

RapiGEN, Inc., Korea	FORM							MTPC DOC. No.: FB 07.11.04	
	List of CE Marked Products (IVD)							Revision 05	
	(Annex Ia of the Authorized Representative Agreement)							Valid from 01.06.2013	

Last update of the list: 2020-04-02				Current number of categories:		Number of categories defined in agreement:			
New products are marked in green / Obsolete products in red				9		10			
Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)

To be filled by MTPC	To be filled by MTPC								To be filled by MTPC
RAP-01	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	D10RHA10 (10tests/kit) D10RHA25 (25tests/kit) D10RHA30 (30tests/kit)	RapiGEN BIOCREDIT Dengue IgG/IgM	BIOCREDIT Dengue IgG/IgM is a immuno-chromatographic assay for the qualitative detection of antibodies of two isotypes (IgG and IgM) specific to dengue virus in human serum, plasma or whole blood. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 16.07.2014 Revised: 06.02.2015 Revised: 13.01.2016 Revised: 04.01.2018 revised: 01.07.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-01	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	D30RHA10 (10tests/kit) D30RHA25 (25tests/kit)	RapiGEN BIOCREDIT Dengue NS1 Ag + Ab Duo	The RapiGEN BIOCREDIT Dengue NS1 Ag + Ab Duo rapid test is an in vitro immuno-chromatographic, one step assay designed to detect both dengue virus NS1 antigen and differential IgG/IgM antibodies to dengue virus in human serum, plasma or whole blood. It contains two test devices (left side; Dengue NS1 Ag test device, right side; Dengue IgG/IgM test device). For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 16.07.2014 Revised: 03.02.2015 Revised: 13.01.2016 Revised: 04.01.2018 revised: 01.07.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020

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RAP-01-02	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	D20RHA10 (10tests/kit) D20RHA25 (25tests/kit) D20RHA30 (30tests/kit)	RapiGEN BIOCREDIT Dengue NS1 Ag	RapiGEN BIOCREDIT Dengue NS1 Ag is a immunochromatographic assay for the qualitative detection from dengue virus in human serum, plasma or whole blood as an aid in the diagnosis of dengue virus infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 16.07.2014 Revised: 09.02.2015 Revised: 13.01.2016 Revised: 01.07.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 02.04.2020
RAP-01-03	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C20RHA25 (25tests/kit) C20RHA30 (30tests/kit)	RapiGEN BIOCREDIT Malaria Ag Pan (pLDH)	RapiGEN BIOCREDIT Malaria Ag Pan (pLDH) is an immuno-chromatographic assay for qualitative determination of Plasmodium spp. (P. falciparum, P. vivax, P. malariae and P. ovale) antigen in human whole blood as an aid in the diagnosis of malaria infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 16.07.2014 Revised: 09.02.2015 Revised: 13.01.2016 Revised: 09.08.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-04	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C10RH25 (25tests/kit) C10RH30 (30tests/kit)	RapiGEN BIOCREDIT Malaria Ag Pf (HRP II)	RapiGEN BIOCREDIT Malaria Ag Pf (HRP II) is an immuno-chromatographic assay for the qualitative detection and differentiation of P. falciparum from Plasmodium spp. in human whole blood as an aid in the diagnosis of malaria infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 16.07.2014 Revised: 09.02.2015 Revised: 14.01.2016 Revised: 14.08.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020

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RAP-01-05	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C30RHA25 (25tests/kit) C30RHA30 (30tests/kit) C32RHA25 (25tests/kit)	RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRP II/ pLDH) is an immuno- chromatographic assay for the qualitative detection and differentiation of Plasmodium falciparum from Plasmodium spp. (P. falciparum, P. vivax, P. malariae and P. ovale) in human whole blood as an aid in the diagnosis of malaria infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 31.07.2014 16.07.2014 Revised: 22.01.2016 09.02.2015 Revised: 21.08.2019 14.01.2016 Revised: 02.04.2020	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-06	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C60RHA25 (25tests/kit) C60RHA30 (30tests/kit)	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (pLDH/ pLDH) is a immuno- chromatographic assay for the qualitative detection and differentiation of Plasmodium falciparum and Plasmodium vivax from Plasmodium spp. (P. falciparum, P. vivax, P. malariae and P. ovale) in human whole blood as an aid in the diagnosis of malaria infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 31.07.2014 16.07.2014 Revised: 22.01.2016 10.02.2015 Revised: 21.08.2019 13.01.2016 Revised: 02.04.2020	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-07	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C40RHA25 (25tests/kit) C40RHA30 (30tests/kit)	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRP II/ pLDH) is an immuno- chromatographic assay for the qualitative detection and differentiation of P. falciparum and P. vivax from Plasmodium spp. in human whole blood as an aid in the diagnosis of malaria infection. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 31.07.2014 16.07.2014 Revised: 22.01.2016 10.02.2015 Revised: 21.08.2019 13.01.2016 Revised: 02.04.2020 20.08.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020

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RAP-01-08	00126354 Notification of Change (due to address change): 00131041 Notification of Change (new zip-code): 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	C50RHA25 (25tests/kit) C50RHA30 (30tests/kit)	RapiGEN BIOCREDIT Malaria Pf/Pv Ab	RapiGEN BIOCREDIT Malaria Pf/Pv Ab is an immunochromatographic assay for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) specific to Plasmodium falciparum and Plasmodium vivax at the same time in human serum, plasma or whole blood. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	15.03.2013 Revised: 31.07.2014 16.07.2014 Revised: 22.01.2016 10.02.2015 Revised: 21.08.2019 14.01.2016 Revised: 02.04.2020 20.08.2019	22.04.2013 Notification of Change 31.07.2014 Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-09	Covered by 00135723 Notification of change (add models): 00150641 Notification of change (add products): 00154804	F41RHA25, F41RHA10	RapiGEN BIOCREDIT Chikungunya IgM	RapiGEN BIOCREDIT Chikungunya IgM test is a lateral flow immunoassay for the simultaneous detection and differentiation of anti-Chikungunya IgM in human serum, plasma or whole blood. For professional use only.	15 70 90 90 00	Other Other Virology Rapid Tests	III	04.08.2017 Revised: 01.07.2019	Covered by Notification of Change: 22.01.2016 Notification of change: 21.08.2019 Notification of change: 02.04.2020
RAP-01-10	00154804	G61RHA20	BIOCREDIT COVID-19 Ag	The BIOCREDIT COVID-19 Ag is a lateral flow immunoassay for the detection of antigen of SARS-CoV-2 antigen in human nasopharyngeal swab specimen. It is intend to be used by the professionals as a screening test and as an aid in the diagnosis of infection with SARS-CoV-2 antigen. And reactive specimen with the BIOCREDIT COVID-19 Ag must be confirmed with alternative testing methods.	15 70 90 90 00	Other Other Virology Rapid Tests	III	2020-04-01	2020-04-02

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RAP-01-11	00154804	G66RHA25	BIOCREREDIT COVID-19 IgG+IgM Duo	The BIOCREREDIT COVID-19 IgG+IgM Duo is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti-SARS-CoV-2 virus and IgM anti-SARS-CoV-2 virus in human serum, plasma or whole blood. It is intended to be used by the professionals as a screening test as an aid in the diagnosis of infection with SARS-CoV-2 viruses. And reactive specimen with the BIOCREREDIT COVID-19 IgG+IgM Duo must be confirmed with alternative testing methods	16 70 90 90 00	Other Other Virology Rapid Tests	III	2020-04-01	2020-04-02
RAP-02	00133336 Notification of Change (new zip-code): 00135724	A10RHA10 (10tests/kit) A10RHA25 (25tests/kit)	RapiGEN BIOCREREDIT HAV IgG	The RapiGEN BIOCREREDIT HAV IgG test is a solid phase immunochromatographic assay for the rapid, qualitative detection of IgG to Hepatitis A virus in human blood (vein blood, capillary blood), serum or plasma. For professional use only.	15 02 01 40 00	Hepatitis A Virus - NA Reagents	III	15.05.2014 Revised: 13.01.2016	04.03.2015 Notification of Change: 22.01.2016
RAP-03	00137534 Notification of change (add prod.): 00150750	I10RHA25 (25tests/kit) I10RHB100 (100tests/kit)	RapiGEN BIOCREREDIT H. pylori Ab	The RapiGEN BIOCREREDIT H. pylori Ab is a lateral flow immunoassay for the detection and differentiation of anti-H. pylori in human serum. It is intend to be used by the professionals as a screening test and as an aid in the diagnosis of infection with H. pylori IgG antibody.	15 70 01 02 00	H. Pylori - Rapid Test	III	01.07.2016 revised: 04.09.2019	21.07.2016 Notification of change: 04.09.2019
RAP-03-01	Covered by 00137534 Notification of change (add prod.): 00150750	I11RHA20	RapiGEN BIOCREREDIT H. pylori Ag	The RapiGEN BIOCREREDIT H. pylori Ag is a lateral flow immunoassay for the detection of H. pylori Ag in feces. It is intend to be used by the professionals as a screening test and as an aid in the diagnosis of infection with H. pylori antigen. And reactive specimen with the BIOCREREDIT H. pylori Ag must be confirmed with alternative testing methods.	15 70 01 02 00	H. Pylori - Rapid Test	III	14.08.2017 revised: 30.08.2019	Covered by 21.07.2016 Notification of change: 04.09.2019
RAP-04	00139092			RapiGEN BIOCREREDIT RSV/Adeno + Influenza Duo test is an adopted	15 70 90 02 00	RSV - Rapid Test			

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RAP-05	00139098	G22RHA20	RapiGEN BIOCREDIT BIOCREDIT RSV/Adeno + Influenza Duo	dual color system for the identification of RSV, adenovirus and Influenza A&B antigen from nasal swab or nasopharyngeal swab with a high degree of accuracy.	15 04 80 01 00	Adenovirus	III	2016-11-25	2017-01-10
RAP-06	00139099				15 04 80 04 00	Influenza & Para Influenza			
RAP-04-01	00139092	G21RHA25	RapiGEN BIOCREDIT RSV/Adeno Combo	RapiGEN BIOCREDIT RSV/Adeno combo test is an adopted dual color system for the identification of RSV/Adeno antigen from nasal swab or nasopharyngeal swab with a high degree of accuracy.	15 70 90 02 00	RSV - Rapid Test	III	2016-11-25	2017-01-10
RAP-05-01	00139098				15 04 80 01 00	Adenovirus			
RAP-04-02	00139092	G20RHS25	RapiGEN BIOCREDIT RSV Ag	RapiGEN BIOCREDIT RSV Ag is immunochromatographic assay for the qualitative detection of Respiratory Syncytial virus (RSV) antigen in nasopharyngeal aspirate or nasal swab. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with Respiratory Syncytial virus (RSV).	15 70 90 02 00	RSV-Rapid Test	III	2017-12-20	Covered by notification : 10.01.2017
RAP-05-02	00139098	I30RHA25	RapiGEN BIOCREDIT Adeno Ag	RapiGEN BIOCREDIT Adeno Ag is immunochromatographic assay for the qualitative detection of antigen in feces. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with Adeno virus antigen.	15 04 80 01 00	Adenovirus	III	2017-12-14	Covered by notification : 10.01.2017
RAP-06-01	00139099	G10RHA20 G10RHA25	RapiGEN BIOCREDIT Influenza A&B Ag Quick Flu 3	RapiGEN BIOCREDIT Influenza A&B Ag Quick Flu 3 is used for the qualitative detection of Influenza A&B virus antigen from human nasal, nasopharyngeal and throat swab.	15 04 80 04 00	Influenza & Para Influenza	III	2016-11-25	2017-01-10

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RAP-06-02	Covered by 00139099	G10RHS25	BIOCREDIT Influenza A&B Ag	The BIOCREDIT Influenza A&B Ag is a lateral flow immunoassay for the detection and differentiation of antigen of Influenza virus in human nasal swab or/and throat swab. It is intend to be used by the professionals as a screening test and as an aid in the diagnosis of infection with Influenza virus type A and B antigen. And reactive specimen with the BIOCREDIT Influenza A&B Ag must be confirmed with alternative testing methods.	15 04 80 04 00	Influenza & Para Influenza	III	2017-08-11	Covered by 10.01.2017
RAP-07	00143028	E10RHA25	RapiGEN BIOCREDIT Syphilis Ab	For the qualitative detection of Syphilis antibody in plasma and serum. For professional use only.	15 70 01 05 00	Syphilis Rapid Tests	III	2018-01-05	2018-01-26
RAP-07-01	00143028	E10RHB100	RapiGEN BIOCREDIT Syphilis Ab Multi	For the qualitative detection of Syphilis antibody in plasma and serum. For professional use only.	15 70 01 05 00	Syphilis Rapid Tests	III	2018-01-05	2018-01-26
RAP-08	00143177	I20RHA20	RapiGEN BIOCREDIT Rota Ag	RapiGEN BIOCREDIT Rota Ag is immunochromatographic assay for the qualitative detection of Rotavirus antigen in feces. It is intend to be used by the professionals as a screening test and as an aid in the diagnosis of infection with Rotavirus.	15 04 80 06 00	Rotavirus	III	2017-12-27	2018-02-16
RAP-09	00150810	L10RHA25	RapiGEN BIOCREDIT Troponin I	RapiGEN BIOCREDIT Troponin I Test is an in vitro one-step immunochromatographic assay designed to detect Troponin I in human blood (serum, plasma or whole blood).	12 70 13 03 00	Troponin I/T – Rapid Test	III	2019-09-05	2019-09-10

Remarks:

- All product, model or trade names haveto be specified
- Please specify the intended use

Prepared: MT Promedt Consulting GmbH

Released: RapiGen, Inc.

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Supplemental Information

Product covered by Technical Documentation (Title, Revision, Date):

TF RapiGEN BIOCREDIT Dengue IgG/IgM, Rev.04, 2015-12-29

TF RapiGEN BIOCREDIT Dengue NS1Ag +Ab Duo, Rev.04, 2015-12-24

Product covered by Technical Documentation (Title, Revision, Date):

TF RapiGEN BIOCREDIT Dengue NS1 Ag, Rev. 04, 2015-12-28

TF RapiGEN BIOCREDIT Malaria Ag Pan (pLDH), Rev. 04, 2015-12-21

TF RapiGEN BIOCREDIT Malaria Ag Pf (HRP II), Rev. 04, 2015-12-17

Product covered by Technical Documentation (Title, Revision, Date):

TF RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH), Rev. 04, 2015-12-17

TF RapiGEN BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH), Rev.04, 2015-12-23

TF RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH), Rev. 04, 2015-12-22

Product covered by Technical Documentation (Title, Revision, Date):

TF RapiGEN BIOCREREDIT Malaria Pf/Pv Ab, Rev. 04, 2015-12-17

TF: RTF-25-01, Rev 01, 2017-08-18

RTF-41-00, 01.04.2020

Product covered by Technical Documentation (Title, Revision, Date):

RTF-40-00, 01.04.2020

TF RapiGEN BIOCREDIT HAV IgG, Rev. 03, 2015-12-28

TF RapiGEN BIOCREDIT H. pylori Ab, Rev. 03, 2019-08-30

TF: RapiGEN BIOCREDIT H. pylori Ag, rev.03, 2019-08-30

Product covered by Technical Documentation (Title, Revision, Date):

TF BIOCREDIT RSV/Adeno + Influenza Duo, Ver.1, 2016-11-25

TF BIOCREDIT RSV/Adeno Combo, Ver.1, 2016-11-29

TF BIOCREDIT RSV Ag, Ver. 1, 2017-12-20

TF BIOCREDIT Adeno Ag, Ver.1, 2017-12-14

TF BIOCREDIT Influenza A&B Ag Quick Flu 3, Ver.1, 2016-12-09

Product covered by Technical Documentation (Title, Revision, Date):

TF BIOCREREDIT Influenza A&B Ag,Ver. 0, 2017-08-11

TF RapiGEN BIOCREREDIT Syphilis Ab, Ver. 3, 2018-01-05

TF RapiGEN BIOCREREDIT Syphilis Ab, Ver. 3, 2018-01-05

TF BIOCREREDIT Rota Ag, Ver. 0, 2017-12-27

TF BIOCREREDIT Troponin I, Ver.0, 2018-02-09

Product covered by Technical Documentation (Title, Revision, Date):

Product covered by Technical Documentation (Title, Revision, Date):

Product covered by Technical Documentation (Title, Revision, Date):