WHO-EN-BW-H

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dates of Review: | | | | | **DD/MM/YYYY** | | **On-site / Desk Review** (circle) | | | Accreditation for calendar year: | | |  | |
| Name of Laboratory: | | |  | | | | | | | | | | |
| Address: | |  | | | | | | | | | | | |
|  | | | | | | | | | | Country |  | | |
| Phone: |  | | | | | | Email: |  | | Website: |  | | |
| Head of Institute: | | | | | |  | | | Head of Department: | | |  | |
| Head of Measles and Rubella Laboratory: | | | | | |  | | |  | | |  | |
| Technical Supervisor: | | | | | |  | | |  | | |  | |
| Number of laboratories under supervision: | | | | | | | | | | | | | |
| *For on-site review only:* Name of Reviewer(s): | | | |  | | | | | | | | | |
| Name of National Accreditation Authority (if appropriate) and current accreditation status from this authority *(e.g. ISO15189 or other, provide documentation)*: | | | | | | | | | | | | | |

**Summary of Accreditation Review**

To be completed by the assessor

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | General Review  Pass ≥80% for NL) | Serology  Score from Checklist (Pass≥80%) | Serology  Score from EQA (Pass≥90%) | | Serology Score from QC  (Pass≥90%) | | Molecular  Score from Checklist (Pass≥80%) | Molecular Score from EQA Detection (Pass/Re-test/Fail) | | Molecular Score from EQA Sequencing (Pass/Re-test/Fail) | | Virus Isolation from Checklist (Pass≥90%) |
|  |  |  | Measles | Rubella | Measles | Rubella |  | Measles | Rubella | Measles | Rubella |  |
| Score (%) |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **General Review** | **Serology** | | | | | **Molecular** | | | | | **Virus Isolation** |
| Accredited |  |  | | | | |  | | | | |  |
| Provisionally accredited |  |  | | | | |  | | | | |  |
| Not accredited |  |  | | | | |  | | | | |  |

**Accredited:** For a **GSL/RRL** to be accredited in each criteria as mentioned above, it needs to have a passing score for **ALL** sections included in the **General Review** (score of ≥90%), **Serology** (checklist, EQA, AND QC), **Molecular** (checklist, EQA for detection, AND EQA for sequencing), and Virus Isolation (score of ≥90%). For **NL/sub-NL,** it will be accredited only based on the **General Review** (required) and the available capacity (Serology, Molecular and/or Virus Isolation). Passing score for NL/sub-NL is ≥80%.

**Provisionally accredited:** If a laboratory passes in at least two of the sections in **Serology** or in at least two of the sections in **Molecular**, it will be **provisionally accredited** for the respective sections. Please see page 5 (point #10) for further actions that need to be taken at the laboratory.

**Not accredited:** If a laboratory fails in at least two of the sections in **Serology** or in at least two of the sections in **Molecular**, it will **not be accredited** for the respective sections. Arrangements must be made for another, fully accredited, laboratory to perform duplicate tests on all appropriate specimens. Every effort will be made to bring any non-accredited laboratory to full accreditation status as soon as possible.

GENERAL SUMMARY, COMMENTS AND RECOMMENDATIONS

**Introduction**

Accreditation of Measles Rubella Laboratory is reviewed annually (if possible) by WHO based on the laboratory performance during the immediately preceding 12 months. Accreditation is given for the next coming calendar year. All laboratories should be assessed annually but for laboratories with a consistently high accreditation score, the WHO Global Measles Laboratory Coordinator and the Regional Laboratory Coordinator may waive **annual** onsite reviews and determine accreditation status after review of criteria 1 to 9 with the internal audit report from the laboratory supervisor. In this situation, onsite reviews of well performing laboratories may be carried out every 2 to 3 accreditation cycles.

**There are 10 criteria for accreditation:**

1. **Confirmation results on at least 80% of National Laboratories’ referred specimens are reported within 14 days.**

To ensure National Laboratories receive a timely response to all validation test results.

1. **Timeliness of reporting to WHO Regional Office as required in respective surveillance guidelines**
2. **IgM tests are performed on at least** **50 specimens annually.**

To maintain skills in performing serological assays, Virus laboratories should maintain appropriate reagents and assay kits and test a minimum of 50 specimens for IgM and or IgG detection annually by EIA, spread over the year. Where surveillance specimens are insufficient to meet this indicator then the lab may use non-surveillance specimens for completing the minimum requirement.

1. **Measles and rubella IgM test results are reported by the laboratory on at least 80% of measles and rubella IgM specimens within 4 days of receipt (according to the recommended regional reporting timeliness for the WHO European Region):**

To allow an appropriate response to measles and rubella cases, test results should be reported to the EPI programme in a timely manner.

1. **The accuracy of measles and rubella IgM detection is at least 90%.**

Accuracy is determined by the agreement in test results on sera submitted by the (sub) National Laboratory to the supervisory laboratory (National or Regional Reference Laboratory (RRL) during the 12-month review period. The percentage of specimens sent for validation is dependent on the quality of the laboratory and could range from 10-100% with the lower proportion for a fully accredited laboratory and 100% for a laboratory that has failed accreditation. Specimens for validation should be representative of all results (positive, negative and equivocal) and outbreaks, and should be sent to the supervisory laboratory at regular intervals.

1. **Minimum number of molecular testing for measles and rubella is in place.**

A minimum of 2 tests per quarter to be done for measles as well as 2 tests per quarter for rubella (detection RT-PCR, GT / sequencing). (Decision established during GMRLN retreat, CDC Atlanta, January 2018)

1. **The score on the most recent WHO approved serological proficiency test is at least 90%.**

Proficiency test (PT) results to be reported within 14 days of panel receipt to receive full credit.

1. **The most recent WHO measles/rubella molecular EQA panel is passed.**

Molecular PT panel results to be reported within 2 months of panel receipt to receive full credit.

1. **Results of virus detection and genotyping (if performed) are completed within 2 months of receipt of specimens AND data reported to WHO through MeaNS or RubeNS monthly, for ≥80% of the specimens appropriate for genetic analysis:** Genotypeinformation can assist national control programmes to determine transmission pathways and needs to be provided in a timely manner. Genetic data on appropriate specimens collected from separate chains of infection should be supplied to the national programme as soon as they become available, and to WHO through MeaNS or RubeNS. Laboratories are also encouraged to submit sequence data to GenBank once sequencing is completed.

**(Note: Virus detection and genotyping performance will be assessed only on specimens meeting the recommended collection and testing strategy.)**

1. **The score from the on-site review of laboratory operating procedures and practices is at least 80% (90% for RRLs and GSLs).** Forlaboratories with consistently high-performance indicators, the Global Laboratory Coordinator may waive the on-site review upon satisfactory completion of the annual check-list by the laboratory (see below).

A laboratory that passes the proficiency tests **(serology and/or molecular)** but achieves less than the passing score on any one of the other criteria is deemed to be **Provisionally Accredited** and will work with the Regional Laboratory Coordinator to:

* Identify areas where improvement is needed.
* Develop and implement a work plan.
* Monitor laboratory progress.
* Provide for re-testing where required.
* Continue activities to achieve full accreditation.

A laboratory that fails to achieve a passing score in either of the most recent proficiency test panels (serological and/or molecular) and also a repeated proficiency test panel within 3 months of the failed panel, is deemed **non-accredited for that function (serological and/or molecular).** Arrangements must be made for another fully accredited laboratory to perform duplicate tests on all appropriate specimens. Every effort will be made to bring any non-accredited laboratory to full accreditation status as soon as possible.

The checklist is divided by **General Review**, **Molecular Review, Virus Isolation Review, and Serology Review.** **All of these sections should be filled for RRL and GSLs. The General Review and Serology Review are mandatory** for all laboratories. The **Molecular Review** and **Virus Isolation Review** should be completed accordingly, depending on the routine activities done at the national/sub-national laboratory.

In the **General Review**, Part I can be entered by the laboratory as it provides a profile of the laboratory, a profile of the measles program in the country that the laboratory serves, and a summary on the laboratory’s availability of epidemiological information of measles/rubella cases. Part II is completed by the assessor, not by the laboratory, and it provides a checklist for evaluating the laboratory operating procedures and practices.

Similarly, in the **Molecular Review**, **Virus Isolation Review**, and **Serology Review**, Part I should be completed by the laboratory to describe the appropriate laboratory performance in the previous 12 months. In Part II, it is completed by the assessor to evaluate the laboratory operating procedures and practices. It is recommended that labs also complete Part II and then be discussed and independently verified by the assessors as part of the lab visit.

This checklist does not include all laboratory activities or cover all situations. It is intended to serve as a guide. The assessor is expected to ask detailed questions and make additional suggestions as appropriate to assure high quality laboratory performance.

Based on the above criteria for accreditation, the table in the following page labelled **“Main General Findings”** should be completed **at the end of the review** after going through each relevant section of the checklists that are appropriate for the laboratory.

**Note on National Laboratories that serve Sub-national Laboratories**

Countries that have established sub-national laboratories for measles and rubella surveillance should endeavour to monitor the quality and performance of these laboratories. National laboratories should consider establishing a confirmatory testing and proficiency testing programme, monitor timeliness of reporting and ensure the performance of IgM assays, in a similar process to that used for determining the quality and performance of the National and Regional measles/rubella LabNet. WHO is willing to provide technical advice to National Laboratories planning to establish a sub-national laboratory monitoring programme.

**Main General Findings:**

(To be completed by the assessor after reviewing each section of the checklists)

**Findings:**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | Confirmatory test results of National Laboratories’ referred specimens are reported within 14 days for ≥ 80% of specimens received: | | **%** |
| 2. | The laboratory reports monthly to WHO | | **Timeliness**  **Completeness** |
| 3. | IgM tests are performed on at least 50 specimens annually: | |  |
| 4. | Measles and Rubella IgM test results conducted for primary diagnostics are reported by the laboratory within 4 days of receipt, for ≥ 80% of specimens | | **%** |
| 5. | The accuracy of IgM detection is ≥ 90% (NLs sending sera to RRL and SNLs to NLs for confirmatory testing)  Measles:  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: Date reported:  dd/mm/yy | Measles: Rubella: | **%**  **%** |
| 8. | Performance on most recent WHO Molecular EQA (if appropriate) is passed (**P**) /re-test (**R**) (provisionally passed)/  fail (**F**)  Panel number for measles: Date reported: dd/mm/yy  Panel number for rubella: Date reported: dd/mm/yy | Measles Mol detection:  Measles Sequencing:  Rubella Mol detection:  Rubella Sequencing: | **P/R/F**  **P/R/F**  **P/R/F**  **P/R/F** |
| 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 ≥80% of the specimens appropriate for genetic analysis | | **%** |
| 10. | Score from on-site review of laboratory operating procedures and practices is ≥ 80%: | | **%** |

**Part I**

**Laboratory Profile**

Number of scientific and technical staff assigned to measles and/or rubella laboratory: Outline role in laboratory, years of measles/rubella laboratory experience and proportion of working time currently spent on measles and rubella related activities.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Full Name of staff** | **Position Title** | **Duties** | **% of time dedicated to measles and rubella at the laboratory** | **Years of experience in Measles or Rubella Lab** | **Undergone WHO measles/ rubella training** |
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| *(Insert more lines if needed)* |  |  |  |  |  |

*Comments and recommendations****:***

**Country-specific data**

|  |  |  |
| --- | --- | --- |
| *Reporting year* |  | |
| Total Population |  | |
| Vaccine coverage |  | |
|  | *Measles* | *Rubella* |
| Total number of suspected cases reported |  |  |
| Reporting rate (per million) |  |  |
| Number of clinically confirmed cases |  |  |
| Number of laboratory confirmed cases |  |  |
| Number of epidemiologically linked cases |  |  |
| Incidence of all confirmed cases (per million)a |  |  |
| Incidence of all lab confirmed and epi-linked cases (per million)b |  |  |

**Laboratory reporting**

|  |  |  |
| --- | --- | --- |
| Percentage of adequate specimens tested in labc | Number of days required to report lab results | Lab reporting timeliness (percent) within the required days |
|  |  |  |

a. Incidence per million population of ALL confirmed (laboratory, epi-linked *and clinically* confirmed) measles cases regardless of the source (endemic, imported, import- related or unknown)

b. Incidence per million population of measles cases that are either laboratory confirmed or confirmed by epidemiological linkage regardless of the source (endemic, imported, import- related or unknown). This incidence measure should exclude any clinically confirmed cases

c. Specimens adequate for detecting measles IgM should be collected from at least 80% of suspected measles cases and tested in a proficient laboratory. Any cases that are epidemiologically linked to a laboratory-confirmed case of measles or other communicable disease should be excluded from the denominator

**Case Identification & Epidemiological Information Availabilities/Needs**

|  |  |  |
| --- | --- | --- |
| **Variable description** | **Measles Rubella GSL/RRL** | |
| **Needed** | **Available** |
| EPID no. | Yes |  |
| Specimen no. from serology lab | Yes |  |
| Name of patient | Yes |  |
| District/municipality code of patient | Yes |  |
| Province/state code of patient | Yes |  |
| Country code of patient | Yes |  |
| Date of last vaccination | Yes |  |
| Date of rash onset | Yes |  |
| Date of specimen collection | Yes |  |

**Part II: Laboratory Operating Procedures and Work Practices**

To be completed by the assessor

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Space (8 points)** | **Score:** |  |
|  | Space is used efficiently with appropriate equipment placement: | |  |
|  | Space configuration is adequate and consistent with good laboratory practices: | |  |
|  | Space is clean and well kept | |  |
| Total m2 available dedicated for laboratory bench work: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Number of rooms dedicated for laboratory bench work: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Provide floor plan or sketch of laboratories | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Staff (8 points)** | **Score:** |  |
|  | Staff are effectively assigned: | |  |
|  | The number of trained staff are adequate to handle the workload: | |  |
|  | Staff have received trainings / guidance on WHO MR LabNet requirements: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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| --- | --- | --- | --- |
|  | **Laboratory management and Supervision (20 points)** | **Score:** |  |
|  | The lines of supervision and accountability are clear to all staff: | |  |
|  | Mechanisms are in place to identify and control nonconformities: | |  |
|  | Laboratory management is committed and engaged in continual improvement of its services meeting the needs of patients and stakeholders: | |  |
|  | Arrangements are in place for qualified back-up staff to maintain services during scheduled staff absences (e.g. during vacation, study, maternity or paternity leave): | |  |
|  | Periodic meetings are held with staff to review and improve laboratory performance. Minute of meetings are readily available: | |  |
|  | Standard Operating Procedures have been developed and arrangements are in place for periodic review, update and evaluation of compliance: | |  |
|  | The supervisor ensures that sufficient supplies, reagents and functioning equipment are available to handle the laboratory's workload: | |  |
|  | Mechanisms are in place for on-site staff training or periodic updating of staff on technical issues: | |  |
|  | Mechanisms are in place for adequate selection and purchasing of external services, equipment, reagents and consumables: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |
|  | | | |
|  | **Document and record control (7 points)** | |  |
|  | The laboratory controls documents that may vary based on changes in versions or time (procedures, flow charts, instructions for use, forms, …): | |  |
|  | The laboratory ensures that unintended use of obsolete document is prevented: | |  |
|  | Documents are periodically reviewed and updated: | |  |
|  | Mechanisms are in place to keep records of sample receipts, work books or work sheets, instruments printouts, examination results and reports, instruments maintenance and calibration, quality control data, nonconformities; and to protect them from alterations: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |
|  | | | |
|  | **Laboratory information management (7 points)** | |  |
|  | Data and information contained in computer and non-computer systems is correctly maintained and managed: | |  |
|  | Data processing conditions protects the integrity and the accuracy of results, including in case of manual recording and transcription: | |  |
|  | Data is protected from unauthorized access: | |  |
|  | Interfaces between instruments and laboratory information system are designed effectively: | |  |
|  | There is a back-up system for laboratory information and data: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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| --- | --- | --- | --- |
|  | **Biosafety (20 points)** | **Score:** |  |
|  | Employees have been instructed in biosafety: | |  |
|  | Validated SOPs (e.g. WHO biosafety manual) are available and implemented by all employees: | |  |
|  | Biosafety practices are enforced, including; | |  |
|  | a. Hand washing: | |  |
|  | b. Pipetting with aid of mechanical device: | |  |
|  | c. Routine use of gloves and laboratory coats: | |  |
|  | d. No eating, drinking, smoking, or storage of food in laboratory: | |  |
|  | e. Decontaminating all infectious or clinical waste before discarding: | |  |
|  | f. Decontaminating lab work surfaces: | |  |
|  | g. Ensuring staff are immunized against measles and rubella infection: | |  |
|  | h. Ensuring staff are immunized against hepatitis B infection: | |  |
|  | Class II Biosafety cabinets are used for materials which are potentially infectious through an aerosol route: | |  |
|  | Biosafety cabinets are assessed at least annually and dates recorded: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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| --- | --- | --- | --- |
|  | **Supplies (10 points)** | **Score:** |  |
|  | Current inventories are maintained: | |  |
|  | Adequate time is allowed for replenishing supplies: | |  |
|  | No interruption to testing due to shortage of supplies has occurred: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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| --- | --- | --- | --- |
|  | **Cooperation with EPI and field Staff (12 points)** | **Score:** |  |
|  | Laboratory and EPI staff communicate/meet at least monthly: (8 points) | |  |
|  | EPI staff are contacted if specimens arrive without adequate information or EPID numbers: (1 point) | |  |
|  | Laboratory staff are familiar with protocols for collecting and transporting specimens and are able to advise field staff: (1 point) | |  |
|  | Laboratory is involved in the preparation of the annual updates for the National Verification Committee : (2 points\*) | |  |
| **\*8.4 is only applicable to laboratories involved in updates for the National Verification Committee. If the laboratory is not involved, 7.4 is not applicable and the 12 points should be allocated from 7.1-7.3. Please mention in the below comments if 7.4 is not applicable.** | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Measles and rubella database (8 points)** | **Score:** | |  |
| * 1. 1 | Laboratory reports are submitted to the WHO regional office with the agreed upon frequency and format: (6 points) |  | |  |
| * 1. 1 | The following data are available on all measles and rubella specimens: (2 points) | |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable description** | **Measles**  **National Lab** | | **Measles**  **Reference Lab** | |
| **Needed** | **Available** | **Needed** | **Available** |
| **Epidemiology and case identification** |  | |  | |
| EPID no. | Yes |  | Yes |  |
| Specimen no. from serology lab | Yes |  | Yes |  |
| Name of patient | Yes |  | Yes |  |
| District/municipality code of patient | Yes |  | Yes |  |
| Province/state code of patient | Yes |  | Yes |  |
| Country code of patient | Yes |  | Yes |  |
| Date of last vaccination | Yes |  | Yes |  |
| Date of rash onset | Yes |  | Yes |  |
| Date of specimen collection | Yes |  | Yes |  |

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| *COMMENTS AND RECOMMENDATIONS:* |

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| *COMMENTS AND RECOMMENDATIONS:*  *DESCRIBE IF OTHER QC PROCEDURES ARE IMPLEMENTED* |

**On-site Review Summary Score:**

|  |  |  |
| --- | --- | --- |
| NL Score of General Review (≥80%) | Score from a possible = 100 | % |