Ministry of Health and Long-Term Care

Infectious Diseases Protocol

Appendix B: Provincial Case Definitions for Diseases of Public Health Significance

Disease: Rubella, congenital syndrome

Effective: February 2019

Ontario

Rubella, congenital syndrome

1.0 Provincial Reporting

Confirmed and probable cases of disease

2.0 Type of Surveillance

Case-by-case

3.0 Case Classification

3.1 Confirmed Case

Live birth: Two clinically compatible manifestations (any combination from Table 1: Congenital Rubella Syndrome: Clinically Compatible Manifestations (Table 1), Columns A and B) with laboratory confirmation of infection:

- Isolation of rubella virus from an appropriate clinical specimen (e.g., throat swab, urine, nasopharyngeal aspirate/wash/swab);

  OR

- Detection of rubella virus ribonucleic acid (RNA) by nucleic acid amplification test (NAAT) from an appropriate clinical specimen;

  OR

- Positive serologic test for rubella Immunoglobulin M (IgM) antibody in the absence of recent immunization with rubella-containing vaccine;

  OR

- Rubella Immunoglobulin G (IgG) persisting for longer than would be expected (approximately 6 months following birth) from passive transfer of maternal antibody, or in the absence of recent immunization.

Still birth: Two clinically compatible manifestations with isolation and/or detection of rubella virus RNA from an appropriate clinical specimen (e.g., placenta and autopsy material)

3.2 Probable Case

In the absence of appropriate laboratory tests, a case that lacks evidence of any other etiology and has at least:

- Two clinically compatible manifestations listed in Table 1, column A (See Section 5.0);

  OR

- One manifestation listed in Table 1, column A, plus one listed in Table 1, column B (See Section 5.0).

4.0 Laboratory Evidence

4.1 Laboratory Confirmation

Any of the following will constitute laboratory confirmation:

- Positive for rubella IgM in the absence of recent (i.e., 7 - 42 days) immunization with rubella-containing vaccine;
- Rubella IgG persisting longer than would be expected (approximately 6 months) from passive transfer of maternal antibody, or in the absence of recent immunization;
- Isolation of rubella virus from an appropriate clinical specimen;
- Detection of rubella virus RNA.

4.2 Approved/Validated Tests

- Standard culture for rubella virus.
- Commercial tests for anti-rubella IgM and IgG antibodies.
- NAAT for rubella virus RNA.
- Consult with laboratory about appropriate specimens for each testing methodology.

4.3 Indications and Limitations

- Rubella IgM may not always be detectable at birth following congenital infection. Virus isolation and/or detection of rubella RNA and monitoring of IgG response may be necessary.
- Do not use cord blood. Many of the commercial kits used are not necessarily approved for testing cord blood and validation studies have not been done at the Public Health Ontario Laboratories.

5.0 Clinical Evidence

Table 1: Congenital Rubella Syndrome: Clinically Compatible Manifestations

Congenital Rubella Syndrome	Clinically Compatible Manifestations
1. Cataracts or congenital glaucoma (either one or both count as one) 2. Congenital heart defect 3. Sensorineural hearing loss 4. Pigmentary retinopathy	1. Purpura 2. Hepatosplenomegaly 3. Microcephaly 4. Micro ophthalmia 5. Developmental delay 6. Meningoencephalitis 7. Radiolucent bone disease

6.0 ICD-10 Code(s)

B06.0 plus G05.1, B06.9

P35.0 Congenital rubella

7.0 Comments

Provincial and territorial ministries of health provide active, weekly case-by-case notification (including zero-notification) to the Canadian Measles/ Rubella Surveillance System (CMRSS).

Weekly reporting is completed from CMRSS to the Pan-American Health Organization, in accordance with the elimination of rubella and congenital rubella syndrome in the Western Hemisphere.

8.0 Sources

Public Health Agency of Canada. Congenital Rubella Syndrome/Infection. In: Case Definitions for Communicable Diseases under National Surveillance. Canada Communicable Disease Report. 2009;35S2.

9.0 Document History

Table 2: History of Revisions

Revision Date	Document Section	Description of Revisions
January 2013	General	New template. Section 9.0 Document History added.
January 2013	1.0 Provincial Reporting	Changed from "Confirmed cases of disease" to "Confirmed **and probable cases** of disease"
January 2013	3.1 Confirmed Case	Changed from "**Live birth**: Two clinically compatible manifestations (any combination from Table 1, Columns A and B) with laboratory confirmation of infection **and documented maternal rubella in pregnancy (*removed)***:" to "**Live birth:** Two clinically compatible manifestations (any combination from Table 1, Columns A and B) with laboratory confirmation of infection:" Changed from "**Still birth**: Two clinically compatible manifestations with isolation and/or detection of rubella virus RNA from an appropriate clinical specimen (e.g., placenta and autopsy material) **and/or documented maternal rubella infection in pregnancy *(removed)***" to "**Still birth**: Two clinically compatible manifestations with isolation and/or detection of rubella virus RNA from an appropriate clinical specimen (e.g., placenta and autopsy material)"

Revision Date	Document Section	Description of Revisions
January 2013	3.2 Probable Case	Change from “In the absence of appropriate laboratory tests a case that has at least:” to “In the absence of appropriate laboratory tests, a case that **lacks evidence of any other etiology** and has at least:”
January 2013	4.1 Laboratory Confirmation	Changed from “Any of the following will constitute **a confirmed case of congenital Rubella Infection: (removed)**” to “Any of the following will constitute **laboratory confirmation**:” Changed from “Positive for rubella IgM in the absence of recent immunization with rubella-containing vaccine” to “Positive for rubella IgM in the absence of recent **(i.e., 7 - 42 days)** immunization with rubella-containing vaccine” Deletion of: • Positive rubella culture • Positive rubella virus by direct NAT Addition of: • Isolation of rubella virus from an appropriate clinical specimen • Detection of rubella virus RNA
January 2013	4.3 Indications and Limitations	Changed from “Many of the commercial kits used… at the Public Health Laboratories of the Ontario Agency for Health Protection and Promotion, **therefore do not use cord blood *(removed)***“ to “**Do not use cord blood.** Many of the commercial kits used… at the Public Health Laboratories of the Ontario Agency for Health Protection and Promotion **(Public Health Ontario)**”

Revision Date	Document Section	Description of Revisions
January 2013	5.0 Clinical Evidence	Deletion of: 8. Developmental or late onset conditions such as diabetes & progressive panencephalitis & any other conditions possibly caused by rubella virus
January 2013	7.0 Comments	Addition of: • Provinces provide active, weekly case-by-case notification… • Weekly reporting to the Pan-American Health Organization…
January 2013	8.0 References	Updated.
February 2019	General	Minor revisions were made to support the regulation change to Diseases of Public Health Significance.
February 2019	8.0 References	Section updated and renamed to Sources.


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