Republic of Bulgaria
Executive Agency
Bulgarian Accreditation Service

Signatory to the EA Multilateral Agreement in this fied

ORDER

№ A 365
Sofia, 10.06.2022

Pursuant to Art. 10, para. 1, items 3 and 4, Art. 28, para. 1 and Art. 30, para. 1 of the Law on National Accreditation of Conformity Assessment Bodies and items 6 and 7 of the BAS QR 2 Accreditation Procedure, in connection with an open procedure reg. № 120/235 ЛИ/ПА/РО/19.04.2021, assessment report reg. № 120/235 ЛИ/ПА/РО/11/В/13.12.2021, Statement of the Accreditation Commission reg. № 120/235 ЛИ/ПА/РО/13/В/20.05.2022 and letter reg. № 120/235 ЛИ/ПА/РО/14/В/Е/26.05.2022, I hereby

RE-ACCREDIT AND EXTEND THE SCOPE OF ACCREDITATION

of National Center of Infectious and Parasitic Diseases
Laboratory Testing Complex

Management address: 1504 Sofia, 26 Yanko Sakazov Blvd.
Laboratory addresses:
Office 1: 1504 Sofia, 26 Yanko Sakazov Blvd.
Office 2: 1233 Sofia, 44A Gen. Stoletov Blvd.

To perform testing of:

OFFICE 1: 1504 Sofia, Oborishte Municipality, 26 Yanko Sakazov Blvd.

Type of the scope: *fixed*			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
LABORATORY IMMUNOLOGY			
1.	Blood	Absolute count of leukocyte subpopulation (number of cells -µl) Index CD4/CD8 (value) Percentage of leukocyte subpopulation (%)	VLM/I1/01/1997
		Production of IFN-γ by specifically stimulated lymphocytes at mycobacterial infection	VLM/I5/05/2005
2.	Lymph node	Absolute count of leukocyte subpopulation (number of cells -µl) Index CD4/CD8 (value) Percentage of leukocyte subpopulation (%)	VLM/I1/01/1997
3.	Bone marrow	Absolute count of leukocyte subpopulation (number of cells -µl) Index CD4/CD8 (value) Percentage of leukocyte subpopulation (%)	VLM/I1/01/1997
4.	Serum	Quantity of IgG (g/L) Quantity of IgA (g/L)	VLM/I3/02/1985

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Type of the scope: *fixed*			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
		Quantity of IgM (g/L)	
		Presence of specific IgA and IgG antibodies against SARS-CoV-2	VLM/I/06/2020
LABORATORY AND PARASITOLOGY			
5.	Blood	Finding blood and tissue protozoa according to Romanowsky - Giemsa	VLM/P/14/1996
6.	Perianal imprint	Ovoscopy by scotch-strip for finding eggs of intestinal parasites	VLM/P/10/2001
7.	Serum	Presence of: - Specific antibodies against *T. spiralis*	VLM/P/07/2001
		- Specific antibodies against *E. granulosus*	VLM/P/05/2001
		- Specific antibodies against *L. donovani* by immune-enzyme method ELISA (IgG)	VLM/P/06/2001
		- Specific IgM antibodies against *T. gondii* by immune-enzyme method ELISA	VLM/P/16/1996
		- Quantitative determination of IgG antibodies against *T. gondii* by immune-enzyme method ELISA	VLM/P/17/1996
		- Specific IgA antibodies against *T. gondii* by immune-enzyme method ELISA	VLM/P/18/1996
8.	Feces	Presence of intestinal helminths and protozoa according to formalin – ether method	VLM/P/09/2001
		Presence of intestinal protozoa according to staining method – Ziehl-Neelsen	VLM/P/13/1996
		Intestinal helminths and protozoa according to native method	VLM/P/12/2001
9.	Vaginal content; urethral secretion	Trichomonas by cultural diagnostics of TV 4 medium	VLM/P/15/1995
10.	Soil, sediments, fertilizer	Intestinal protozoa and helminths in soil, sediments, and fertilizer	VLM/P/19/1995
11.	Water samples	Intestinal protozoa and helminths in water samples	VLM/P/20/1996
MICROBIOLOGY LABORATORY			
12.	Primary clinical materials-Ascitic fluid; Autopsy material; Broncho-alveolar lavage; Vaginal discharge; Throat discharge; Exudate; Bile;	Pathogenic microorganisms: Gram-negative and Gram-positive aerobic and anaerobic bacteria; Fungi	VLM/M3/07/1990

Type of the scope: *fixed*			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
	Conjunctival discharge; Bone marrow; Cerebrospinal fluid; Blood; Liquor; Necrotic tissue; Nasopharyngeal discharge; Pericardial and pleural fluid; Peritoneal contents; Vomited material; Washing samples; Wound discharge; Transtracheal aspirate; Urine; Ear secretion; Feces; Sputum; Cervical discharge	Identification of pathogenic microorganisms by DNA analysis	VLM/M4/10/2000
13.	Materials from the environment	Enterobacteriaceae Family, Fungi	VLM/M2/03/1990 VLM/M2/04/1990 VLM/M10/28/1990 VLM/M4/10/2000
14.	Foodstuff	*Enterobacteriaceae* Family	VLM/M2/04/1990
		Identification of pathogenic microorganisms by DNA analysis	VLM/M4/10/2000
15.	Isolate	Identification of *E. coli*	VLM/M2/04/1990
		Identification of Streptococci	VLM/M5/12/1990
		Identification of Aspergillus	VLM/M10/28/1990
		Identification of Enterococci	VLM/M5/12/1990
		Identification of Campylobacter	VLM/M8/25/1990
		Identification of Candida	VLM/M10/28/1990
		Identification of Corynebacterium	VLM/M5/13/1996
		Identification of Cryptococci	VLM/M10/28/1990
		Identification of Mould	VLM/M10/28/1990
		Identification of Salmonella	VLM/M2/03/1990
		Identification of Enterobacteriaceae Family	VLM/M2/03/1990
		Identification of Staphylococci	VLM/M1/01/1990
		Identification of Shigella	VLM/M2/03/1990
		Identification of Gram-positive and Gram-negative microorganisms	VLM/M3/08/1990
16.	Isolate Gram-negative aerobic bacteria	Determination of minimum inhibitory concentration (MIC) of antimicrobial agents	VLM/M3/06/2001
17	Isolate Gram-negative and Gram-positive aerobic bacteria	Determination of sensitivity to antimicrobials	VLM/M3/09/1990
		Identification of Gram-negative and Gram-positive bacteria	VLM/M3/31/2021
18.	Staphylococci isolate	Determination of oxacillin resistance	VLM/M1/02/1993
19.	Cerebrospinal fluid	Antibodies against *B. burgdorferi*	VLM/M9/27/1993
20.	Serum	Qualitative determination of antibodies	VLM/M9/27/1993

Type of the scope: *fixed*			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
		against *B. burgdorferi*-ELISA	
		Agglutination latex test for qualitative detection of non-treponemal antibodies in human serum	VLM/M10/29/2020
		Indirect hemagglutination test for qualitative determination of specific antitreponemal antibodies in human serum	VLM/M10/30/2020
DDD LABORATORY			
21	Insecticide	Contact action by mortality in percentage	VLM/D/01/1997
		Intestinal action by mortality in percentage	VLM/D/02/1997
		Aerosol action by mortality in percentage	VLM/D/03/1997
		Larvicide action by mortality in percentage	VLM/D/04/1997

OFFICE 2: 1233 Sofia, Serdika Municipality, 44 Gen. Stoletov Blvd.

Type of the scope: *flexible for part of the scope**			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
VIROLOGY LABORATORY			
1.	Viral isolate	Identification of enteroviral isolates by viral-neutralizing reaction /VNR/	VLM/B1/02/2001
2.	Liquor	Isolation of poliomyelitis and other enteroviruses from clinical materials of diseased persons at cellular cultures	VLM/B1/01/2001
3.	Nasopharyngeal secretion	Isolation of poliomyelitis and other enteroviruses from clinical materials of diseased persons at cellular cultures	VLM/B1/01/2001
		Virological examination of material from patients on cell cultures for the isolation of influenza viruses	VLM/B9/12/2012
4.	Serum	Availability of :	
		- HBsAg	VLM/B6/04/2001
		- Anti-HCV	VLM/B6/17/2008
		- Anti-HAV-IgM	VLM/B6/18/2008
		- Anti-HDV-IgG	VLM/B6/19/2008
		- Anti-HBc/IgG against the nuclear antigen of the Hepatitis B virus	VLM/B6/20/2008
		- Anti-HEV-IgM	VLM/B6/21/2021
		Presence of specific antibodies against HIV 1/2	VLM/B7/06/2016
		Presence of specific antibodies against HIV 1/2 and p24 antigen	VLM/B7/05/2001
		Specific antibodies against HSV-1	VLM/B8/06/2016
		Specific antibodies against HSV-2	VLM/B8/07/2001
		Specific antibodies against chlamydia	VLM/B10/13/1994
		Specific IgM antibodies against measles	VLM/B11/14/1994
		Specific IgM antibodies against parotitis	VLM/B11/15/1994
		Specific IgM antibodies against rubella	VLM/B11/16/1994
5.	Corpse material	Virological examination of material from	VLM/B9/12/2012

Type of the scope: *flexible for part of the scope**			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
		patients on cell cultures for the isolation of influenza viruses	
		Isolation of poliomyelitis and other enteroviruses from clinical materials of diseased persons on cellular cultures	VLM/B1/01/2001
6.	Feces	Isolation of poliomyelitis and other enteroviruses from clinical materials of diseased persons on cellular cultures	VLM/B1/01/2001
DDD LABORATORY			
7.	Disinfectant	chlorhexidine gluconatein %	VLM/D/11/1997
		Active Chlorine in %	VLM/D/06/1997
		Aldehydes in % -total -glyoxal -glutaric	VLM/D/14/2011
		Reduction (R) of test-strains expressed as a decimal logarithm	BDS EN 1040
		Reduction (R) of test-strains expressed as a decimal logarithm	BDS EN 1275
		Superficial active substance in %	BDS EN ISO 2871-2
		Reduction (R) for bacteria and fungi	BDS EN 13697+A1
MICROBIOLOGY LABORATORY			
8.	Clinical materials – sputum/ induced sputum, broncho-alveolar lavage, tracheal aspirate, transthoracic aspirational biopsy, gastric washings, feces, urine, ejaculate, menstrual blood, wound secretions, tissue particles from wounds and biopsy, pleural puncture, pericardial puncture, peritoneal puncture, liquor, joint puncture, bone marrow, pus from an abscess, lymph node puncture, corpse materials, intraoperative aspirates and tissue samples	Acid-fast bacilli	VLM/M7/20/2006
		Mycobaterium tuberculosis	VLM/M7/21/2006
		Legionella spp.	VLM/M6/19/2004
		Vibrio cholerae	VLM/M6/32/2021
		B. anthracis	VLM/M6/32/2021
		F. tularensis	VLM/M6/32/2021
		Y. pestis	VLM/M6/32/2021
		Brucella spp.	VLM/M6/32/2021

Type of the scope: *flexible for part of the scope**			
№	**Tested products**	**Type of test / characteristic**	**Testing methods (standard / validated method)**
1	**2**	**3**	**4**
9.	Materials from the environment	*Vibrio cholerae*	VLM/M6/15/1990 VLM/M6/32/2021
		Legionella spp.	VLM/M6/19/2004
		B. anthracis	VLM/M6/32/2021
		F. tularensis	VLM/M6/32/2021
		Y. pestis	VLM/M6/32/2021
		Brucella spp.	VLM/M6/32/2021
10.	Isolate	Identification of vibrions	VLM/M6/15/1990 VLM/M6/32/2021
		Identification of *B. anthracis*	VLM/M6/16/1990 VLM/M6/17/1990 VLM/M6/32/2021
		Identification of *F. tularensis*	VLM/M6/17/1990 VLM/M6/32/2021
		Identification of *Y. pestis*	VLM/M6/17/1990 VLM/M6/32/2021
		Identification of *Brucella spp.*	VLM/M6/17/1990 VLM/M6/32/2021
11	Mycobacterium tuberculosis	Drug susceptibility testing	VLM/M7/22/2006

***Flexible scope:** Implementing a new version of standards/documents or standards / documents replacing them is allowed. An updated list of standards/documents and their dated versions is provided by laboratory.*

Fixed scope
References:
OFFICE 1: 1504 Sofia, Oborishte Municipality, 26 Yanko Sakazov Blvd.
LABORATORY IMMUNOLOGY

VLM/I1/01/1997 20.05.2019	*Immunophenotypisation of leukocyte subpopulations*
VLM/I3/02/1985 26.04.2019	*Radial immunodiffusion /Manchini/ for quantitative determination of IgG, IgA, IgM.*
VLM/I5/05/2005 19.04.2019	*Production of IFN- γ by specifically stimulated lymphocytes at microbacterial infection*
VLM/I/06/2020 10.09.2020	*anti-SARS-CoV-2 ELISA, method for qualitative detection of antibodies IgG against SARS-CoV-2*
VLM/M1/01/1990 19.07.2019	*Microbiological identification of Staphylococci*
VLM/M1/02/1993 18.07.2019	*Identification of oxacillin resistant staphylococci*
VLM/M2/03/1990 22.07.2019	*Microbiological identification of pathogenic intestinal bacteria*
VLM/M2/04/1990 22.07.2019	*Cultural test for pathogenic intestinal bacteria*
VLM/M3/06/2001 19.02/2019	*Determination of minimum suppressing concentrations (MSC) of antimicrobial agents.*
VLM/M3/07/1990 21.02.2019	*Cultural testing of initial microbiological materials.*
VLM/M3/08/1990 21.02.2019	*Biochemical identification of Gram-positive and Gram-negative microorganisms.*
VLM M3/09/1990 25.02.2019	*Determination of susceptibility to antibacterial agents .*

VLM M3/31/2021 20.01.2021	MALDI-TOF method of identification of bacteria
VLM/M4/10/2000 18.04.2019	DNA analysis of pathogenic microorganisms of clinical materials, strains, environment, corpse material and foodstuff.
VLM/M5/12/1990 02.07.2019	Microbiological identification of Streptococci.
VLM/M5/13/1996 10.07.2019	Microbiological identification of Corynebacteria.
VLM/M8/25/1990 22.07.2019	Microbiological identification of Campylobacter.
VLM/M9/27/1993 04.09.2019	Qualitative determination of antibodies against B. burgdorferi with immune-enzyme method (ELISA).
VLM/M10/28/1990 04.02.2019	Microbiological identification of medically significant fungi
VLM/M10/29/2020 25.11.2020	Agglutination latex test for qualitative detection of non-treponemal antibodies in human serum
VLM/M10/30/2020 25.11.2020	Indirect hemagglutination test for qualitative determination of specific antitreponemal antibodies in human serum

LABORATORY AND PARASITOLOGY

VLM/P/05/2001 18.04.2019	Detection of specific antibodies against E. granulosis ELISA IgG
VLM/P/06/2001 17.04.2019	Detection of specific antibodies against L. donovani-ELISA IgG
VLM/P/07/2001 14.05.2019	Detection of specific antibodies against T. spiralis-ELISA IgG
VLM/P/09/2001 20.03.2019	Formaline – ether method for intestinal helminths and protozoa
VLM/P/10/2001 03.04.2019	Ovoscopy by scotch-strip
VLM/P/12/2001 22.04.2019	Native method for intestinal protozoa and helminths.
VLM/P/13/1996 15.05.2019	Staining method for intestinal protozoa – Ziehl Neelsen
VLM/P/14/1996 02.05.2019	Staining method for blood and tissue protozoa – Romanowsky-Giemza.
VLM/P/15/1995 11.06.2019	Cultural diagnostics of Trichomonas-media TV4.
VLM/P/16/1996 03.04.2019	ELISA- Detection of specific IgM antibodies against T. gondii
VLM/P/17/1996 03.04.2019	ELISA- quantitative determination of IgG antibodies against T. gondii
VLM/P/18/1996 25.04.2019	ELISA- Detection of specific antibodies against T. gondi
VLM/P/19/1995 29.03.2019	Testing soil, sediments and fertilizers for intestinal protozoa and helminths.
VLM/P/20/1996 18.06.2019	Testing water samples for intestinal protozoa and helminths.

DDD LABORATORY

VLM/D/01/1997 19/08/2019	Method for determination of contact effect of insecticides. Mortality in percentage.
VLM/D/02/1997 23.05/2019	Method for determination of intestinal effect of insecticides. Mortality in percentage.
VLM/D/03/1997 02.12.2019	Method for determination of aerosol effect of insecticides. Mortality in percentage.
VLM/D/04/1997 27.12.2019	Method for determination of larvicide effect of insecticides. Mortality in percentage.

OFFICE 2: 1233 Sofia, Serdika Municipality, 44 Gen. Stoletov Blvd.

VIROLOGY LABORATORY

VLM/B1/01/2001 11.03.2019	*Isolation of poliomyelitis and other enteroviruses by cellular materials of diseased and healthy persons at cellular cultures*
VLM/B1/02/2001 18.03.2019	*Viral-neutralizing reaction /VNR/ for identification of enteroviral isolates*
VLM/B6/04/2001 10.02.2021	*Immuno-enzume method ELISA for availability of HBsAg*
VLM/B6/17/2008 16.02.2021	*Immune-enzyme method ELISA for finding anti-HCV*
VLM/B6/18/2008 04.02.2021	*Immune-enzyme method ELISA for finding anti-HAV-IgM*
VLM/B6/19/2008 12.02.2021	*Immune-enzyme method ELISA for finding anti-HDV-IgG*
VLM/B6/20/2008 08.02.2021	*Immune-enzyme method ELISA for finding anti-HBc/IgG against nuclear antigen of virus Hepatitis B*
VLM/B6/21/2021 19.09.2021	*Immune-enzyme method ELISA for finding anti-HEV-IgM*
VLM/B7/05/2001 20.02.2020	*Immune-enzyme method ELISA for presence of specific antibodies to HIV-1/2*
VLM/B7/06/2016 10.03.2020	*Western-Blot method – Line Immunoassay for presence of specific anti- HIV-1/2 antibodies*
VLM/B8/06/2001 07.06.2019	*Immune-enzyme method ELISA for availability of specific antibodies for HSV-1.*
VLM/B8/07/2001 07.06.2019	*Immune-enzyme method ELISA for availability of specific antibodies for HSV-2.*
VLM/B9/12/2001 11.03.2019	*Virological test of materials from diseased persons at cellular cultures for isolating flu viruses.*
VLM/B10/13/1994 13.03.2020	*Immune-enzyme method ELISA for availability of specific antibodies against chlamydia and proving chlamydial antigens*
VLM/B11/14/1994 16.09.2019	*Immune-enzyme method ELISA for availability of specific IgM antibodies against morbilli.*
VLM/B11/15/1994 16.09.2019	*Immune-enzyme method ELISA for availability of specific IgM antibodies against parotitis.*
VLM/B11/16/1994 16.09.2019	*Immune-enzyme method ELISA for availability of specific IgM antibodies against Rubella.*

MICROBIOLOGY LABORATORY

VLM/M6/15/1990 11.04.2019	*Microbiological identification of cholera vibrios.*
VLM/M6/16/1990 18.04.2019	*Microbiological identification of B. anthracis.*
VLM/M6/17/1990 24.04.2019	*Qualittaive immune-fluorescent method for identification of special bacterial pathogens.*
VLM/M6/19/2004 17.05.2019	*Cultural test for bacteria from Genus Legionella.*
VLM/M6/32/2021 03.02.2021	*DNA analysis from clinical materials, external environment and bacterial isolates suspected for special bacterial pathogens.*
VLM/M7/20/2006 05.03.2019	*Ziehl-Neelsen smear microscopy for acid-fast bacilli.*
VLM/M7/21/2006 08.04.2019	*Cultural test for Mycobacterium tuberculosis complex.*
VLM/M7/22/2006 08.04.2019	*Drug susceptibility testing of Mycobacterium tuberculosis strains*

DDD LABORATORY

VLM/D/06/1997 13.08.2019	*Method of quantitative determination of active Chlorine.*
VLM/D/11/1997 08.10.2019	*Method of quantitative determination of Chlorine-Hexedine Gluconate.*
VLM/D/14/2011 23.08.2019	*Quantitative determination of aldehydes.*

I ORDER

To issue the Certificate of accreditation reg. № 235 ЛИ/10.06.2022, valid until 10.06.2026, and this order as an integral part of it.

The Certificate of accreditation with the enclosure to be received at the office of EA BAS by the Manager / representative of the National Center of Infectious and Parasitic Diseases, the head of Laboratory Testing Complex at National Center of Infectious and Parasitic Diseases, or other authorized person in the office of EA BAS.

Upon receipt of the certificate and the enclosure issued, the accredited CAB is obliged to return to EA BAS the originals of accreditation certificate № 235 ЛИ / 17.09.2020 and enclosure – EA BAS order reg. № А 553/17.09.2020 as an integral part of it, valid until 20.12.2021, extended by EA BAS order reg. № А 805/20.12.2021.

This order shall be notified to the National Center of Infectious and Parasitic Diseases, within 3 (three) days from its issuance.

Eng. Irena Borislavova

Executive Director of EA BAS