National HIVDR Laboratories (NDRL)

Requirements

A NDRL is a national institution designated by the national MOH and accredited by the WHO for the purpose of supporting the country's HIVDR surveillance and monitoring surveys. Upon such recognition by the WHO, a NDRL becomes a member of the WHO/HIVResNet Laboratory Network. Although a NDRL is preferably a public health laboratory, with an active role in HIV surveillance, other types of laboratories may also be designated by the MOH as candidate laboratories for HIVDR genotyping.

Tasks and responsibilities

1. The NDRL conducts genotyping of specimens collected during HIVDR surveillance and monitoring surveys and provides accurate HIV sequences to the National HIVDR Database in a timely manner.

2. The NDRL participates in a WHO-recognized quality assurance program for genotyping and is able to support the cost of the testing and shipment of the annual proficiency panel.

3. The NDRL alerts the WHO HIVResNet Laboratory Network about any HIV isolate that cannot be sequenced and forwards the isolate to a regional or specialized laboratory.

Regional HIVDR Laboratories (RDRL)

Requirements

A RDRL is an institution designated by the national MOH and accredited by the WHO for the purpose of supporting the region's HIVDR surveillance and monitoring surveys. Upon such recognition by the WHO, the RDRL becomes a member of the WHO/HIVResNet Laboratory Network. Ideally, there should be at least one accredited RDRL in each WHO region. The presence of more than one laboratory for each region may be warranted. The RDRL should preferably be located in the same region as that of the surveyed countries. Experience as public health laboratories, although not compulsory, is an asset.

Tasks and responsibilities

1. The RDRL functions as a genotyping facility for countries within the region that do not have an accredited NDRL. It must provide support and back-up to at least two NDRLs in
countries that are implementing WHO-recommended HIVDR surveillance and monitoring surveys.

2. The RDRL may serve as the NDRL in its own country.

3. The RDRL, in coordination with a designated Specialized HIVDR Laboratory, facilitates the training, education and capacity-building of laboratory personnel from NDRLs within the region. The RDRL hosts laboratory technicians from candidate laboratories and trains them to become competent in HIV genotyping.

4. Representatives from the RDRL are available to visit the NDRLs for technical assistance when necessary.

5. Representatives from the RDRL are available to participate in assessment of candidate laboratories within the specified region, including on-site inspection visits.

6. Representatives from the RDRL participate in HIVResNet Laboratory Network regional meetings. These meetings will be organized at least once a year and offer an excellent opportunity for discussion of program development and problem solving.

7. A RDRL provides good quality sequence results in a timely manner to the Network

**Specialized HIVDR Laboratories (SDRL)**

**Requirements**
A small number of laboratories are identified by the WHO based on:

- the excellence of their performance;
- their recognized expertise on selected key topics relevant to the development of the HIVDR Laboratory Network;
- their capacity, resources, commitment and motivation.

Experience as public health laboratories, although not compulsory, is an asset. As with the national and regional laboratories, candidate laboratories are also assessed for accreditation as a SDRL by the WHO.

**Tasks and responsibilities**
The SDRL must be willing to:

1. be represented in the WHO HIVResNet Laboratory Network Advisory Group and contribute actively to the development of the WHO HIVResNet Laboratory Network;

2. provide support, technical assistance and back-up to National or Regional HIVDR Laboratories, where needed;

3. host laboratory technicians from candidate laboratories and train them to become competent in HIV genotyping, when not possible at a RDRL;
4. provide high quality sequence results in a timely manner to the Network;
5. serve as a RDRL to countries within a region that do not have an accredited RDRL;
6. serve as a NDRRL to specified countries where there is no national accredited genotyping laboratory, and:
   • the regional laboratory is not able to assist; and/or
   • a special relationship between the SDRL and the specified country is already in place.

In addition, SDRLs should actively participate in one or more of the four core activities listed below. These may not be equally distributed between the laboratories, with some laboratories being the sole provider of certain functions, according to availability, commitment and expertise. Nevertheless, each SDRL must be willing to take responsibility for at least one of the four core activities.

Core activities

1. Quality assurance system
   • Coordinate the participation of accredited laboratories in a WHO-recognized quality assurance program for genotyping, including proficiency panels (PP).
   • Participate in the performance evaluation of laboratories participating in any WHO-recognized proficiency testing program.
   • Assist in the development and supply of WHO-recognized PP.
   • Harmonize WHO-recognized quality assurance systems and identify methods for attaining comparative results.
   • Assist in the development and distribution of standardized reagents and validation panels for all laboratories in the Network, as needed.

2. Capacity building/training
   • Coordinate the development of training materials and educational programs for laboratories within the HIVResNet Laboratory Network.
   • Organize technical workshops at the regional level, as necessary.

3. Operational research
   • Participate in collaborative studies to develop and validate methodologies aimed at improving the feasibility of genotype testing under field conditions.
   • Participate in research aimed at improving the sensitivity, specificity, applicability, turn-around-time and reporting of HIVDR testing in surveillance and monitoring surveys of adult and pediatric populations.
4. **Dried fluid spot activities**

Function as a genotyping reference laboratory for dried fluid spot (DFS) specimens by:

- coordinating the development of a validated protocol for DFS specimens and sharing the protocol amongst the laboratories in the Network, in order to reach consensus;
- performing HIVDR testing for countries without an accredited laboratory for DFS testing;
- coordinating the development of a DFS-based PP (e.g. dried plasma or blood spots) which is more affordable and easier to ship than standard frozen plasma.