WHO-EN-BW-H

Measles and Rubella National Laboratory or sub-National Laboratory

**Checklist for WHO Accreditation**

**Section 3: Molecular Review**

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| --- | --- | --- | --- | --- | --- |
| Date of Review: | | **DD/MM/YYYY** |  |  |  |
| Name of Laboratory: |  | | | | |

**Criteria evaluated at the laboratory:**

Measles RT-PCR/RT-qPCR  Rubella RT-PCR/RT-qPCR

Measles Sequencing  Rubella Sequencing

GENERAL SUMMARY, COMMENTS AND RECOMMENDATIONS ON MOLECULAR REVIEW:

**Molecular Criteria**

**This section of the MR accreditation checklist provides an assessment on real time PCR, endpoint (conventional) PCR, and sequencing including an evaluation of the following:**

1. Internal quality control (QC) procedures are in place.

Appropriate QC procedures for molecular diagnostics are in place and followed including molecular controls such as for PCR.

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

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

1. **If genotyping is performed, results of virus detection 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: Genotyping performance will be assessed only on specimens meeting the recommended collection and testing strategy.)**

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. (Decision established during GMRLN retreat, CDC Atlanta, January 2018)

**Part I: Laboratory Performance in Molecular Investigation**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dates from: | | **/** | | **/** | |  | | To | | **/** | | **/** | |  | |
|  | | *dd* | | *mm* | | *yyyy* | |  | | *dd* | | *mm* | | *yyyy* | |

|  |  |  |
| --- | --- | --- |
| **1.** | **Specimens received for molecular detection:** |  |
|  | **Measles specimens received for molecular detection:** |  |
|  | **RT-(q)PCR:** |  |
|  | Number of specimens received from suspected/confirmed cases: |  |
|  | Number of specimens measles RT-(q)PCR positive : |  |
|  | Number forwarded to designated sequencing laboratory for confirmation: |  |
|  | Number of specimens sequenced to determine genotype: |  |
|  | | |
|  | **Rubella specimens received for molecular detection:** |  |
|  | **RT-(q)PCR:** |  |
|  | Number of specimens received from suspected/confirmed cases: |  |
|  | Number of specimens rubella RT-PCR positive: |  |
|  | Number forwarded to designated sequencing laboratory for confirmation: |  |
|  | Number sequenced to determine genotype: |  |
|  | **There is parallel or serial testing for measles and rubella** | **Yes/No/Partially** |
|  | | |
| *Comments and recommendations:* | | |

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| --- | --- | --- | --- | --- |
|  | **Result of most recent Molecular EQA Panel:** | **Measles:**  Detection RT-PCR/RT-qPCR  Sequencing | | **Pass/Re-test/Fail**  **Pass/Re-test/Fail**  (circle) |
|  | **Rubella:**  Detection RT-PCR/RT-qPCR  Sequencing | | **Pass/Re-test/Fail**  **Pass/Re-test/Fail**  (circle) |
|  | Molecular EQA Panel Number or Round |  | | |
|  | Date of panel receipt: | **/** | **/** |  |
|  | Date of test report: | **/** | **/** |  |
|  | | | | |
| *NATURE OF DEFICIENCY, IF ANY, AND CORRECTIVE ACTION TAKEN:*  *Comments and recommendations****:*** | | | | |

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|  | **If genotyping is performed, results are completed within 2 months of receipt of specimen AND data reported to WHO through MeaNS or RubeNS, for ≥80% of the specimens appropriate for genetic analysis**  *(Note: Virus detection and genotyping performance assessed on specimens meeting the recommended collection and testing strategy)* | **MeaNS : %**  **(= 4.2.4 / 4.2.1 x 100)**  **RubeNS : %**  **(= 4.3.4 / 4.3.1 x 100)** |
| **4.1** | **Breakdown of methods used for measles or rubella virus detection** |  |
| 4.1.1 | Number of measles or rubella clinical specimens or virus isolates tested by conventional PCR methods for measles/rubella sequencing: | **Measles :**  **Rubella :** |
| 4.1.2 | Number of measles or rubella clinical specimens or virus isolates tested by conventional RT-PCR methods for direct amplification in preparation for sequencing: | **Measles :**  **Rubella :** |
| 4.1.3 | Number of measles or rubella clinical specimens or virus isolates tested by real-time RT-PCR methods: | **Measles :**  **Rubella :** |
| **4.2** | **Breakdown of number of specimens for measles genotyping received at sequencing lab** |  |
| 4.2.1 | Number of specimens appropriate[[1]](#footnote-1) for measles genotyping received at sequencing lab: |  |
| 4.2.2 | Number of specimens genotyped at sequencing lab among those received from 4.2.1 |  |
| 4.2.3 | Number of measles specimens genotyped within 2 months of receipt: |  |
| 4.2.4 | Number of measles sequence data reported to MeaNS within 2 months of sample reception: |  |
| 4.2.5 | Number (and percentage) of chains of transmission genotyped: |  |
| **4.3** | **Breakdown of number of specimens for rubella genotyping received at sequencing lab** |  |
| 4.3.1 | Number of specimens appropriate for rubella genotyping received at sequencing lab: |  |
| 4.3.2 | Number of specimens genotyped at sequencing lab among those received from 4.3.1: |  |
| 4.3.3 | Number of rubella specimens genotyped within 2 months of receipt: |  |
| 4.3.4 | Number of rubella sequence data reported to RubeNS within 2 months of sample reception: |  |
| 4.3.5 | Number (and percentage) of chains of transmission genotyped: |  |
|  | | |
| *Comments and recommendations****:*** | | |

**Summary of Molecular Capacities/Needs**

|  |  |  |
| --- | --- | --- |
| **Variable description** | **Measles/Rubella**  **National or sub-National Lab** | |
| **Needed** | **Available** |
| **Sequencing information** |  | |
| Date measles/rubella virus specimen received for sequencing | Yes |  |
| Date sequence result available | Yes |  |
| Name of sequencing laboratory | Yes |  |

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| *OTHER COMMENTS AND RECOMMENDATIONS ON MOLECULAR REVIEW:* |

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

To be completed by the assessor

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|  | **Pre-analytical processes (15 points)** | **Score:** |  |
|  | Sample reception procedure ensure traceability and recording of all specimens: | |  |
|  | Specimens are processed in accordance with WHO protocols: | |  |
|  | Specimens are stored separately from non-infectious materials in designated freezers and refrigerators: | |  |
|  | Specimens for virus detection are stored at ≤ –70oC if not tested within a day of receipt: | |  |
|  | The laboratory’s request form (or its electronic equivalent) includes relevant fields for patient identification and relevant information for molecular testing: | |  |
|  | The laboratory has a documented procedure for collection, transport and handling of primary samples: | |  |
|  | Storage vials are clearly and permanently labelled: | |  |
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| *COMMENTS AND RECOMMENDATIONS:* | | | |
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|  | **Analytical processes (25 points)** | **Score:** |  |
|  | Validated SOPs are available and used for RT-PCR detection for measles and for rubella: | |  |
|  | Validated SOPs are available and used for GT PCR for measles and for rubella: | |  |
|  | Validated SOPs are available and used for sequencing for measles and for rubella: | |  |
|  | SOPs for molecular methods are acceptable and include (not limited to) procedural steps, quality control procedures, principles for result determination and for clinical interpretation: | |  |
|  | Source of molecular protocols is specified: | |  |
|  | Source of primers, probes and control RNA is specified: | |  |
|  | Minimum number of 2 tests per quarter is done for each measles and rubella (detection RT-PCR, GT / sequencing): | |  |
|  | Records are maintained on all procedures: | |  |
|  | In-house and external controls are used with each PCR and sequencing run (measles, rubella): | |  |
|  | QC results are recorded electronically: | |  |
|  | Appropriate physical separation of PCR preparation and testing procedures are established: | |  |
|  | Staff have received specific training in DNA sequencing editing and database interpretation: | |  |
|  | | | |
| *DESCRIBE OTHER QC PROCEDURES IMPLEMENTED:*  *SUMMARISE DETAILS OF CONTROLS USED FOR PCR AND/OR SEQUENCING:*  *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Post-analytical processes (20 points)** | **Score:** |  |
|  | Chromatograms are correctly analysed: | |  |
|  | Software for sequence alignment and phylogenetic analysis is adequate: | |  |
|  | Most recent versions of WHO reference strains are used: | |  |
|  | Sequence processing, analysis and phylogeny are correctly managed: | |  |
|  | Supervisor or his/her delegate critically reviews test worksheets and results for accuracy and completeness before release, evaluating them against internal quality controls to prevent their release in the event of quality control failure, and indicate the need for any follow up actions: | |  |
|  | Results are transcribed and reported correctly and accurately: | |  |
|  | Sequence chromatogram files are stored properly: | |  |
|  | Lab has “contributing user” accounts on MeaNS and RubeNS and is submitting sequences with the required timeliness and completeness: | |  |
|  | Original specimens are stored appropriately at –70oC or lower for at least 12 months: | |  |
|  | Permanent records are maintained on the identity and location of all specimens: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Biosafety for Molecular Techniques (15 points)** | **Score:** |  |
|  | Chemical safety plan is use (e.g. for ethidium bromide): | |  |
|  | Eye protection for labs using UV transilluminators for agarose gels: | |  |
|  | All potentially infectious clinical materials are processed in a certified biological safety cabinet: | |  |
|  | Specimens for isolation, all virus isolates, and other potentially infectious materials are stored separately from non-infectious materials in designated freezers and refrigerators: | |  |
|  | Adequate biosafety measures are in place for RNA extraction methods: | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Molecular Equipment (10 points)** | **Score:** |  |
|  | Equipment is functioning and in good condition: | |  |
|  | Equipment is maintained periodically with in-house calibration as recommended and dates recorded: | |  |
|  | Thermocyclers and real time instruments have been calibrated and properly maintained: | |  |
|  | Equipment location is conducive to optimal performance: | |  |
|  | Records are kept on daily temperature readings of incubators, refrigerators, and freezers: | |  |
|  | Calibrated pipettes available with certificates/calibration records    Current date of certification expiry: \_\_ /\_\_\_\_/\_\_\_\_\_ | |  |
|  | Calibrated thermometer available (certified every 6 months)  Current date of certification expiry: \_\_\_/\_\_\_\_/\_\_\_\_\_  Temperature correction factors in relation to calibrated thermometers applied to adjust to obtain actual temperature readings as necessary. | |  |
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| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Laboratory Space Dedicated for Molecular Techniques (15 points) Score:** |  |
| * 1. 4 | Dedicated space for molecular laboratory bench work: |  |
| * 1. 4 | Space dedicated for molecular laboratory bench work is well-maintained: |  |
|  | Physically separate areas for nucleic acid amplification: |  |
|  | Dedicated clean area for preparation of reagents (including dispensing of master mix): |  |
|  | Area for extraction of nucleic acids and for the addition of sample RNA to master mix prior to amplification: |  |
| * 1. 4 | Dedicated, contained area for amplification and product detection: |  |
|  | | |
| *COMMENTS AND RECOMMENDATIONS:* | | |

**On-site Review Summary Score:**

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| --- | --- | --- |
| National/sub-National Laboratory Laboratory Onsite Review for Molecular Techniques | Score from a possible = 100 | % |

1. Specimens appropriate for measles include throat swabs, urine, oral fluids, etc. that have been collected during the period of viral shedding and transported in cold chain. [↑](#footnote-ref-1)