

Relation between product groups and Bios reagents and EDMS classification: Antibodies to Bacteria

(Pfad: Handbuch Herstellung/12 CE Konformität/01 Konformität DIMDI Gruppen)

Stand November 2018

<u>DIMDI Registration No.</u>	<u>Bios product group</u>	<u>Reagents which belong to (kits and separately available reagents)</u>	<u>EDMS term</u>	<u>EDMS number/DIMDI formular-No.</u>
DE/CA61/1B20/50	Biognost® Bartonella henselae Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Other Bacteriology Rapid Tests	15 70 01 90 00 00029960
DE/CA61/1B20/51	Biognost® Bartonella quintana Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Other Bacteriology Rapid Tests	15 70 01 90 00 00029961
DE/CA61/1B20/52	Biognost® Bordetella parapertussis Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG, IgM and IgA assay	Bordetella pertussis/parapertussis	15 01 90 07 00 00029962
DE/CA61/1B20/53	Biognost® Bordetella parapertussis Ag	Conjugates, control slide, misc. comp.	Bordetella pertussis/parapertussis	15 01 90 07 00 00029963
DE/CA61/1B20/54	Biognost® Bordetella pertussis Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG, IgM and IgA assay	Bordetella pertussis/parapertussis	15 01 90 07 00 00029964
DE/CA61/1B20/55	Biognost® Bordetella pertussis Ag	Conjugates, control slide, misc. comp.	Bordetella pertussis/parapertussis	15 01 90 07 00 00029965
DE/CA61/1B20/56	Biognost® Borrelia burgdorferi und Borrelia species Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Lyme Antibodies Total	15 01 06 03 00 00029966
DE/CA61/1B20/57	Biolisa® Borrelia burgdorferi Ab*	Kits	Lyme Antibodies Total	15 01 06 03 00 00029967
DE/CA61/1B20/89	Biosave® Borrelia burgdorferi Ab	Kits and sets	Lyme Antibodies Total	15 01 06 03 00 00055945
DE/CA61/1B20/58	Biognost® Coxiella burnetii Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Coxiella	15 01 90 03 00 00029959
DE/CA61/1B20/59	Biognost® Helicobacter pylori Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgA assay	Helicobacter pylori Antibody Assays	15 01 04 03 00 00029971

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DE/CA61/1B20/60	Biognost® Haemophilus influenzae Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgA assay	Haemophilus influenzae	15 01 90 10 00 00029972
DE/CA61/1B20/61	Biognost® Legionella pneumophila und Legionella species Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for polyvalent and IgM assay	Legionella Antibody Assays	15 01 05 03 00 00029973
DE/CA61/1B20/62	Biognost® Legionella pneumophila und Legionella species Ag	Conjugates, controll slides, misc. comp.	Legionella Antigen Detection	15 01 05 01 00 00029974
DE/CA61/1B20/88	Biognost® Leptospira interrogans Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Leptospira	15 01 90 04 00 00055939
DE/CA61/1B20/80	Biolisa® Leptospira interrogans Ak*	Kits	Leptospira	15 01 90 04 00 00029976
DE/CA61/1B20/81	Biosave® Leptospira interrogans Ab	Kits and sets	Leptospira	15 01 90 04 00 00055938
DE/CA61/1B20/82	Biognost® Listeria monocytogenes Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgM assay	Listeria Antibody Assays	15 01 13 03 00 00029978
DE/CA61/1B20/83	Biognost® Mycoplasma pneumoniae Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG, IgM and IgA assay	Mycoplasma Antibody Assays	15 01 08 03 00 00029979
DE/CA61/1B20/84	Biognost® Yersinia enterocolitica Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG and IgA assay	Yersinia	15 01 90 06 00 00055937
DE/CA61/1B20/86	Biosorb® Rheumafactor Absorbens	Reagent for the removal of IgG from human serum or plasma	Other Bacteriology Rapid Tests	15 70 01 90 00 00030298
DE/CA61/1B20/87	Biosorb® ReiterSpirochäten Absorbens	Reagent for the removal of crossreacting Spirochetes antibodies from human serum or plasma	Other Bacteriology Rapid Tests	15 70 01 90 00 00055936

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DE/CA61/1B20/99	Biognost® Rickettsia conorii Ab	Kits and slides with conjugates, positive controls, negative control, misc. comp. for IgG, IgM and IgA assay	Rickettsia NA Reagents	15 01 40 05 00 00134696

Misc. comp., miscellaneous components are other aids for Biognost® tests: conjugates, PBS buffer, mounting medium, cover slips, blotters, uncoated slides

*Actually not available