

AccuSpan™ Zika RNA Linearity Panel

2410-0318 / Batch # 10249280

OVERVIEW

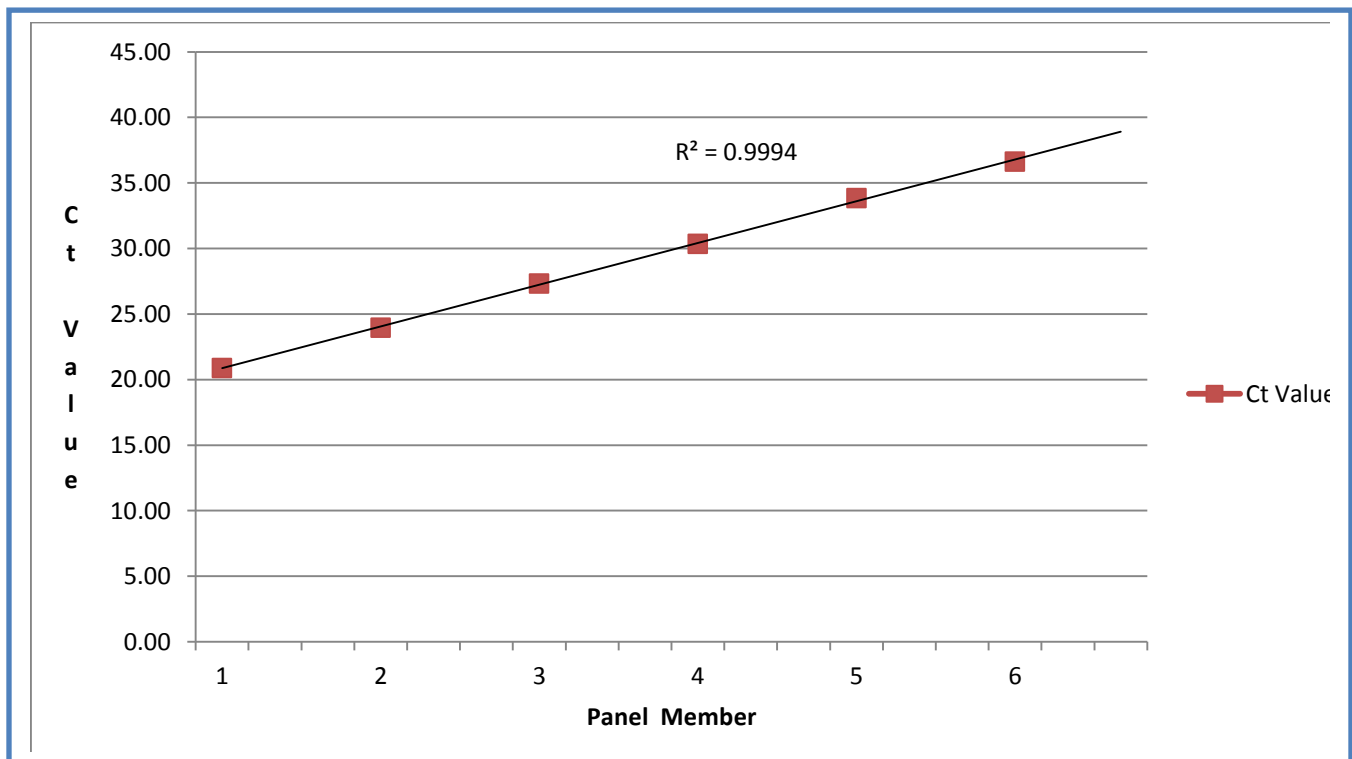
The AccuSpan Zika RNA Linearity Panel is a seven member panel made from serial dilutions of a recombinant Zika virus with established reactivity for Zika RNA and one negative member. This panel consists of six members representing serial log dilutions of AccuPlex recombinant Zika virus in negative diluent and one negative member prepared from the diluent. Panel member 1 was extracted and characterized by digital PCR and the average concentration was found to be 1.01 E+06 copies/mL. The diluent was prepared from normal human plasma that was defibrinated and 0.2 micron filtered. Sodium azide (0.9%) was added as a preservative.

Results are reported for each panel member on each specific test method. Linearity is shown graphically by plotting observed Ct results.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Follow Universal Precautions.

AccuSpan Zika RNA Linearity Panel Members 1-6



Zika RNA results were obtained using the Roche COBAS® Zika EUA test method. A line of best fit is shown. The Ct value represents cycle threshold required for the fluorescent signal to rise above background levels. A higher Ct value indicates a lower amount of analyte. A 3.33 change in Ct value is equivalent to a 10-fold change in concentration.

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Panel Member	Target c/mL	Roche COBAS® Ct ¹	CDC TrioPlex Rt-PCR Ct ^{2, 4}	In-house Rt-PCR Ct ²	Hologic Aptima® TMA Result ¹
01	1,000,000	20.89	22.61	25.72	POS
02	100,000	23.97	25.88	28.94	POS
03	10,000	27.33	29.32	32.10	POS
04	1,000	30.36	32.62	35.21	POS
05	100	33.84	34.89	38.26	POS
06	10	36.63	37.60	40.00, TND³	POS
07	TND	TND	TND	TND	NEG

¹ Results are reported as the mean result of duplicate testing. Results in red are considered positive.

² Results are reported as the mean result of triplicate testing. Results in red are considered positive.

³ Zika RNA detected in one of three replicates.

⁴ Assay reagents and method as per CDC TrioPlex RT-PCR assay but not obtained through CDC.

TND = Target Not Detected

The package insert for this panel can be found at www.seracare.com

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400