

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTÉ WELTGESUNDHEITSORGANISATION ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ

REGIONAL OFFICE FOR EUROPE BUREAU RÉGIONAL DE L'EUROPE REGIONALBŪRO FÜR EUROPA ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

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Our reference:

Notre référence: Unser Zeichen: См. наш номер: Your reference: Ihr Zeichen:

Votre référence: На Ваш номер: Date: 21 August 2019

Professor Aurelijus Veryga

Minister of Health Ministry of Health

Vilniaus g. 33

Lithuania

felijus Veryga

2019 -08- 7 6

Dear Sir,

As part of the annual accreditation procedure, the National Measles/Rubella Laboratory of your country was reviewed by the WHO Regional Office for Europe.

Based on the results of this review, I am pleased to inform you that the National Laboratory is fully accredited as a WHO Measles/Rubella National Laboratory for 2020. Enclosed are the scope of the accreditation and the recommendations of the review for your information.

I would like to take this opportunity to draw your attention to the newly released WHO Manual for the laboratory-based surveillance of measles, rubella, and congenital rubella syndrome (https://www.who.int/immunization/monitoring_surveillance/burden/laboratory/manual/en/), which provides updated information on WHO Measles and Rubella Laboratory Network standards, requirements and testing algorithms to adequately support case-based surveillance for measles, rubella and congenital rubella syndrome. The Manual also provides useful guidance for laboratory contribution to the verification of disease elimination, in line with the recent recommendations of the European Regional Verification Commission for Measles and Rubella Elimination.

Since WHO-accredited national laboratories play an increasing role in securing high-quality laboratory investigations through oversight, coordination of national laboratory networks and measles and rubella external quality assessment programmes, I would like to thank you personally for your ongoing support for the National Measles/Rubella Laboratory and to congratulate the staff of the Laboratory on the successful accreditation.

Yours very truly,

Dr Piroska Östlin

Acting Regional Director

Copy for information to:

Ms Radvilė Jakaitienė, Adviser, Strategic Management and International Cooperation Division, Ministry of Health, Vilniaus g. 16, LT-01506 Vilnius, Lithuania

H.E. Mr Andrius Krivas, Ambassador, Permanent Mission of Lithuania to the United Nations Office and other international organizations in Geneva, Chemin Louis-Dunant 15, CH-1202 Geneva, Switzerland H.E. Ms Gintė Bernadeta Damušis, Ambassador Extraordinary and Plenipotentiary, Embassy of the Republic

of Lithuania, Bernstorffsvej 214, 2920 Charlottenlund, Denmark

Ms Ingrida Zurlyte, Head of WHO Office, WHO Country Office, Lithuania, Didžioji gatvė 22, LT-01128 Vilnius, Lithuania



Measles and Rubella National Laboratory Check-list for WHO Accreditation Section 1: General Review & Overall Findings

Dates of 01/01/201 Review: 31/12/201				Accreditation for 2020 calendar year:				
Name of NATIONAL PUBLIC HEALTH SURVEILLANCE LABORATORY								
Laboratory	: CLINIC	AL TESTING DEPARTMI	ENT					
Address: ŽOLYNO str. 36, LT-10210, VILNIUS								
				Country	LITHUANIA			
Phone:	+3705233792	5 Email: nvspl	@nvspl.lt	Website:	www.nvspl.lt			
Head of Institute:		Vytautas Vidmantas Head of De		Department:	Algirdas			
		Zimnickas			Griškevičius			
Head of Measles and Vilnelė Lipnickienė								
Rubella La	boratory:							
Technical Supervisor: Ilona Kušlevičiūtė								
Number of laboratories under supervision: 0								
Name of								
Reviewer(s	s): Dr. My	riam Ben Mamou & Dovile	Videbaek, WF	IO/Europe				
Name of National Accreditation Authority (if appropriate) and current accreditation status from this								
authority (e	e.g. ISO15189 or ot	her, provide documentation):						

Summary of Accreditation Review

 \bowtie Accredit: Laboratory meets all criteria Measles: Rubella: Serology Serology Detection RT-PCR/RT-qPCR Detection RT-PCR/RT-qPCR Sequencing Sequencing Cell Culture Cell Culture Rubella testing not done Measles testing not done Provisionally accredit: Laboratory passed the most recent proficiency test, but needs to strengthen one or more of the remaining criteria (check off relevant criteria): Measles: Rubella: Serology Serology Detection RT-PCR/RT-qPCR Detection RT-PCR/RT-qPCR Sequencing Sequencing Cell Culture Cell Culture Rubella testing not done Measles testing not done Do not accredit: Laboratory did not pass the most recent proficiency test and/or did not meet other performance indicators. Rubella: Measles: Serology Serology Detection RT-PCR/RT-qPCR Detection RT-PCR/RT-qPCR

Sequencing

Cell Culture

Rubella testing not done

Sequencing

Cell Culture

Measles testing not done

Recommendations (check one):

Main General Findings:

Findings:

2. The laboratory reports monthly to WHO: Timeliness: 10 Timeliness: 10 Timeliness: 10 Timeliness: 10 Timeliness: 10 Timeliness: 10 Timeliness: 8 3. IgM tests are performed on at least 50 specimens annually: Measles: Rubella: Measles and Rubella IgM test results conducted for primary 4. diagnostics are reported by the laboratory within 4 days of receipt, for ≥ 80% of specimens The accuracy of IgM detection is ≥ 90% (NLs sending sera to Rubella: PRL and SNLs to NLs for confirmatory testing) - At measles and 25 rubella samples Molecular tests are performed on at least 2 specimens per quarter, for measles and rubella (RT-PCR, GT) Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Passed (P) /re-test (R) (P	Fine	dings:		
2. The laboratory reports monthly to WHO: Timeliness: 8 3. IgM tests are performed on at least 50 specimens annually: Measles: Rubella: Measles and Rubella IgM test results conducted for primary 4. diagnostics are reported by the laboratory within 4 days of receipt, for ≥ 80% of specimens The accuracy of IgM detection is ≥ 90% (NLs sending sera to reported): RRL and SNLs to NLs for confirmatory testing) - 45 measles and 25 rubella samples Molecular tests are performed on at least 2 specimens per quarter, for measles and rubella (RT-PCR, GT) 7. Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: 01802 Date reported: 06/11/2018 Rubella: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Panel number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18 Rubella Sequencing: Date reported: 23/11/18	1.		NA	
Measles and Rubella IgM test results conducted for primary 4. diagnostics are reported by the laboratory within 4 days of receipt, for ≥ 80% of specimens The accuracy of IgM detection is ≥ 90% (NLs sending sera to RRL and SNLs to NLs for confirmatory testing) - Rubella: 5. RRL and SNLs to NLs for confirmatory testing) - Rubella: 6. Molecular tests are performed on at least 2 specimens per quarter, for measles and rubella (RT-PCR, GT) 7. Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: 01802 Date reported: 06/11/2018 Rubella: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Panel number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18 Rubella Sequencing: Date reported: 23/11/18	2.	The laboratory reports monthly to WHO:	-	100% 83%
4. diagnostics are reported by the laboratory within 4 days of receipt, for ≥ 80% of specimens The accuracy of IgM detection is ≥ 90% (NLs sending sera to RRL and SNLs to NLs for confirmatory testing) - Rubella: 6. Molecular tests are performed on at least 2 specimens per quarter, for measles and rubella (RT-PCR, GT) 7. Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: 01802 Date reported: 06/11/2018 Rubella: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Passed number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18 Passed number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18	3.	IgM tests are performed on at least 50 specimens annually:		81 67
5. RRL and SNLs to NLs for confirmatory testing) - 45 measles and 25 rubella samples Molecular tests are performed on at least 2 specimens per quarter, for measles and rubella (RT-PCR, GT) 7. Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: 01802 Date reported: 06/11/2018 Measles: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Passed (P) /re-test (R) (provisionally passed)/fail (F) Rubella Sequencing: Date reported: 23/11/18	4.	diagnostics are reported by the laboratory within 4 days of		95% 94%
7. Score on most recent WHO Serology proficiency test is ≥ 90%: PT panel number: 01802 Date reported: 06/11/2018 Measles: Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Panel number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18	5.	RRL and SNLs to NLs for confirmatory testing) -		100%/91%* 100%
PT panel number: 01802 Date reported: 06/11/2018 Rubella: 10 Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Measles Mol detection: Panel number for measles: 18-1 Measles Sequencing: Date reported: 23/11/18 Rubella Mol detection: Pasel number for rubella: 18-1 Rubella Sequencing: Date reported: 23/11/18	6.		Yes	
is passed (P) /re-test (R) (provisionally passed)/fail (F) Panel number for measles: 18-1 Date reported: 23/11/18 Panel number for rubella: 18-1 Date reported: 23/11/18 Panel number for rubella: 18-1 Date reported: 23/11/18	7.		Measies:	100% 100%
	8.	is passed (P) /re-test (R) (provisionally passed)/fail (F) Panel number for measles: 18-1 Date reported: 23/11/18 Panel number for rubella: 18-1	Measles Sequencing: Rubella Mol detection:	Passed NA Passed NA
AND reported to WHO through MeaNS or RubeNS within 2 months of	9.	For labs that conduct virus sequencing: Virus sequencing is con AND reported to WHO through MeaNS or RubeNS within 2 m receipt of specimens, for ≥80% of the specimens appropriate for	nonths of MeaNS;	NA
10. Score from on-site review of laboratory operating procedures and practices is ≥ 80%:	10.	Score from on-site review of laboratory operating procedures at		

^{* 100% (11/11)} concordance for specimens tested with Siemens at NL; 91% (29/32) - for tested with Virion Serion.

Conclusion

• Excellent performance for serology and RT-PCR.