

35. SPECIFIC TERMS OF REFERENCE FOR THE NRC FOR SEXUALLY TRANSMITTED INFECTIONS: *TREPONEMA PALLIDUM*, *CHLAMYDIA TRACHOMATIS*, *NEISSERIA GONORRHOEAE*, *MYCOPLASMA GENITALIUM*

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.

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SPECIFIC MISSIONS

1. To provide diagnostic support to routine laboratories.
2. To type the isolated strains of *Chlamydia trachomatis*.
3. To monitor the antibiotic susceptibility of *Neisseria gonorrhoeae*.
4. To collaborate with existing national and international networks.
5. 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.
6. 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, ...).

TREPONEMA PALLIDUM

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Perform gold standard serology tests on serum and CSF.
2. Confirm neurosyphilis.
3. Confirm congenital syphilis.
4. Identify *T. pallidum* microscopically (dark field).
5. Detect the pathogen using molecular methods on a wide range of clinical samples.
6. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To provide diagnostic support to routine laboratories in case of unclear serology results.
2. To participate to the investigation of clustered infections by using molecular typing techniques.
3. To discriminate between reinfection versus syphilitic reactivation/relapse of infection.
4. To ensure a good representativeness for surveillance purposes, including geographical coverage when relevant.
5. 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>

CHLAMYDIA TRACHOMATIS

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the diagnosis by molecular methods.
2. Perform molecular genotyping.
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.
2. To monitor the antibiotic susceptibility on isolated strains relevant to curative and preventive care, i.e first line treatment when necessary.
3. To be able to confirm Lymphogranuloma Venereum.
4. To ensure a good representativeness for surveillance purposes, including geographical coverage when relevant.
5. To participate to prevalence study, if requested.

NEISSERIA GONORRHOEAE

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the diagnosis by bacterial and molecular techniques.
2. Determine the antibiotic susceptibility.
3. Determine the resistance mechanism.
4. Monitor the antibiotic susceptibility of circulating strains.
5. Perform molecular genotyping.
6. Have access to whole genome sequencing and expertise in species specific bioinformatics analysis.
7. Manage a collection of representative strains.

TASKS THAT WILL BE ASKED IN A PARTICULAR CONTEXT

1. To confirm the diagnosis if relevant.
2. To determine the susceptibility to antibiotics relevant to curative and preventive care.
3. To ensure a good representativeness for surveillance purposes, including geographical coverage when relevant.

MYCOPLASMA GENITALIUM

THE NRC MUST BE ABLE TO (LEVEL OF COMPETENCES)

1. Confirm the diagnosis by molecular techniques on a broad range of sample types.
2. Monitor antibiotics susceptibility of antibiotics relevant to curative and preventive care.

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.
2. To confirm Macrolide Resistance-Mediating Mutations and Fluoroquinolone Resistance Mediating Mutations of *M. genitalium*.
3. To ensure a good representativeness for surveillance purposes, including geographical coverage when relevant.