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(As of 21 June 2016)

I. *Lab based detection: nucleic acid test kits*

Test Developer /Manufacturer	Brief description	Regulatory Approval/Commercialization Plans
SINGLE ZIKA TEST		
Genekam Zika virus PCR (Genekam Biotechnology AG)	Zika Virus Single check Realtime PCR-Kit (FR325) Zika Virus Double check Realtime PCR-Kit (FR340) Zika Virus conventional PCR -Kit (K850)	Kit FR325 (Single Check) submitted to WHO EUAL and CE-IVD Other kits available under RUO
ZIKV PCR kit (Fast-track Diagnostics)	PCR kit for detection of ZIKV	CE/IVD certified Submitted to ANVISA Plan to submit to WHO EUAL
RealStar®Zika Virus RT-PCR Kit 1.0 (Altona, Germany)	PCR kit for detection of ZIKV	CE/IVD certified, US FDA EUA authorized Submitted to WHO EUAL
careGENE™ Zika Virus RT-PCR kit (WELLS BIO, Inc.)	PCR kit for detection of ZIKV	Submitted to WHO EUAL Submitted to MFDS (Korea Regulatory Authority) EUA, plan to submit to MFDS and plan to submit for CE/IVD certification
Genesig® Advanced Kit (Genesig, UK)	PCR kit for detection of ZIKV	
MyBioSource Zika PCR Kit (USA)	PCR kit for detection of ZIKV	Available under RUO
Zika Real time PCR kit (Liferiver/Shanghai ZJ Bio-Tech Co)	PCR kit for detection of ZIKV	Submitted to WHO EUAL
Detection Kit for Zika Virus RNA (PCR-	PCR kit for detection of ZIKV	Submitted to WHO EUAL and to CFDA (China FDA)

Fluorescence Probing) (Daan Gene Co., LTD of Sun Yat-Sen University)		
Co-Diagnostics, Inc.	PCR kit for detection of ZIKV	Available as RUO Submitted to WHO EUAL Plan to submit US FDA EUA, India Regulatory
LightMix® Zika rRT-PCR Test TIB MOLBIOL GmbH	PCR kit for detection of ZIKV	Submitted for CE IVD certification Plan to submit to US FDA EUA
Theranos™ ZIKA TNA Assay Theranos	PCR kit for detection of ZIKV	Plan to submit to US FDA EUA
Aptima Zika Virus Assay (for diagnostic use) Hologic	TMA kit for the detection of ZIKV RNA	Submitted to US FDA EUA, Plan to submit for CE/IVD certification and WHO EUAL
SD Biosensors	PCR kit for detection of ZIKV	In development
Vista NanoBioSensor Vista Therapeutics, USA	Identification of ZIKV using nanotechnology	In development
Cobas® Zika test Roche Molecular Systems	PCR kit for detection of ZIKV	Approved for blood screening under US FDA IND protocol
Zika Virus RNA Qualitative Real Time RT-PCR test Focus Diagnostics, Inc	PCR kit for detection of ZIKV	US FDA EUA authorized
Institute Pasteur/Citech	RT- LAMP based kit for detection of ZIKV (IP Shanghai) TaqMan probe-based ZIKA detection test (IP Shanghai)	RT-LAMP kit: developed and will be evaluated in Dakar or France Taqman Zika test: developed and will be evaluated in Dakar or France
VERSANT®Zika RNA 1.0. Assay (kPCR) Siemens Healthcare Diagnostics	Real time PCR kit for the qualitative detection of ZIKV	Submitted to WHO EUAL and US FDA EUA

MULTIPLEX TEST		
Trioplex rRT-PCR (US CDC)	PCR kit for detection of ZIKV, DENV and CHIKV	US FDA EUA authorized Not commercially available. Available only to qualified labs/country request.
Kit Nat by Fiocruz (Brazil)	PCR kit for detection of ZIKV, DENV and CHIKV	
Bioneer Corporation AccuPower ZIK (DENV,CHIKV) Multiplex Real-Time RT-PCR Kit	PCR kit for detection of ZIKV, DENV and CHIKV	Submitted to WHO EUAL
Genekam Biotechnology AG	Zika Virus + Dengue-Virus(1-4) + Chikungunya Virus Multiplex Realtime PCR-Kit (FR342) Zika Virus + Yellow Fever Virus + Chikungunya Virus Multiplex Realtime PCR-Kit (FR351)	Available under RUO
Fast-track Diagnostics	PCR kit for detection of ZIKV, DENV and CHIKV	CE/IVD certified Submitted to ANVISA Plan to submit to WHO EUAL
GenArraytion/Luminex Multiflex bead-based assay panel		
Experimental Therapeutics Centre (ETC) Singapore	PCR kit for ZIKV, DENV and CHIKV	In development
Vela Diagnostics Zika RT-PCR test (VELA Diagnostics, Singapore)	PCR kit for ZIKV, DENV and CHIKV	In development
Thermo Fisher	PCR kit for ZIKV, DENV and CHIKV	
DiaPlexQ™ ZCD Detection Kit Solgent Molecular Diagnostics South Korea	PCR kit for ZIKV, DENV and CHIKV	Submitted to WHO EUAL

II. *All Integrated NAT*

Test Developer/Manufacturer	Brief description	Regulatory Approval/Commercialization Plans
Idylla™ Zika, Dengue 1,2,3,4 and Chikungunya Test AND Arbovirus Tropical Fever Panel Test (includes also Zika, Dengue and Chikungunya) Biocartis	Idylla™ Zika, Dengue 1,2,3,4 and Chikungunya Test single Cartridge, multiplexed real-time RT-PCR test run on the Idylla™ Platform (qualitative detection)	In development, Kit version is under evaluation in Brazil Plan to submit to WHO EUAL and US FDA EUA
Biofire Defense	Multiplex test	In development
Gene-RADAR®Zika Virus Test (Nanobiosym Diagnostics, Inc)	RT-PCR using Gene-RADAR platform	Submitted to EUAL

II. *Lab based detection: immunoassays*

Test Developer/Manufacturer	Brief description	Regulatory Approval/Commercialization Plans
IIFT: Arbovirus Fever Mosaic2 IgG or IgM Euroimmun AG, Lübeck	Kit for detection of IgG or IgM by Immunofluorescence Assay of ZIKV, DENV 1, DENV 2, DENV 3, DENV 4, CHIKV	CE/IVD certified Approved by ANVISA (Brazil), Venezuela, Paraguay Submitted to WHO EUAL and US FDA EUA Submitted to: El Salvador, Mexico, Peru, Serbia, Macedonia, Ecuador, Australia
Anti-Zika IgM + IgG ELISA Euroimmun AG, Lübeck	Kit for detection of IgM and IgG by ELISA	CE/IVD certified Approved by ANVISA (Brazil), Venezuela, Paraguay, Mexico, Australia Submitted to WHO EUAL and US FDA EUA Submitted to: El Salvador, Canada, Peru, Serbia, Cuba, Ecuador, Columbia, Korea
MyBiosource (USA)	Various ELISA kits for detection of gM and IgG	Available under RUO
RecombiLISA Zika IgM ELISA kit (CTK Biotech, Inc)	Kit for detection of IgM by ELISA	Submitted to WHO EUAL
Zika MAC-ELISA (US CDC)	Kit for detection of IgM by ELISA	US FDA EUA authorized Available only to qualified labs (domestic and international); not for US hospitals or other primary care settings.
Novagnost Zika Virus IgM μ -capture ELISA and IgG capture ELISA NovaTec Immunodiagnosics GmbH Distributed by Siemens Healthcare Diagnostics	2 kits: for detection of IgM and IgG by ELISA	CE/IVD certified (IgM μ -capture ELISA) Submitted to WHO EUAL Plan to submit to US FDA EUA and ANVISA (end of June) In development (IgG ELISA)
Theranos TM ZIKA IgM Assay Theranos	Kit for detection of IgM	Plan to submit for CE/IVD certification and to US FDA EUA
SD Biosensors	Kit for detection of IgG, IgM and Antigen by ELISA	In development
Institute Pasteur/Citech	CIBU MIA serological test (ED3-SNAP; IP Paris)	CIBU MIA test: developed and evaluated in Brasil

	ED3 MAC-ELISA test (IP Paris)	ED3 MAC ELISA test: Under development
	Zika NS1 antigen detection test (IP Paris)	NS1 Antigen: Under development
Alpha diagnostics Intl Inc USA	Kits for detection of IgG and IgM by ELISA	
Diasorin	2 kits for detection of IgM and IgG (for use on Diasorin LIAISON XL platform)	In development Plan to submit to US FDA EUA (late 2016)
ZIKV Detect™ IgM Capture ELISA InBios International, Inc	IgM ELISA	Submitted to WHO EUAL
IBL International GmbH	Zika virus IgM μ -capture ELISA	CE/IVD certified

III. *RDT type tests*

Test Developer/Manufacturer	Brief description	Regulatory Approval/Commercialization Plans
Biocan Diagnostics (Canada)	Zika IgG/IgM Antibody Rapid Test	Approved by ANVISA, CE/IVD Certified and approved in Guatemala and Dominican Republic. Plan to submit to USFDA EUA & WHO EUAL
Biocan Diagnostics	Zika IgG/IgM Ab/Dengue IgG/IgM Ab & NS1 Ag/Chikungunya IgG/IgM Ab Combo Rapid Test	CE/IVD Certified, Pending ANVISA approval
DPP® Zika Assay and DPP® Zika/Dengue/Chikungunya Assay Chembio	2 point of care Zika assays – measurement of IgM and IgG antibodies. Result quantification utilizing a DPP® Micro Reader	Submitted to WHO EUAL
Orangelife	Zika IgG and IgM rapid test AND Combo ZIKV/CHIKV/DENV multiplex test (DENV IgG, IgM, NS1 Ag; CHIKV IgG, IgM and ZIKV IgG, IgM, NS1 Ag)	Both submitted to ANVISA
NG Biotech	Rapid qualitative lateral flow in vitro diagnostic assay for IgG and IgM Anti-Zika virus antibodies detection in human whole blood or serum AND Rapid qualitative lateral flow in vitro diagnostic assay multiplex development for Zika, Dengue and Chikungunya	ZIKV IgG and IgM test – submitted to WHO EUAL. Plan to submit to US FDA EUA (end 2016) and ANVISA Undergoing product evaluation in Brazil by local distributor who will register the product locally (ANVISA)

	(IgG/IgM)	Multiplex test- in development
InBios International, Inc	Antigen detection test (during acute/febrile phase and an IgM/IgG test for convalescent phase samples.	In development Plan to submit for CE/IVD certification, WHO EUAL and US FDA EUA
SD Biosensors	Lateral flow RDT: NS1 Antigen detection	In development
Applied Biomedical	RDT for detection of Zika IgG and IgM	Plan to submit to WHO EUAL
OneStep Zika Virus IgG/IgM Rapicard™ Insta Test Diagnostic Automation/Cortez Diagnostics, Inc		Intended for RUO
One Step test for Zika Virus Antibody Bioventive Triple Aim Telehealth Technology team	Lateral flow sandwich assay – IgG/IgM	In development Plan to submit to ANVISA and InVima (Colombia), US FDA EUA
Alere	Lateral flow RDT IgM/IgG and Ag detection (ZIKV)	In development Plan to submit to WHO EUAL, US FDA EUA, CE/IVD and ANVISA
Zika Virus ViraStripe® IgG, IgM Viramed	IgM and IgG immunoassay	
CareStart Zika NS1 Test Access Bio, Inc	Zika NS1 antigen detection rapid test	Submitted to WHO EUAL
Lumiquick Diagnostics, Inc Santa Clara, California	Zika IgG/IgM RDT	CE IVD certified
BluSense Diagnostics ApS (Denmark)	Multiplex test quantitative Point-of-Care for ZIKV/DENV with parallelized opto-magnetic detection VIRO-Track® for differential NS1 Ag(ZIKV)/NS1(DENV) SERO-Track® for differential IgG/IgM(ZIKV)/IgG/IgM(DENV) COMBO-Track® for NS1 Ag/IgG/IgM(ZIKV)	In development Plan to submit to EUAL and ANVISA

NOTE: This list is not complete. There are several companies working on a ZIKV diagnostic test that choose not to disclose the current status of their development.

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