10. SPECIFIC TERMS OF REFERENCE FOR THE NRC FOR CONGENITAL DISEASES INCLUDING: TOXOPLASMA, RUBELLA, CYTOMEGALOVIRUS AND PARVOVIRUS B19

AIMS

- Each National Reference Centre (NRC) must meet both the general and the specific terms of reference.

- In the specific terms of reference, the NRC tasks dedicated to each selected pathogen or group of pathogens are described.

- These aim to guarantee the knowledge, the know-how and the epidemiological surveillance expertise of each NRC.

- The task list is not exhaustive and can be modified in function of the requirements and the evolution of knowledge and techniques.

- In the event a NRC is unable to perform a specific task, this can be subcontracted to preserve the knowledge in the NRC. If this is the case, quality of the subcontracted task has to be proven and assured.

- Each list of specific terms of reference is divided into three parts: 1) a reminder of the specific missions, 2) a description of the tasks that the NRC must be able to do including the competencies and 3) a list of the tasks that will be asked in a particular context.

- The type of analysis indicated for each specific pathogen in each particular situation (diagnosis or confirmation, typing, sensitivity to antimicrobial substances, virulence…) is defined.

- The collaboration with national and international surveillance systems (e.g. ECDC) and when relevant with other reference centres (European Medicines Agency, food safety reference centres, veterinary reference centres, …) is also a priority.

10. SPECIFIC TERMS OF REFERENCE FOR THE NRC FOR CONGENITAL DISEASES INCLUDING: TOXOPLASMA, RUBELLA, CYTOMEGALOVIRUS AND PARVOVIRUS B19

SPECIFIC MISSIONS

1. To confirm the diagnosis of infection in pregnant women and of congenital infection and to give scientific and technical support for result interpretation.

2. To monitor circulating strains by performing microbial typing.

3. To maintain an up to date knowledge on the different aspects of congenital infections and on each pathogen.

4. To collaborate with existing relevant networks.

5. To request epidemiological information on confirmed cases of congenitally infected children.

6. To participate in national surveillance, transfer microbiological data (through e-health reporting) and contribute to the presentation and interpretation of the results in a public health approach.

7. To interact with epidemiologists and other NRC's with the aim to sustain/adapt the use of the various outputs (with regards to quality of care, recommendations for control/prevention, ...).

TOXOPLASMA

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the serological diagnosis by detection of specific IgG and IgM, and avidity methods.

2. Detect *T. gondii* by molecular techniques.

3. Perform genotyping of *T. gondii* using a standardized method.

4. Have access to whole genome sequencing.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To confirm the diagnosis of infection in pregnant woman and congenital infection in pre- and postnatal period.

2. To contribute to the development of new diagnostic techniques.

3. To monitor any virulence increase.

4. To request additional data related to pregnancy, clinical diagnosis, outcome … when the case is confirmed.

5. To participate to the seroprevalence monitoring in population groups when requested.

6. To perform the verification by laboratory testing, of the claimed performances and conformity of IVD devices intended to assess the suitability of blood, blood components, cells, tissues or organs or their derivatives for transfusion, transplantation or cell administration, within the Belgian EURL (European Union Reference Laboratory Network) after its designation by the European commission under Regulation (EU) 2017/746.
(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC.

RUBELLA

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Detect the presence of specific antibodies (IgM and IgG) and to perform avidity testing.

2. Detect viral RNA by RT-PCR.

3. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To confirm the diagnosis of infection in pregnant woman and congenital infection in pre- and postnatal period.

2. To request additional data related to the vaccine status (date of doses) and to the pregnancy on confirmed cases.

3. To participate to recommendations on vaccination.

4. To collaborate with the committee for rubella eradication.

5. To participate to the seroprevalence monitoring in population groups when requested.

CYTOMEGALOVIRUS (CMV)

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the serological diagnosis by detection of specific IgG and IgM, and avidity methods.

2. Perform CMV culture.

3. Detect the viral DNA by molecular techniques.

4. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To confirm the diagnosis of congenital infection in pre- and postnatal period.

2. To contribute to the development and the validation of diagnostic tools (molecular and immunological).

3. To request additional data related to the pregnancy status, the infection status of the mother if the new-born is infected.

4. To participate to the seroprevalence monitoring in population groups when requested.

5. To provide technical advice for prevention recommendations.

6. To establish contacts with paediatricians and obstetricians.

7. To perform the verification by laboratory testing, of the claimed performances and conformity of IVD devices intended to assess the suitability of blood, blood components, cells, tissues or organs or their derivatives for transfusion, transplantation or cell administration, within the Belgian EURL (European Union Reference Laboratory Network) after its designation by the European commission under Regulation (EU) 2017/746.
(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC).

PARVOVIRUS B19

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Detect the viral DNA by molecular techniques.

2. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To confirm the diagnosis of infection in pregnant woman and congenital infection in pre- and postnatal period.

2. To participate to the seroprevalence monitoring in population groups when requested.

3. To request additional data related to the pregnancy status, the infection status of the mother if the new-born is infected.