

Measles and Rubella National Laboratory or sub-National Laboratory Check- list for WHO Accreditation

Section 1: General Review & Overall Findings

Dates of Review:	01/01/2023 – 31/12/2023	On-site Desk Review	Accreditation for calendar year: 2025
Name of Laboratory:	Laboratory of Communicable Diseases Republic of Estonia Health Board		
Address:	Paldiski mnt 81, 10614 Tallinn		
	Country ESTONIA		
Phone:	+372 794 3599	Email: oksana.joamets@terviseamet.ee janne.pullat@terviseamet.ee	Website: www.terviseamet.ee
Head of Institute:	Brigit Lao	Head of Department:	Janne Pullat
Head of Measles and Rubella Laboratory:	Oksana Joamets		
Technical Supervisor:	Oksana Joamets		
Number of laboratories under supervision:	1		
Name of Reviewer(s):	Dr. Myriam Ben Mamou & Dovile Videbaek, WHO/Europe		
Name of National Accreditation Authority (if appropriate) and current accreditation status from this authority (<i>e.g. ISO15189 or other, provide documentation</i>):			
Estonian Accreditation Centre, EVS-EN ISO 15189:2012.			
Accreditation Certificate No M004. Accreditation is valid until 29.06.2024			
http://eak.ee/dokumendid/pdf/kasitlusala/M004.pdf			

Summary of Accreditation Review

Recommendations (check one):

☒ **Accredit:** Laboratory meets all criteria

Measles:

- ☒ Serology
- ☒ Detection RT-PCR/RT-qPCR
- ☒ Sequencing
- ☐ Cell Culture
- ☐ Measles testing not done

Rubella:

- ☒ Serology
- ☐ Detection RT-PCR/RT-qPCR
- ☐ Sequencing
- ☐ Cell Culture
- ☐ Rubella 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:

- ☐ Serology
- ☐ Detection RT-PCR/RT-qPCR
- ☐ Sequencing
- ☐ Cell Culture
- ☐ Measles testing not done

Rubella:

- ☐ Serology
- ☐ Detection RT-PCR/RT-qPCR
- ☐ Sequencing
- ☐ Cell Culture
- ☐ Rubella testing not done

☐ **Do not accredit:** Laboratory did not pass the most recent proficiency test and/or did not meet other performance indicators.

Measles:

- ☐ Serology
- ☐ Detection RT-PCR/RT-qPCR
- ☐ Sequencing
- ☐ Cell Culture
- ☐ Measles testing not done

Rubella:

- ☐ Serology
- ☐ Detection RT-PCR/RT-qPCR
- ☐ Sequencing
- ☐ Cell Culture
- ☐ Rubella testing not done

Main General Findings:

Findings:

1.	Confirmatory test results of Sub-national Laboratories' referred specimens are reported within 14 days for $\geq 80\%$ of specimens received:		100%
2.	The laboratory reports monthly to WHO ($\geq 80\%$):	Completeness: Timeliness:	100% 92%
3.	IgM tests are performed on at least 50 specimens annually:	Measles: Rubella:	253 150
4a.	Measles and Rubella IgM test results conducted for primary diagnostics are reported by the laboratory within 4 days of receipt, for $\geq 80\%$ of specimens	Measles: Rubella:	92.1% 100%
4b.	If molecular virus detection by real-time RT-PCR is performed in addition to serology, positive test results are reported by the laboratory within 4 days of receipt, for $\geq 80\%$ of specimens	Measles: Rubella:	100% NA
5.	The accuracy of IgM detection is $\geq 90\%$ (NLs sending sera to RRL and SNLs to NLs for confirmatory testing) - 31 measles and 30 rubella samples	Measles: Rubella:	97% 100%
6a.	At least one run per month is performed for measles and rubella detection Realtime RT-PCR	Measles: Rubella:	Yes NA
6b.	At least one run per quarter is performed for measles and rubella GT RT-PCR, sequencing	Measles: Rubella:	Yes NA
7.	Score on most recent WHO Serology proficiency test is $\geq 90\%$: PT panel number: 02302 Date reported: 26/01/2023	Measles: Rubella:	100% 100%
8.	Performance on most recent WHO Molecular EQA is passed (P) /re-test (R) (provisionally passed)/fail (F) Panel number for measles: 23-1 Date reported: 28/12/2023 Panel number for rubella: Date reported: dd/mm/yyyy	Measles Mol detection: Measles Sequencing: Rubella Mol detection: Rubella Sequencing:	Passed Passed NA NA
9.	For labs that conduct virus sequencing: Virus sequencing is completed AND reported to WHO through MeaNS or RubeNS within 2 months of receipt of specimens, for $\geq 80\%$ of the specimens appropriate for genetic analysis	MeaNS; RubeNS:	100% (2/2) NA
10.	Score from on-site review of laboratory operating procedures and practices is $\geq 80\%$:		

Conclusion

- Excellent performance for serology and measles RT-PCR & sequencing
- Laboratory is commended for excellent monthly data reporting to WHO