Development and Application of Reference Materials for SARS-CoV-2 Testing

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Diagnostic testing for SARS-CoV-2 is the first and a very critical step in slowing down the epidemic. Nucleic Acid Test (NAT) and Immunological Detection Method (IDM) are the two most widely used methods, with NAT being recognized as a "gold standard", and IDM serving as an important supplement to NAT.

To address the rising concerns over test kit product performance and quality control, the National Institute of Metrology (NIM), China has developed two categories of Certified Reference Materials (CRMs) for SARS-CoV-2 testing:

1. SARS-CoV-2 RNA reference materials

Name	Numbering	Reference value and uncertainty	Concentration		
			E gene (copy/μL)	ORF1ab gene (copy/μL)	N gene (copy/μL)
SARS-CoV-2 RNA reference material (high concentration)	GBW(E)091089	Reference value	5.03×10^5	9.39×10^5	7.00×10^5
		Expanded Uncertainty (k=2)	0.47×10^5	0.92×10^5	0.71×10^5
SARS-CoV-2 RNA reference material (low concentration)	GBW(E)091090	Reference value	5.78×10^2	1.07×10^3	7.75×10^2
		Expanded Uncertainty (k=2)	0.64×10^2	0.14×10^3	0.81×10^2

2. SARS-CoV-2 immunoassay reference materials

Name	Numbering	Concentration	
		Reference value (μg/g)	Expanded uncertainty (k=2)(μg/g)
Human IgG monoclonal antibody to spike glycoprotein solution reference material of SARS-CoV-2	GBW(E)091109	70.8	5.7
Human IgG monoclonal antibody to nucleocapsid protein solution reference material of SARS-CoV-2	GBW(E)091110	85.3	8.5

Upon feedback from various users in China, these CRMs have been found very useful in helping test kit manufacturers evaluate product performance and control product quality, helping hospitals and testing laboratories of CDCs validate testing methods, and providing metrological traceability to the similar reference materials developed at some regional metrology institutes in China.

Now, CCQM Working Group on Nucleic Acid Analysis (NAWG) is organizing a

pilot study on SARS-CoV-2 RNA measurement. NIM, as one pilot laboratory, will contribute to this study, providing certain comparison samples, and other relevant reagents and reference materials.

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