

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K083430

B. Purpose for Submission:

Nanogen's Real-Time PCR internal control material falls under CFR 862.1660 Quality Control Material (assayed and unassayed) and is Class I exempt. However, since it operates using a different fundamental scientific technology than a legally marketed device, it trips the limitations of exemptions in CFR 862.9b and requires premarket notification.

C. Measurand:

Internal control template

D. Type of Test:

PCR

E. Applicant:

Nanogen, Inc.

F. Proprietary and Established Names:

Real-Time PCR Internal Control 2B Set

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

Class I exempt

3. Product code:

OLD-Internal control, not assay specific

4. Panel:

H. Intended Use:

1. Intended use(s):

The Real-Time PCR Internal Control 2B Set consists of reagents intended for use as an unassayed internal extraction and amplification process control in any real-time polymerase chain reaction (PCR) assay. The Internal Control 2B Set can be used to detect systemic variation that may arise during the extraction and amplification process associated with real-time PCR assays. The set is not intended to monitor other real-time PCR processes.

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

In Vitro diagnostic use only

4. Special instrument requirements:

NA

I. Device Description:

The Real-Time PCR Internal Control 2B Set contains the IC2 Template, the IC2-B Primers, and the IC2-B Probe. The IC2-B Primers and Probe are optional, and can be used to amplify and detect the IC2 Template. Alternatively, other primers and probe may be used if targeted toward the IC2 Template. Laboratories should dilute the IC2 Template as well as primers and probe that are to be used for the amplification and determine empirically the optimal concentrations of all control reagents for your assay.

The IC2 Template consists of a nonsense, non-specific target DNA fragment cloned into the plasmid vector pUC19 in a 1X TE buffer solution. The target DNA fragment of the IC2 Template is as follows:

5' –
CTGCACGGACCAGTTACTTTACGGACCACGTACCGCATTGGTACAAGA
TCTCCGGTAGAAAAAATGAG – 3'

The IC2-B Primers consists of two primers in a 1X TE buffer solution. The sequences of the primers are as follows:

5' – CTGCACGGACCAGTTACTTTACG – 3'
 5' – CTCATTTTTTCTACCGGAGATCTTGT – 3'

The IC2-B Probe consists of one probe in a 1X TE buffer solution. The IC2-B Probe is labeled with a proprietary dye and has an excitation wavelength maxima of 523 nm and an emission wavelength maxima of 554 nm. The sequence of the probe is as follows:

5' – MGB Moiety – Fluorescent Dye – AATGCGCTACGTGGTCC – Quencher – 3'

J. Substantial Equivalence Information:

1. Predicate device name(s):

VITROS Chemistry Products HCY Performance Verifiers I, II & III

2. Predicate K number(s):

K061588

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Type of Material	Quality control material	Quality control material
Purpose	Monitors performance and process	Monitors performance and process

Differences		
Item	Device	Predicate
Intended Use	The Real-Time PCR Internal Control 2B Set consists of reagents intended for use as an unassayed internal extraction and amplification process control in any real-time polymerase chain reaction (PCR) assay. The Internal Control 2B Set can be used to detect systemic variation that may arise during the extraction and amplification process associated with real-time PCR assays. The set is not intended to monitor	CITROS Chemistry Products HCY Performance Verifiers are assayed controls used to monitor performance of VITROS HCY Reagents on VITROS 5,1 Chemistry Systems

Differences		
Item	Device	Predicate
	other real-time PCR processes.	
Product Type	Unassayed control	Assayed control
Assay Method	Real-time PCR	Homogeneous Enzymatic
Matrix	DNA fragment cloned into a plasmid vector in a buffer solution	Prepared human serum with preservatives added

K. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry and FDA Staff Assayed and Unassayed Quality Control Material, <http://www.fda.gov/cdrh/oivd/guidance/2231.pdf>.

L. Test Principle:

NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

NA

b. Linearity/assay reportable range:

NA

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Provided stability studies to justify expiration dating.

d. Detection limit:

NA

e. Analytical specificity:

NA

f. Assay cut-off:

NA

2. Comparison studies:

a. *Method comparison with predicate device:*

NA

b. *Matrix comparison:*

NA

3. Clinical studies:

a. *Clinical Sensitivity:*

NA

b. *Clinical specificity:*

NA

c. Other clinical supportive data (when a. and b. are not applicable):

NA

4. Clinical cut-off:

NA

5. Expected values/Reference range:

NA

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.