

## 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 <b>Desk Review</b>	Accreditation for calendar year: 2025
Name of Laboratory:	Laboratory of Communicable Diseases Republic of Estonia Health Board		
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	Country <b>ESTONIA</b>		
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		Website:	<a href="http://www.terviseamet.ee">www.terviseamet.ee</a>
Head of Institute:	<b>Brigit Lao</b>	Head of Department:	<b>Janne Pullat</b>
Head of Measles and Rubella Laboratory:	<b>Oksana Joamets</b>		
Technical Supervisor:	<b>Oksana Joamets</b>		
Number of laboratories under supervision:	1		
Name of Reviewer(s):	<b>Dr. Myriam Ben Mamou &amp; Dovile Videbaek, WHO/Europe</b>		
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			
<a href="http://eak.ee/dokumendid/pdf/kasitlusala/M004.pdf">http://eak.ee/dokumendid/pdf/kasitlusala/M004.pdf</a>			

## 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:		<b>100%</b>
2.	The laboratory reports monthly to WHO ( $\geq 80\%$ ):	Completeness: Timeliness:	<b>100%</b> <b>92%</b>
3.	IgM tests are performed on at least 50 specimens annually:	Measles: Rubella:	<b>253</b> <b>150</b>
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:	<b>92.1%</b> <b>100%</b>
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:	<b>100%</b> <b>NA</b>
5.	The accuracy of IgM detection is $\geq 90\%$ (NLs sending sera to RRL and SNLs to NLs for confirmatory testing) - <b>31 measles and 30 rubella samples</b>	Measles: Rubella:	<b>97%</b> <b>100%</b>
6a.	At least one run per month is performed for measles and rubella detection Realtime RT-PCR	Measles: Rubella:	<b>Yes</b> <b>NA</b>
6b.	At least one run per quarter is performed for measles and rubella GT RT-PCR, sequencing	Measles: Rubella:	<b>Yes</b> <b>NA</b>
7.	Score on most recent WHO Serology proficiency test is $\geq 90\%$ : PT panel number: <b>02302</b> Date reported: <b>26/01/2023</b>	Measles: Rubella:	<b>100%</b> <b>100%</b>
8.	Performance on most recent WHO Molecular EQA is passed ( <b>P</b> ) /re-test ( <b>R</b> ) (provisionally passed)/fail ( <b>F</b> ) Panel number for measles: <b>23-1</b> Date reported: <b>28/12/2023</b> Panel number for rubella:      Date reported: <b>dd/mm/yyyy</b>	Measles Mol detection: Measles Sequencing: Rubella Mol detection: Rubella Sequencing:	<b>Passed</b> <b>Passed</b> <b>NA</b> <b>NA</b>
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:	<b>100% (2/2)</b> <b>NA</b>
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