

RealStar[®] Zika Virus RT-PCR Kit 1.0

In 2015 Brazil faced the start of a Zika virus outbreak. Although the disease is usually mild or asymptomatic in adults, a massive increase of babies and fetuses with microcephaly in regions with high numbers of Zika virus infections has been noticed.

Zika virus is an enveloped, single stranded (+) RNA virus of the family *Flaviviridae*. Like many other members of the family it is mainly transmitted by mosquitoes belonging to the genus *Aedes*. Since 2015 the virus is also endemic in South America, namely Brazil, where since then large numbers of suspected cases were recorded. Fever, rash and arthralgia are common symptoms of Zika virus infections which usually are mild and self-limiting.

Because Zika, Dengue and Chikungunya virus are endemic to the same geographical regions and cause similar symptoms, definite identification of the etiological agent is only possible with laboratory testing. Zika virus detection by means of real-time RT-PCR should be done early (up to 10 days) after illness onset. Antibody assays commonly cross-reacted with closely related flaviviruses and detection of neutralising antibodies by plaque reduction assays is troublesome and can only be done in specialised laboratories. altona Diagnostics developed the **RealStar[®] Zika Virus RT-PCR Kit 1.0** for the qualitative detection of Zika virus specific RNA. The assay contains an Internal Control for reliable diagnostics.

Figure 1: The 95% Limit of Detection was determined by performing replicate testing of diluted RNA and subsequent probit analysis. The limit of detection for Zika virus using the RealStar[®] Zika Virus RT-PCR Kit 1.0 is 0.61 copies/μl (95% confidence interval 0.39 to 1.27 copies/μl).

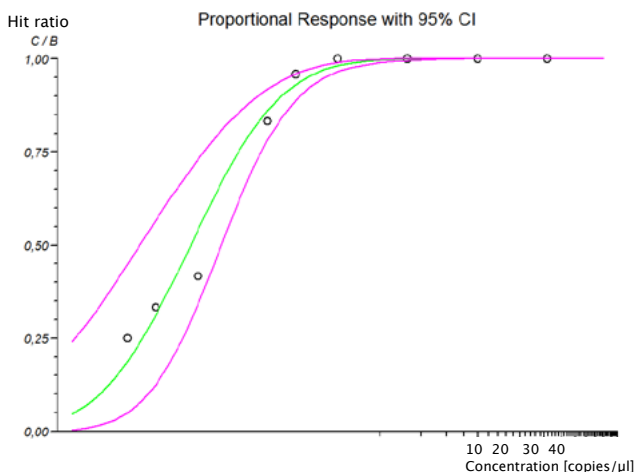


Table 1: Organisms tested to demonstrate the analytical specificity of the RealStar[®] Zika Virus RT-PCR Kit 1.0

Organisms	RealStar [®] Zika Virus RT-PCR Kit 1.0	
	FAM Channel (Zika virus)	JOE Channel (Internal Control)
Japanese encephalitis virus	Negative	Valid
St. Louis encephalitis virus	Negative	Valid
West Nile virus	Negative	Valid
Yellow fever virus	Negative	Valid
Murray Valley encephalitis virus	Negative	Valid
SEBOV Gulu	Negative	Valid
ZEBOV Mayinga	Negative	Valid
MARV Musoke	Negative	Valid
Dengue virus serotype 1	Negative	Valid
Dengue virus serotype 2	Negative	Valid
Dengue virus serotype 3	Negative	Valid
Dengue virus serotype 4	Negative	Valid

Since Brazil reported the first case of local transmission in 2015, the number of infections are increasing rapidly also in other countries. Zika virus has the potential to spread through South, Central and parts of North America. In suspected Zika virus infections, Chikungunya and Dengue virus infections should also be ruled out.

altona Diagnostics distributes CE-IVD marked real-time PCR test kits for Zika virus detection as well as Dengue and Chikungunya virus (RealStar[®] Zika Virus RT-PCR Kit 1.0, RealStar[®] Dengue RT-PCR Kit 2.0 und RealStar[®] Chikungunya RT-PCR Kit 1.0).