Table 1: Molecular Zika Virus (ZIKV) Emergency Use Authorization (EUA) Assays - Performance Characteristics

EUA Holder Assay Name* Date of Authorization	Authorized Human Specimens#	ZIKV Gene Target(s)	ZIKV Limit of Detection$ (Specimen)	Clinical Performance^ (Specimen) [Rate] {95% CI}		FDA Reference Material Testing (RNA NAAT Detectable Units/mL)	
				Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)	S1	S2
Centers for Disease Control and Prevention (CDC) Trioplex Real-time RT-PCR Assay March 17, 2016	Serum (S) Whole blood (WB) Cerebrospinal fluid (CSF) Amniotic fluid (AF) Urine (U)	Envelope	(S) 19300 GCE/mL~ (U) 53800 GCE/mL~ (WB) 2430 GCE/mL	(S) 100.0% [19/19] {83.2-100%} (WB) 96.1% [146/152] {91.7-98.2%}	(S) 99.1% [110/111] {95.1-99.8%} (WB) 100.0% [116/116] {96.8-100%}	(S) 3300 (U) 1000	(S) 1670 (U) 1670
Quest Diagnostics Infectious Disease, Inc. Zika Virus RNA Qualitative Real-Time RT-PCR April 28, 2016	Serum Urine	Envelope and Membrane	(S) 250 copies/mL (U) 500 copies/mL	(S) 94.6% [53/56] {85.4-98.2%} (U) 100% [60/60] {94.0-100%	(S) 100.0% [54/54] {93.4-100%} (U) 100% [59/59] {93.9-100%}	(S) 1000 (U) 1000	(S) 500 (U) 1500
altona Diagnostics GmbH RealStar Zika Virus RT-PCR Kit U.S. May 13, 2016	Serum EDTA Plasma Urine	Proprietary	(S) 251.6 GEQ/mL (U) 79.6 GEQ/mL	(S) 96.8% [60/62] {89.0-99.1%}[a]	(S) 95.1% [39/41] {83.9-98.7%}[a]	(S) 3162 (U) 3162	(S) 5000 (U) 5000 Manual Ext. (U) 1581 Auto. Ext.
Hologic, Inc. Aptima Zika Virus Assay June 17, 2016	Serum Plasma Processed urine Processed whole blood K2EDTA	NS2 NS4/NS5	(P) 5.9 copies/mL (U) 8.5 copies/mL	(P) 100.0% [114/114] {96.7-100%} (U) 100% [109/109] {96.6-100%} (WB) 95.3% [46/48] {86.0-98.9%}	(P) 97.2% [70/72] {90.4-99.2%} (U) 100% (123/123) {97.0-100%} (WB) 100% [50/50] {92.9-100%}	(P) 100 (U) 300 (WB) 1000	(P) 150 (U) 150 (WB) 167
Viracor Eurofins Zika Virus Real-time RT-PCR Test July 19, 2016	Serum Plasma Urine	Proprietary	(P) 50 copies/mL (U) 35 copies/mL	(P) 95.7% [67/70] {88.1-98.5%} (S) 100% [12/12] {69.8-100%} (U) 100.0% [61/61] {94.1-	(P) 89.7% [52/58] {79.2-95.2%} (S) 96.4% [54/56] {86.6-99.4%} (U) 95.3% [41/43] {84.5-	(P) 1000 (U) 1000	(P) 500 (U) 500

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				Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)	S1	S2
				100%}	98.7%}		
Siemens Healthcare Diagnostics Inc. VERSANT Zika RNA 1.0 Assay (kPCR) Kit July 29, 2016	Serum EDTA plasma Urine	Proprietary	(S), (P) 721 GCE/mL (U) 1081 GCE/mL	(P) 100.0% [64/64] {94.3-100%} (S) 90.6% [87/96] {83.1-95.0%} (U) 86.7% [39/45] {73.8-93.7%}	(P) 88.5% [54/61] {78.2-94.3%} (S) 85.2% [46/54] {73.4-92.3%} (U) 84.5% [71/84] {75.3-90.7%}	(S) 1000 (U) 3000	(S) 5000 (U) 5000
Luminex Corporation xMAP MultiFLEX Zika RNA Assay August 4, 2016	Serum Plasma Urine	6 Distinct genomic regions Proprietary	(S), (P), (U) 687 copies/mL	(S) 95.8% [46/48] {85.1-99.5%} (U) 94.3% [50/53] {84.6-98.1%}	(S) 98.1% [104/106] {93.4-99.5%} (U) 96.8% [60/62] {89.3-99.1%}	(S) 3000 (U) 3330	(S) 5000 (U) 5000
Vela Diagnostics USA, Inc. Sentosa SA ZIKV RT-PCR Test September 23, 2016	Serum EDTA plasma Urine	NS4A	(S), (P), (U) 3000 copies/mL	(P) 94.9% [74/78] {87.5-98.0%} (S) 94.2% [65/69] {86.0-97.7%} (U) 100.0% [61/61] {94.1-100%}	(P) 100.0% [56/56] {93.6-100%} (S) 100% [59/59] {93.9-100%} (U) 100.0% [49/49] {92.7-100%}	(S) 30000 (U) 10000	(S) 15000 (U) 5000
ARUP Laboratories Zika Virus Detection by RT-PCR September 28, 2016	Serum EDTA plasma Urine	Proprietary	(S), (P), (U) 160 copies/mL	(P) 90.7% [68/75] {82.0-95.4%} (S) 98.0% [49/50] {89.5-99.7%} (U) 91.1% [51/56] {80.7-96.1%}	(P) 93.3% [70/75] {85.3-97.1%} (S) 100.0% [15/15] {79.6-100%} (U) 95.7% [66/69] {87.9-96.7%}	(P) 3000 (U) 3300	(P) 1650 (U) 4500
Abbott Molecular Inc. Abbott RealTi*m*e Zika November 21, 2016	Serum EDTA Plasma Whole blood Urine	prM precursor membrane protein and NS3	(S) 30 copies/mL (P) (U) 40 copies/mL (WB) 120 copies/mL	(P) 93.4% [57/61] {84.1-98.2%} (S) 92.6% [50/54] {82.1-97.9%} (U) 87.3% [69/79] {78.0-93.8%}	(P) 100.0% [60/60] {94.0-100%} (S) 97.0% [65/67] {89.6-99.6%} (U) 95.5% [64/67] {87.5-99.1%}	(S) 1000 (U) 300 (WB) 1000	(S) 500 (U) 500 (WB) 1500

EUA Holder Assay Name* Date of Authorization	Authorized Human Specimens[#]	ZIKV Gene Target(s)	ZIKV Limit of Detection[$] (Specimen)	Clinical Performance^ (Specimen) [Rate] {95% CI}		FDA Reference Material Testing (RNA NAAT Detectable Units/mL)	
				Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)	S1	S2
				(WB) 96.0% [48/50] {86.3-99.5%}	(WB) 100.0% [50/50] {92.9-100%}		
ELITechGroup Inc. Molecular Diagnostics Zika ELITe MGB Kit U.S. December 9, 2016	Serum EDTA plasma	NS3	(P) 270 copies/mL	(P) 94.7% [89/94] {88.1-97.7%}	(P) 90.9% [70/77] {82.4-95.5%}	(P) 3330	(P) 5560
Nanobiosym Diagnostics, Inc. Gene-RADAR Zika Virus Test March 20, 2017	Serum	Proprietary	(S) 18000 copies/mL[b]	(S) 100.0% [50/50] {92.9-100%}	(S) 100.0% [50/50] {92.9-100%}	(S) 3300	(S) 5000
Thermo Fisher Scientific TaqPath Zika Virus Kit August 2, 2017	Serum Urine	Proprietary	(S) 50 GC/mL (U) 35 GC/mL	(S) 94.9% [111/117] {90.8-98.9%} (U) 88.6% [93/105] {82.4-94.8%}	(S) 100.0% [76/76] {95.3-100%} (U) 100.0% [74/74] {95.1-100%}	(S) 3330 (U) 3300	(S) 500 (U) 500
Columbia University CII-ArboViroPlex rRT-PCR assay August 11, 2017	Serum Urine	3' UTR	(S) (U) 5160 GEQ/mL	(S) 97.0% [65/67] {89.8-99.2%} (U) 98.1% [51/52] {89.9-99.7%}	(S) 100.0% [129/129] {97.1-100%} (U) 100.0% [50/50] {92.9-100%}	(S) 1000 (U) 1000	(S) 500 (U) 500

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

[#]P = Plasma, S = Serum, U = Urine, WB = Whole blood, CSF = Cerebrospinal fluid.

[$]Manufacturer determined LoD, please see manufacturer Instructions for Use to specific material used to characterize the analytical sensitivity/LoD; unit definitions GCE = Genome Copy Equivalent, GEQ = genomic equivalent quantity, GC = Genomic Copies.

~Large volume extraction protocols have improved sensitivity (S) $2.5x10^3$ GCE/mL and (U) $4.6x10^3$ GCE/mL

^The clinical validations that were performed for currently authorized PCR tests differ with respect to the comparator method used, and therefore depend on the performance of the comparator. They also differ with respect to the number of natural clinical and contrived specimens used in the evaluation and the population of patients tested (i.e., endemic and non-endemic area samples in different numbers). These factors impact the performance of an assay and a comparison between the assays based on the clinical performance, thus these factors have to be taken into consideration. In particular, it is critical to note that those firms that have sourced their negative samples in the endemic areas or that have tested a higher number of clinical samples from endemic areas usually have slightly lower performance because of the frequency of true low positive samples in the endemic population. Another example is when the comparator of choice was more

sensitive than the device under evaluation, therefore decreasing the performance of the assay under study. Please see individual manufacturer instructions for the breakdown of the clinical specimens used to evaluate clinical performance.

[a]A matrix equivalency study was used to demonstrate equivalency between serum and EDTA plasma clinical matrices. The urine claim was evaluated using paired urine and serum specimens from 52 patients whose patient infected status was determined to be positive from the results of testing the serum and urine specimens with the Zika virus real-time RT-PCR assay described by Lanciotti et al.

[b]LoD 200 PFU/mL was converted to 18000 copies/mL using a standard curve which determined 1 PFU to be equivalent to 90 RNA copies.