

Table 2: Molecular Zika Virus (ZIKV) Emergency Use Authorization (EUA) Assays - Key Characteristics

EUA Holder Assay Name* (Date of Authorization)	Authorized Human Specimens (Volume) [§]	RNA Extraction		Reaction Amplification Set-up		Approx. Turn Around Time per run	Approx. Through-put [^] per Instrument (Specimens per run)	Summary Characteristics
		Man.	Auto.	Man.	Auto.			
Centers for Disease Control and Prevention (CDC) Triplex Real-time RT-PCR Assay March 17, 2016	Serum Whole blood Cerebrospinal fluid Amniotic fluid Urine (140 – 1000 µL)	X	X	X		4 h	Low (24)	<ul style="list-style-type: none"> • First PCR assay to be granted an EUA • Triplex -Differentiation of ZIKV, DENV and CHIKV • 2 different instruments for PCR • 4 automated and 1 manual sample prep • Limited hand-on time for sample prep. and transfer to PCR cyclers; manual sample prep requires manual PCR set up as well. • Sample Input: 1.0 mL (automated); 0.14 mL (manual) • 5 sample types authorized: Serum, whole blood, CSF, amniotic fluid and urine
Quest Diagnostics Infectious Disease, Inc. Zika Virus RNA Qualitative Real-Time RT-PCR April 28, 2016	Serum Urine (500 µL)		X	X		5h	Low (30)	<ul style="list-style-type: none"> • Reference Laboratory • 1 instrument for PCR • 1 automated sample prep method • Limited hand-on time for sample prep. and transfer to PCR cyclers. • Sample Input: 0.5 mL • 1 sample type authorized: Serum
altona Diagnostics GmbH RealStar Zika Virus RT-PCR Kit U.S. May 13, 2016	Serum EDTA Plasma Urine (140 –200 µL)	X	X	X		6 h	Low (72)	<ul style="list-style-type: none"> • 7 different instruments for PCR • 2 automated and 1 manual sample prep • Limited hand-on time for sample prep. and transfer to PCR cyclers; manual sample prep requires manual PCR set up as well. • Sample Input: 0.2 mL (automated); 0.14 mL (manual) • 3 sample types authorized: Serum, EDTA plasma and urine
Hologic, Inc. Aptima Zika Virus Assay June 17, 2016	Serum Plasma Processed urine Processed whole		●		●	3.5 h first results - then 5 results	High (275/ 8 hours)	<ul style="list-style-type: none"> • Fully automated (sample to result) Panther System • Sample Input: 0.7 mL • 4 sample types authorized: Serum, plasma,

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		Man.	Auto.	Man.	Auto.			
	blood (700 µL)					every 5 min.		processed whole blood and processed urine
Viracor Eurofins Zika Virus Real-time RT-PCR Test July 19, 2016	Serum Plasma Urine (500 µL)		X	X		5h	Low (40)	<ul style="list-style-type: none"> Reference Laboratory 1 instrument for PCR 1 automated sample prep method Limited hand-on time for sample prep. and transfer to PCR cyclers Sample Input: 0.5 mL 3 sample types authorized: Plasma, Serum and urine
Siemens Healthcare Diagnostics Inc. VERSANT Zika RNA 1.0 Assay (kPCR) Kit July 29, 2016	Serum EDTA plasma Urine (140 –500 µL)	X	X	X		5 h	Low-Medium (94)	<ul style="list-style-type: none"> 3 different instruments for PCR Automated and manual sample prep Limited hand-on time for sample prep. and transfer to PCR cyclers; manual sample prep requires manual PCR set up as well. Sample prep reagents manufactured under GMP because they are also used for PMA products. Sample Input: 0.5 mL (automated); 0.14 mL (manual) 3 sample types authorized: Plasma, Serum and urine
Luminex Corporation xMAP MultiFLEX Zika RNA Assay August 4, 2016	Serum Plasma Urine (200 µL)	X		X		4 h	Low - medium (50-100)	<ul style="list-style-type: none"> 1 instrument for PCR Targets 6 distinct Zika genomic regions 1 instrument for detection 1 automated sample prep method Limited hand-on time for sample prep. and transfer to PCR cyclers Sample Input: 0.2 mL 3 sample types authorized: Plasma, serum and urine

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		Man.	Auto.	Man.	Auto.			
Vela Diagnostics USA, Inc. Sentosa SA ZIKV RT-PCR Test September 23, 2016	Serum EDTA plasma Urine (250 µL)		●		●	~3 h	Low (22)	<ul style="list-style-type: none"> ● Fully automated (sample to result) ● Sample Input: 0.25 mL ● 3 sample types authorized: Serum, EDTA plasma and urine
ARUP Laboratories Zika Virus Detection by RT-PCR September 28, 2016	Serum EDTA plasma Urine (200 µL)		X	X		6-7 h	Low (93)	<ul style="list-style-type: none"> ● Reference Laboratory ● 1 instrument for PCR ● 1 automated sample prep method ● Limited hand-on time for sample prep. and transfer to PCR cyclers ● Sample Input: 0.5 mL ● 3 sample types authorized: Plasma, serum and urine
Abbott Molecular Inc. Abbott RealTime Zika November 21, 2016	Serum EDTA Plasma Whole blood Urine (500 µL)		X		X	6.75 h	Low (94) (46 –WB)	<ul style="list-style-type: none"> ● Automated sample prep ● Sample prep reagents manufactured under GMP because they are also used for PMA products. ● Instruments (m2000sp and m2000rt) readily available in many labs as they are used to run other diagnostic tests (i.e., HBV, HCV viral load testing). ● Limited hand-on time for sample prep. and transfer to PCR cyclers ● 96 samples/run ● Sample input: 0.5 mL volume ● 4 sample types authorized: EDTA Plasma, serum, whole blood and urine
ELITechGroup Inc. Molecular Diagnostics Zika ELITE MGB Kit U.S. December 9, 2016	Serum EDTA plasma (200 µL)		●		●	2.5 h	Low (12)	<ul style="list-style-type: none"> ● Fully automated (sample to result) ● Sample Input: 0.2 mL ● 2 sample types authorized: Serum and EDTA plasma

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		Man.	Auto.	Man.	Auto.			
Nanobiosym Diagnostics, Inc. Gene-RADAR Zika Virus Test March 20, 2017	Serum (50 µL)	X			X	2 h	Low (1)	<ul style="list-style-type: none"> • 1 instrument for PCR • Small footprint PCR instrument • 1 automated sample prep method • Sample Input: 0.05 mL • 1 sample type authorized: Serum
Thermo Fisher Scientific TaqPath Zika Virus Kit August 2, 2017	Serum Urine (300 µL)		X		X	3 h	Medium - High (94)	<ul style="list-style-type: none"> • 1 instrument for PCR • 1 automated sample prep method • Sample Input: 0.3 mL • 2 sample types authorized: Serum and urine
Columbia University CII-ArboViroPlex rRT-PCR assay August 11, 2017	Serum Urine (250 µL)		X		X	6 h	Low (88)	<ul style="list-style-type: none"> • Quadraplex -Differentiation between ZIKV, DENV WNV and CHIKV • 1 instrument for PCR • 1 automated sample prep method • Sample Input: 0.25 mL • 2 sample types authorized: Serum and urine

*Listed in order of initial EUA issuance, information current as of May 1, 2018;

[§]Specimen volume dependent on the extraction method used

[^]Throughput parameters used: High = >250/8-10h day; Medium = 100 to 250/8-10h day; Low = < 100/8-10h day

• = Same instrument for extraction and amplification reaction set-up.