WHO-EN-BW-H

Measles and Rubella National Laboratory or sub-National Laboratory

**Checklist for WHO Accreditation**

**Section 4: Virus Isolation Review**

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

**Criteria evaluated at the laboratory:**

Measles Virus Isolation  Rubella Virus Isolation

GENERAL SUMMARY, COMMENTS AND RECOMMENDATIONS ON VIRUS ISOLATION:

**Part I: Laboratory Performance in Virus Isolation**

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

|  |  |  |
| --- | --- | --- |
| 1. 1 | 1. **Specimens received for virus isolation:** |  |
|  | **1.1 Measles specimens received for virus isolation:** |  |
|  | Number of specimens received from suspected/confirmed cases: |  |
|  | Number of specimens collected within 5 days of rash onset: |  |
|  | Number of specimens received in laboratory within 3 days of collection: |  |
|  | Number of specimens with isolation attempted: |  |
|  | Number of measles isolates made: |  |
|  | Number of isolates forwarded to designated sequencing laboratory for sequencing within one month after date of isolation: |  |
|  | **1.2 Rubella specimens received for virus isolation:** |  |
|  | Number of specimens received from suspected/confirmed cases: |  |
|  | Number of specimens collected within 5 days of rash onset: |  |
|  | Number of specimens received in laboratory within 3 days of collection: |  |
|  | Number of specimens with isolation attempted: |  |
|  | Number of rubella isolates made: |  |
|  | Number of isolates forwarded to designated sequencing laboratory for sequencing within one month after date of isolation: |  |
|  | | |
| *Comments and recommendations:* | | |

**Summary of Virus Isolation Capacities/Needs**

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| --- | --- | --- |
| **Variable description** | **Measles/Rubella**  **National or sub-National Lab** | |
| **Needed** | **Available** |
| **Specimen for virus isolation** |  | |
| Condition of specimen upon arrival | Yes |  |
| Date specimen inoculated or stored (as appropriate) | Yes |  |
| Specimen source | Yes |  |
| Name of virus detection/isolation Lab | Yes |  |
| **Virus isolation results** |  | |
| Date specimen tested | Yes |  |
| Measles/rubella virus isolated | Yes |  |
| Date specimen sent to sequencing lab | Yes |  |

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

To be completed by the assessor

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|  | **Specimens (10 points)** | **Score:** |  |
|  | Specimens are processed in accordance with WHO protocols: | |  |
|  | Specimens for virus detection are stored at –70oC if not tested within a day of receipt: | |  |
|  | Specimens for isolation, all virus isolates, and other potentially infectious materials are stored separately from non-infectious materials in designated freezers and refrigerators: | |  |
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| *COMMENTS AND RECOMMENDATIONS* | | | |

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|  | **Cell Lines (25 points)** | **Score:** |  |
|  | Validated SOPs are available and used for; | |  |
|  | a. Freezing and recovery of cells: | |  |
|  | b. Routine passage of cells: | |  |
|  | c. Inoculation of cells | |  |
|  | h. Harvest and storage of viral isolates | |  |
|  | Vero/hSLAM cells for measles and Vero (or Vero/hSLAM) for Rubella are available for use: | |  |
|  | Cells are obtained from approved WHO stocks: | |  |
|  | Geneticin (G418) is used in the media for preparation of frozen cell stocks: | |  |
|  | Foetal calf serum is derived from certified, disease–free sources: | |  |
|  | Low passage cell stocks are labelled appropriately and stored in liquid nitrogen: | |  |
|  | Cells are routinely replaced at regular intervals of at least 3 months or 15 passages: | |  |
|  | Cells remain healthy for at least 5 days: | |  |
|  | Cells are passaged and maintained in space separate from that used for specimen processing and virus inoculation: | |  |
|  | Media and cells are prepared at separate times, sterility checks performed for media prepared in house: | |  |
|  | Permanent records are maintained on cell passage and storage histories: | |  |
|  | Reagents and stock solutions are labelled correctly, including dates of preparation and expiration, and stored at appropriate temperatures: | |  |
|  | Cells are routinely tested for the presence of mycoplasma | |  |
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| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Virus Isolation (25 points)** | **Score:** |  |
|  | Validated SOPs are available and used: | |  |
|  | Specimens are inoculated on Vero/hSLAM (measles), or Vero (or Vero/hSLAM) (rubella) | |  |
|  | Records are maintained on daily observations of inoculated cells: | |  |
|  | Two sequential passages of 4-5 days are performed before recorded as negative (minimum time in culture is 8 days): | |  |
|  | Isolates are confirmed with IFA, ICA, RT-PCR or other recommended method: | |  |
|  | Isolates are sequenced or transported to designated sequencing laboratory within 2 months of receipt of the specimen. | |  |
|  | Aliquots of isolates are stored appropriately at –70oC or lower for at least 12 months: | |  |
|  | Storage vials are clearly and permanently labelled: | |  |
|  | Permanent records are maintained on the identity and location of all isolates: | |  |
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| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Biosafety (20 points)** | **Score:** |  |
|  | Employees have been properly trained in biosafety for cell culture: | |  |
|  | Validated SOPs for cell culture are available to all employees: | |  |
|  | 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: | |  |
|  | All potentially infectious clinical materials are processed in a certified biological safety cabinet: | |  |
|  | Liquid nitrogen placed, secured and stored in an appropriate place, and appropriate PPE is used during the operation: | |  |
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| *COMMENTS AND RECOMMENDATIONS:* | | | |

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|  | **Laboratory Space Dedicated for Virus Isolation (10 points) Score:** |  |
| 5.1 | Separate cell culture room available, clean and well kept: |  |
| 5.2 | Space is used efficiently with appropriate equipment placement: |  |
| 5.3 | Space configuration is adequate and consistent with good laboratory practices: |  |
|  | | |
| *COMMENTS AND RECOMMENDATIONS:* | | |
|  | | |
|  | **Equipment (10 points)** |  |
|  | Equipment is functioning and in good condition: |  |
|  | Equipment is maintained periodically as recommended and dates recorded: |  |
|  | 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:* |

**On-site Review Summary Score:**

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| National or sub-National Laboratory Onsite Review for Virus Isolation | Score from a possible 100 = | % |