLC Method)	to expiry date	Relative uncertainty 4.06% (*)
Accuracy Control Substance (Product Control)				

* An uncertainty as K= 2