

# *The JCCLS-Certificated Reference Material (JCCLS-CRM)*

*(JCCLS-Certified Reference Standard for Enzyme of  
JSCC method)*

*Japanese Committee for Clinical Laboratory  
Standards (JCCLS)*

## Outline 1: JCCLS-Certified Reference Standard for Enzyme of Japan Society of Clinical chemistry (JSCC) Method

JSCC offered JSCC consensus method for AST, ALT, CK, ALP, LD and  $\gamma$ -GT in 1989 and 1994.

The certified values of the JCCLS-CRM is evaluated based on the JSCC consensus method and JCCLS standard method for enzyme activity measurement except AMY based on IFCC-SOP at 37 .

The purpose of this product is to expand the use of the values based on JCCLS standard method for enzyme activity measurement in a routine laboratory test.

<u>Range of property values</u>	<u>Expanded uncertainty(k=2)</u>
AST: 100 ~ 200 U/L	2.4%
ALT: 100 ~ 200 U/L	2.4%
CK: 300 ~ 600 U/L	2.2%
ALP: 300 ~ 600 U/L	3.0%
LD: 300 ~ 600 U/L	1.9%
$\gamma$ -GT: 100 ~ 200 U/L	3.2%
AMY: 250 ~ 550 U/L	2.5%

An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95% level of confidence, including homogeneity and stability of the material.



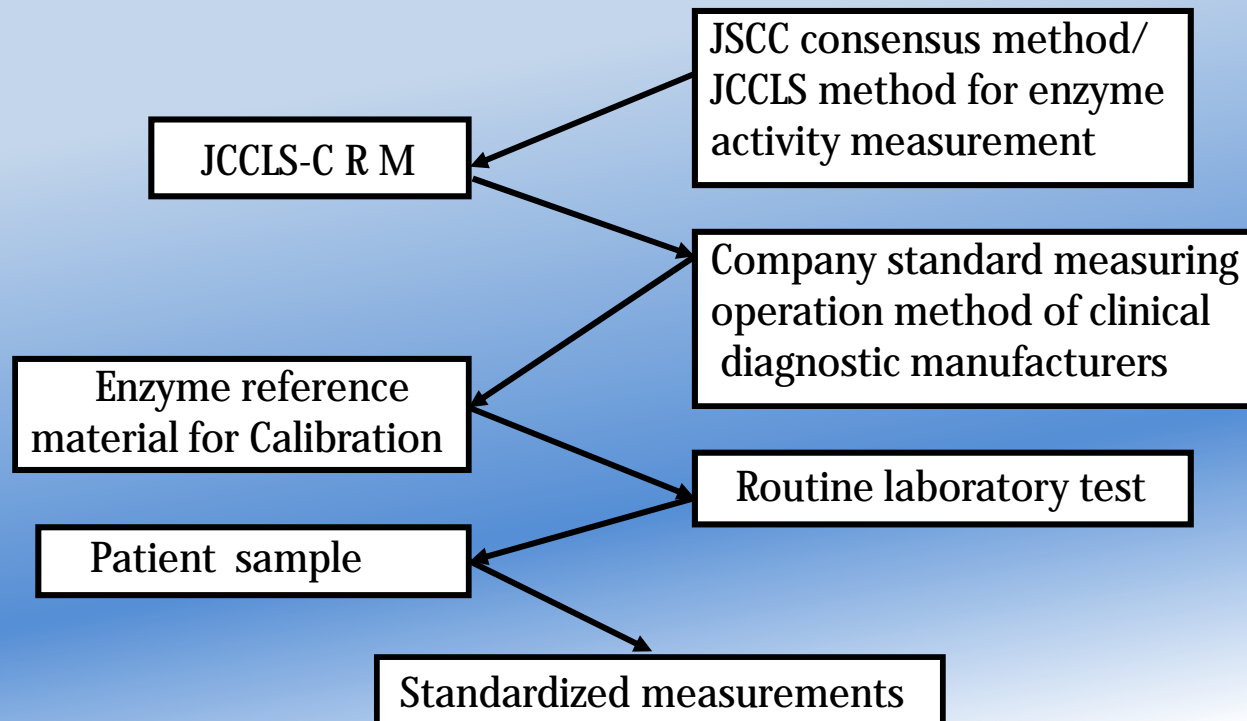
3.0ml X 1 vial container  
freeze-dried product

## Outline 2: JCCLS-Certified Reference Standard for Enzyme of Japan Society of Clinical chemistry (JSCC) Method

### Applicable scope

The JCCLS-Certificated Reference Material (JCCLS-CRM) is equivalent to secondary calibration based on ISO 18153, and used as a calibration material for company standard measuring operation method of clinical diagnostic manufacturers.

### Traceability of serum enzyme activity measurement



## Recommendation values on JCCLS-CRM by IFCC reference method

	Values by IFCC reference method			
	Activity	Expanded uncertainty*	Expanded uncertainty	Uncertainty of long-term stability**
	U/L	U/L	%	%
AST	167	±4	2.2	0.34
ALT	163	±4	2.2	0.30
CK	436	±11	2.4	0.35
ALP	149	±4	2.5	0.48
GGT	150	±3	2.5	0.33
LD	428	±10	2.3	0.34
AMY	343	±10	2.8	0.33

Measurement by IFCC reference measurement procedure was done in Reference Institute for Bioanalytic (RfB), which was accredited by DAkkS, a German Accreditation Service.

\* Expanded uncertainty of the measurement by IFCC method was calculated according to the document DAkkS-DKD-3.

\*\* Uncertainty of long-term stability put down with the table was estimated from the measurement values by JSCC reference method.