WHO-EN-BW-H

Measles and Rubella National Laboratory or sub-National Laboratory

Checklist for WHO Accreditation

Section 2: Serology Review

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

**Criteria evaluated at the laboratory:**

Measles serology  Rubella serology

GENERAL SUMMARY, COMMENTS AND RECOMMENDATIONS ON SEROLOGY REVIEW:

**Serology Criteria**

**This section of the MR accreditation checklist provides an assessment on serology including an evaluation of the following:**

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

Appropriate QC procedures for serology diagnostics are in place and followed including serological controls for EIA.

1. **Most recent WHO measles/rubella serology proficiency test is passed.**

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

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. **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 (depending on the region and according to the recommended regional reporting timeliness):**

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

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

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

|  |  |  |
| --- | --- | --- |
|  | **Percentage of measles and rubella IgM antibody test results reported within 4 days of receipt:**  **(1.2/1.1 x 100)** | **Measles : %**  **(=1.2 / 1.1 x 100)**  **Rubella : %**  **(=1.4 / 1.3 x 100)** |
|  | Number of specimens tested for measles IgM: |  |
|  | Number (1.1) with measles IgM antibody results reported within 4 days of receipt: |  |
|  | Number of specimens tested for rubella IgM: |  |
|  | Number (1.3) with rubella IgM antibody results reported within 4 days of receipt: |  |
|  | | |
| *Comments and recommendations****:*** | | |

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| --- | --- | --- |
|  | **Timeliness of reporting confirmatory results on sub-National Laboratories’ referred specimens (if National Lab supports sub-National Lab)** | **%**  **(=2.2 / 2.1 x 100)** |
|  | Number of specimens for confirmatory IgM testing from sub-National Laboratories received: |  |
|  | Number of confirmatory results reported within 14 days: |  |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **sub-National Laboratory submitting specimens for confirmation** | **Date specimens received at NL** | **Number of specimens received at NL** | **Number of specimens tested at NL** | **Concordance** | **Date reported to (sub)National Lab** | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | |  |  |  |  | **%** |  | | | |
|  | | |
| *Comments and recommendations****:*** | | |

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| --- | --- | --- |
|  | **Total number of serological tests performed (excluding QC testing):** |  |
|  | Measles and rubella cases are being serologically tested according to the algorithm indicated on the WHO manual: | **Yes/No/Partially** |
|  | For measles: |  |
|  | Total number of specimens tested for IgM: |  |
|  | Number of specimens tested for IgM confirmatory tests (from subnational or other laboratories): |  |
|  | Number of specimens tested for IgM (received directly from National surveillance programme): |  |
|  | Number (%) of IgM tested positive: |  |
|  | Number (%) of IgM tested equivocal: |  |
|  | Number (%) of IgM tested negative: |  |
|  | Number (%) of IgM not tested: |  |
|  | Number (%) of IgG tested positive: |  |
|  | Number (%) of IgG tested negative: |  |
|  | Special surveys (specify): |  |
|  | For rubella: |  |
|  | Total number of specimens tested for IgM: |  |
|  | Number of specimens tested for IgM confirmatory tests (from subnational or other laboratories): |  |
|  | Number of specimens tested for IgM (received directly from National surveillance programme): |  |
|  | Number (%) of IgM tested positive: |  |
|  | Number (%) of IgM tested equivocal: |  |
|  | Number (%) of IgM tested negative: |  |
|  | Number (%) of IgM not tested: |  |
|  | Number (%) of IgG tested positive: |  |
|  | Number (%) of IgG tested negative: |  |
|  | Special surveys (specify): |  |
|  | Serological tests performed for all other viruses: |  |
|  | IgM (state which viruses): |  |
|  | IgG (state which viruses): |  |
|  | Other serological assays (specify): |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Percent accuracy of IgM detection:** | **Measles** | **%** |
| **Rubella** | **%** |
|  | Number of IgM specimens tested: **Measles:**  **Rubella:** |  | |
|  | Number and percentage forwarded to supervisory laboratory (NL/RRL):  **Measles:**  **Rubella:** |  | |
|  | Number confirmed accurate by supervisory laboratory (NL/RRL):  **Measles:**  **Rubella:** |  | |
|  | Number of times IgM specimens sent to supervisory laboratory (NL/RRL) for confirmation during review period: |  | |
|  | | | |
| *Comments and recommendations****:*** | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Result of most recent IgM Proficiency Test:** | **Measles:** | | **%** |
|  | **Rubella:** | | | **%** |
|  | Serology PT panel number: |  | | |
|  | Date of panel receipt: | **/** | **/** |  |
|  | Date of test report: | **/** | **/** |  |
|  | | | | |
| *NATURE OF DEFICIENCY, IF ANY, AND CORRECTIVE ACTION TAKEN:*  *Comments and recommendations****:*** | | | | |

**Summary of Serology Capacities/Needs**

|  |  |  |
| --- | --- | --- |
| **Variable description** | **Measles/Rubella**  **National or sub-National Lab** | |
| **Needed** | **Available** |
| **Specimen for serology** |  | |
| Type of specimen | Yes |  |
| Condition of specimen upon arrival | Yes |  |
| Date specimen tested | Yes |  |
| Date result reported | Yes |  |
| Date of QC result reported | Yes |  |

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| *COMMENTS AND RECOMMENDATIONS:* |

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

To be completed by the assessor

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| --- | --- | --- | --- |
|  | **Pre-analytical processes (20 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: | |  |
|  | All potentially infectious clinical materials are processed in a certified biological safety cabinet: |  |  |
|  | The laboratory’s request form (or its electronic equivalent) includes relevant fields for patient identification and relevant information for serological testing: | |  |
|  | The laboratory has a documented procedure for collection, transport and handling of primary samples: | |  |
|  | Permanent records are maintained on the identity and location of all specimens: | |  |
|  |  |  |  |
|  | **Analytical processes (40 points)** | **Score:** |  |
|  | Validated SOPs are available and used for measles IgM detection: | |  |
|  | Validated SOPs are available and used for rubella IgM detection: | |  |
|  | SOPs for EIAs are acceptable and include (not limited to) procedural steps, quality control procedures, principles for result calculation and for clinical interpretation: | |  |
|  | IgM tests are performed on at least 50 specimens annually: | |  |
|  | Electronic records and hard copies are maintained on all serological assays performed, including: | |  |
|  | a. kit manufacturer and batch number: | |  |
|  | b. reagent expiry dates: | |  |
|  | c. positive and negative controls: | |  |
|  | d. OD values and calculation details of all specimens tested: | |  |
|  | e. assay validation using in-house controls: | |  |
|  | Validated assays used for IgM detection (list kits in comments section below): | |  |
|  | Kit validation criteria are followed  (Briefly describe the the kit validation in the comments section below ): | |  |
|  | In-house positive control(s) are used for each measles and rubella EIA run: | |  |
|  | Monitoring of in-house and kit controls presented as a graphic display:  Attach graphs from review period to completed checklist. | |  |
|  | | | |
| *DESCRIBE other QC Procedures IMPLEMENTED:*  *Summarise details of EIA kits used and controls and validation criteria :*  *Comments and recommendations****:*** | | | |
|  | | | |
|  | **Post-analytical processes (30 points)** | |  |
|  | Specimens giving indeterminate/equivocal results are retested, taking into consideration the context of all other results, and appropriate action taken if still indeterminate/equivocal: | |  |
|  | 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 recorded electronically and with back up: | |  |
|  | Results are transcribed and reported correctly and accurately: | |  |
|  | Serological specimens are appropriately labelled and stored at ≤–20oC for at least 12 months: | |  |
|  | Positive specimens are stored for at least 12 months and only discarded after discussion with WHO. (Positive specimens of > 0.5 ml can be used for QA purposes) : | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

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| --- | --- | --- | --- |
|  | **Equipment (10 points)** | **Score:** |  |
|  | 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. | |  |
|  | | | |
| *COMMENTS AND RECOMMENDATIONS:* | | | |

**On-site Review Summary Score:**

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