WHO/HSE/GCR/LYO/2012.2

# Laboratory Assessment Tool

## Annex 2: Laboratory Assessment Tool / Facility Questionnaire

April 2012

# Table of content

# Laboratory identification

| | |
|---|---|
| Country | |
| Region/Province/District | |
| Name of the laboratory | |
| Address | |
| Telephone | |
| Fax | |
| E-mail | |
| Name of the laboratory director | |

| | |
|---|---|
| Qualification and contact details of the laboratory director | |

| | |
|---|---|
| Date of the assessment (DD/MM/YYYY) | |
| Name of the assessor/s | |
| Contact details of the assessor/s | |
| Name of the responding person/s | |
| Qualification and contact details of the responding person/s | |

Annex 2: LAT/Facility - Laboratory identification

| | |
|---|---|
| Level of laboratory | Central/Reference<br>Intermediate<br>Peripheral<br>Other<br>NA |
| Affiliation/ type of laboratory (several answers possible) | |

*Public Health / Hospital / Health Centre / Environment / Food Control / Veterinary / Private / University / Research / Other?*

| | |
|---|---|
| Affiliated Ministry (if applicable) | |

*Health / Agriculture / Trade, Commerce / Education / Defense / Other?*

| | |
|---|---|
| Estimated population covered by this laboratory | |
| Describe participation in international programmes/networks (if applicable) | |

*Polio, FluNet, INFOSAN, Global Foodborne Infections Network, etc.*

Annex 2: LAT/Facility - Laboratory identification

*Indicate relevant disciplines addressed in the laboratory by checking relevant box/es*

| | |
|---|---|
| Clinical chemistry | ☐ |
| Haematology and haemostasis | ☐ |
| Parasitology | ☐ |
| Mycology | ☐ |
| Bacteriology (except serology) | ☐ |
| Virology (except serology) | ☐ |
| Viral serology | ☐ |
| Bacterial serology | ☐ |
| Toxicology | ☐ |
| Histopathology | ☐ |
| Cytology | ☐ |
| Human genetics | ☐ |
| Transfusion medicine | ☐ |
| Food testing (microbiology) | ☐ |
| Food testing (chemicals and others) | ☐ |
| Water testing | ☐ |

| | |
|---|---|
| Veterinary testing | ☐ |
| Environmental testing (air, soil) | ☐ |
| Other | ☐ |
| *If other, please describe below:* | |
| | |

**Comments**

# 1. Organization and management

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Service hours** | | | |
| 1.1 | *What are the days and hours of operation of routine service?* | | | |
| 1.2 | *If relevant, what are the days and hours of operation of emergency service?* | | | |
| | **External communication** | | | |
| | Is the laboratory equipped with: | | | |
| 1.3 | Telephone? | | | |
| 1.4 | Fax? | | | |
| 1.5 | Computer with Internet access? | | | |
| 1.6 | If yes or partial, does laboratory staff have access to the Internet? | | | |
| 1.7 | Is relevant information on costs and turnaround time for test results available to patients? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 1.8 | Is there timely notification to patients when delay is anticipated due to machine breakdown, etc.? | | | |
| 1.9 | If applicable, do you organize customer surveys at least once a year? | X | | |

**Internal communication and structure**

| | | | | |
|---|---|---|---|---|
| 1.10 | Is there an organizational structure defining the lines of authorities and responsibilities for key laboratory staff? | X | | |
| 1.11 | Are staff meetings organized at least once a month? | | | |
| 1.12 | If applicable, are team manager meetings organized at least once a month? | | | |
| 1.13 | Are meetings organized to solve a particular problem when it occurs? | | | |
| 1.14 | Are written reports or minutes of these meetings produced? | X | | |
| 1.15 | *Please describe the means by which information is internally communicated (notice board, e-mail, etc.).* | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 1.16 | Do laboratory staff participate in annual laboratory meetings specifically focused on sharing of knowledge and experiences and the opportunity to make improvements? | | | |
| 1.17 | Do laboratory representatives participate in hospital/institution board meetings as relevant? | | | |

**Budget**

| | | | | |
|---|---|---|---|---|
| 1.18 | Is the budget for staff salaries adequate for the need? | | | |
| 1.19 | *Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)* | | X | |
| 1.20 | Is there an adequate budget assigned for staff education? | | | |
| 1.21 | *Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)* | | X | |
| 1.22 | Is there an adequate budget assigned for consumable and reagent purchase? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 1.23 | *Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)* | | | |
| 1.24 | Is there an adequate budget assigned for equipment purchase/maintenance? | | | |
| 1.25 | *Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)* | | | |
| 1.26 | Is there an adequate budget assigned for surveillance and/or overall public health activities? | | | |
| 1.27 | *Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)* | | | |

## Licensing/Supervision/Accreditation

| | | | | |
|---|---|---|---|---|
| 1.28 | Has the laboratory been licensed (i.e. authorized to operate) by the authorities? If licensing is not required, please indicate “Non applicable”. | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 1.29 | Does the laboratory have an internal audit programme? | | | |
| 1.30 | *If yes or partial, please describe* | | | |
| 1.31 | Has the laboratory undergone an audit or assessment by a third party within the last two years? | | | |
| 1.32 | *If yes or partial, please provide details* | | | |
| 1.33 | Are copies of any reports on reviews by a third party available to the laboratory? | X | | |
| 1.34 | Are recommendations from third party reviews implemented where relevant? | | | |
| 1.35 | Does the laboratory hold any form of certification (ISO 9001, other)? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 1.36 | *If yes, please detail the relevant standards and the names of the certification bodies.* | | | |
| 1.37 | Does the laboratory hold any form of accreditation (ISO 17025, ISO 15189, WHO polio or measles, etc.)? | X | | |
| 1.38 | *If yes, please details the relevant standards and the names of the accreditation bodies.* | | | |

**Comments**

# 2. Documents

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Document control** | | | |
| 2.1 | Is a system in place to organize the management of laboratory documents and records? | X | | |
| | If yes, are the documents: | | | |
| 2.2 | Listed? | | | |
| 2.3 | Numbered? | | | |
| 2.4 | Approved and signed by authorized personnel? | | | |
| 2.5 | Reviewed periodically? | | | |
| 2.6 | Archived according to national or international guidelines? | | | |
| 2.7 | Does the laboratory have an archive system? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 2.8 | Are the archived documents retrievable? | | | |
| 2.9 | *For how long are the archived documents kept?* | | | |

**Quality procedures**

| | | | | |
|---|---|---|---|---|
| 2.10 | Is a quality manual describing the quality system policy and the quality procedures available? | X | | |
| | If yes or partial, does it cover these topics: | | | |
| 2.11 | Laboratory organization and management? | | | |
| 2.12 | Documentation and records? | | | |
| 2.13 | Pre-examination procedures? | | | |
| 2.14 | Examination procedures? | | | |
| 2.15 | Post-examination procedures and reporting of results? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 2.16 | Management of nonconformities? | | | |
| 2.17 | Personnel and education requirements? | | | |
| 2.18 | Safety and facilities? | | | |
| 2.19 | Equipment? | | | |
| 2.20 | Consumables and reagents? | | | |
| 2.21 | Reference materials? | | | |
| 2.22 | Collaboration with referral laboratories? | | | |
| 2.23 | Internal quality control procedures? | | | |
| 2.24 | External quality assessment procedures? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 2.25 | Are all procedures related to relationship with other relevant institutes and organizations documented? | X | | |
| 2.26 | Are procedures readily available to staff, as relevant? | | | |
| 2.27 | Are changes in procedures tracked? | X | | |
| 2.28 | Are laboratory procedures reviewed at least annually and any necessary amendments incorporated? | X | | |
| 2.29 | Are confidentiality protected and access limited, as appropriate? | | | |
| 2.30 | Are current versions of published standards and other similar documents in use in the laboratory available (e.g. norms, guidelines, instrument manuals, test kit inserts etc.)? | X | | |
| 2.31 | Does the laboratory have procedures that were developed in-house? | X | | |
| 2.32 | If so, are they clearly documented according to a defined format? | | | |
| 2.33 | Is there a procedure for the storage of primary specimens once analysed? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 2.34 | Are there procedures for the validation and verification of methods and equipment as relevant? | X | | |
| 2.35 | Are procedures in place to record incidents or complaints? | X | | |
| 2.36 | If yes or partial, are corrective actions implemented and recorded? | X | | |

**Biosafety**

| | | | | |
|---|---|---|---|---|
| 2.37 | Are written biosafety procedures available? | X | | |
| 2.38 | *If yes or partial, please provide the name and reference of these procedures/guidelines:* | | | |
| | If yes or partial, are the following subjects addressed: | | | |
| 2.39 | Personal protective equipment? | | | |
| 2.40 | Disinfection and sterilization? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 2.41 | Waste disposal? | | | |
| 2.42 | Access restrictions? | | | |
| 2.43 | Biosafety equipments? | | | |
| 2.44 | Emergency protocols (e.g. in case of contamination)? | | | |
| 2.45 | Are Material Safety Data Sheets available for review in the immediate laboratory area? | X | | |

**Comments**

# 3. Specimen collection, handling and transport

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Specimen collection** | | | |
| 3.1 | Are written instructions available for patient preparation prior to collection (e.g. glucose tolerance test)? | X | | |
| 3.2 | Are collection procedures documented and available to relevant personnel? | X | | |
| 3.3 | Do these include minimum patient identification details? | | | |
| 3.4 | Is a standard specimen request form available for those requesting tests? | X | | |
| | If yes or partial, does it include: | | | |
| 3.5 | Name of the patient? | | | |
| 3.6 | Gender? | | | |
| 3.7 | Date of birth? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 3.8 | Patient identification number (if applicable)? | | | |
| 3.9 | Identification of the prescriber? | | | |
| 3.10 | Date of collection? | | | |
| 3.11 | Time of collection? | | | |
| 3.12 | Type of specimen? | | | |
| 3.13 | Specimen identification number (if applicable)? | | | |
| 3.14 | Examinations requested? | | | |
| 3.15 | Clinical information? | | | |
| 3.16 | Are specimens recorded in a book, worksheet, computer or other comparable system? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | If yes or partial, is there: | | | |
| 3.17 | A unique identification number? | | | |
| 3.18 | The date of receipt? | | | |
| 3.19 | The time of receipt? | | | |
| 3.20 | Are specimen portions traceable to the original primary sample (identification number, etc.)? | | | |

## Specimen handling

| | | | | |
|---|---|---|---|---|
| | Does the laboratory experience problems with specimens from outside the facility due to (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable): | | | |
| 3.21 | No request form | | | |
| 3.22 | Incomplete request form | | | |
| 3.23 | Incorrect specimen identification | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 3.24 | Incorrect patient identification | | | |
| 3.25 | Inadequate container | | | |
| 3.26 | Inadequate volume | | | |
| 3.27 | Inadequate transport media/anticoagulant | | | |
| 3.28 | Inadequate package | | | |
| 3.29 | Inadequate transportation temperature | | | |
| 3.30 | Delay in receipt | | | |
| | Does the laboratory experience problems with collecting specimens inside the facility due to (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable): | | | |
| 3.31 | Lack of proper collection materials | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 3.32 | No request form | | | |
| 3.33 | Incomplete request form | | | |
| 3.34 | Incorrect specimen identification | | | |
| 3.35 | Incorrect patient identification | | | |
| 3.36 | Inadequate volume | | | |
| 3.37 | Are there any criteria for acceptance or rejection of primary specimens (including potential caution if non-conforming specimens are accepted)? | X | | |
| 3.38 | Are primary specimens adequately stored if not immediately examined? | | | |
| 3.39 | Are specimens stored for a specific time under appropriate conditions to enable further testing? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Specimen referral / transport** | | | |
| 3.40 | Does the laboratory receive specimens or isolates from other laboratories? | | | |
| 3.41 | Does the laboratory refer specimens or isolates to other laboratories? | | | |
| 3.42 | *If yes or partial, please describe which specimens to which laboratories in what circumstances:* | | | |
| 3.43 | Does the laboratory have appropriate packaging for referring specimens (triple package if air transport, or any package in conformity with local regulations or recommendations)? | | | |
| 3.44 | Is/are the person/s in charge of shipments trained for the transport of infectious substances? | | | |
| | If yes or partial: | | | |
| 3.45 | Is he/she trained for local or national regulations or recommendations? | | | |
| 3.46 | Is he/she trained in international regulations? | | | |

**Comments**

# 4. Data and information management

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Test results and reports** | | | |
| 4.1 | Are all original observations/results of the laboratory recorded in a worksheet or electronic database? | | | |
| 4.2 | Are results reported and recorded in a standardized format? | X | | |
| | If yes or partial, does the report form include the following: | | | |
| 4.3 | Name of the laboratory? | | | |
| 4.4 | Patient identification? | | | |
| 4.5 | Requester identification? | | | |
| 4.6 | Sample type? | | | |
| 4.7 | Examination method? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 4.8 | Date of sample collection? | | | |
| 4.9 | Time of sample collection? | | | |
| 4.10 | Date of receipt of the sample by the laboratory? | | | |
| 4.11 | Time of receipt of the sample by the laboratory? | | | |
| 4.12 | Date of release of report? | | | |
| 4.13 | Time of release of report? | | | |
| 4.14 | Results reported in International System of Units (where applicable)? | | | |
| 4.15 | Biological reference intervals (where applicable)? | | | |
| 4.16 | Interpretation (where appropriate)? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 4.17 | Identification and signature of the person authorizing the release of the report? | | | |
| 4.18 | Are the results reviewed and authorized before the results are released? | | | |
| 4.19 | Is there a system in place to track if reports have been issued and received? | | | |
| 4.20 | When samples need to be referred further to another laboratory, is there procedure to define how report is then issued and by which laboratory? | | | |
| 4.21 | Is there an immediate notification of physicians when results are critical for patient care? | X | | |
| 4.22 | Is there an immediate notification of relevant ministry/surveillance network when results are critical? | X | | |

**Data analysis and statistics**

| | | | | |
|---|---|---|---|---|
| 4.23 | Can the laboratory provide basic statistical data (e.g. number of tests ordered, aggregated qualitative/quantitative data, etc.)? | | | |
| 4.24 | If yes or partial, are statistical data analysed and used? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 4.25 | Are periodic summary activity reports prepared? | X | | |

## Data security - Confidentiality

| | | | | |
|---|---|---|---|---|
| 4.26 | Are access and modification of patient data protected for paper-based system? | | | |
| 4.27 | Are access and modification of patient data protected for electronic system? | | | |
| 4.28 | Is efficient back-up in place to prevent loss of patient result data in case of theft or other incident for paper-based system? | | | |
| 4.29 | Is efficient back-up in place to prevent loss of patient result data in case of theft or computer failure or other incident for electronic system? | | | |
| 4.30 | Are reported data (copies) retained as long as medically relevant or required by the legislation? | | | |

## IT and Laboratory Information System (LIS)

| | | | | |
|---|---|---|---|---|
| | What are the softwares/applications used in the laboratory: | | | |
| 4.31 | Word processor? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 4.32 | Spreadsheet processor? | | | |
| 4.33 | Presentation software? | | | |
| 4.34 | Database software? | | | |
| 4.35 | Internet browsing? | | | |
| 4.36 | E-mail? | | | |
| 4.37 | LIS? | | | |
| | If yes or partial for LIS: | | | |
| 4.38 | Are data retrievable within an acceptable timeframe? | | | |
| 4.39 | Can the system be used for data analysis? | | | |

**Comments**

# 5. Consumables and reagents

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Procurement** | | | |
| 5.1 | Are lists of manufacturers/suppliers and catalogues of reagents available? | X | | |
| 5.2 | If applicable, are the consumables and reagents ordered in the list of registered supplies at national level? | | | |
| 5.3 | Does the laboratory experience problems with reagent delivery like delays, temperature not adequate, reference error, etc. (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable)? | | | |
| 5.4 | Is there a responsible staff for consumable and reagent management (inventory, order, etc.)? | | | |
| 5.5 | Is the purchase of consumables and reagents recorded? | X | | |
| | **Inventory and storage** | | | |
| 5.6 | Is there an inventory system for consumables and reagents? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | If yes or partial, does it include: | | | |
| 5.7 | Quantity? | | | |
| 5.8 | Quality? | | | |
| 5.9 | Supplier? | | | |
| 5.10 | Lot number? | | | |
| 5.11 | Date of receipt? | | | |
| 5.12 | Appropriate storage? | | | |
| 5.13 | Expiration date? | | | |
| 5.14 | Expected shelf life? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 5.15 | Date the material is placed in service? | | | |
| 5.16 | Are consumables and reagents inspected upon receipt? | | | |
| 5.17 | If yes or partial, are there protocols for acceptance/rejection of consumables and reagents? | | | |
| 5.18 | Are consumables and reagents appropriately stored (temperature, humidity, etc.)? | | | |

**Use**

| | | | | |
|---|---|---|---|---|
| 5.19 | Is the date of opening clearly written on the reagents/kits? | | | |
| 5.20 | Are new reagents (new product, new lot, including home-made reagents) validated against old reagents or reference materials before use? | | | |
| 5.21 | Is the consumption rate monitored for consumables and reagents? | X | | |
| 5.22 | Is there a system for accurately forecasting needs for consumables and reagents? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 5.23 | Are disposable supplies (e.g. tips, plastic pipettes, gloves) reused (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable)? | | | |

**Expired reagents**

| | | | | |
|---|---|---|---|---|
| 5.24 | Are expired reagents used (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable)? | | | |
| 5.25 | If sometimes or regularly, is quality control performed on these expired reagents? | | | |
| 5.26 | If sometimes or regularly, does quality control testing demonstrate that the quality of reagents is still acceptable? | | | |

**Comments**

# 6. Equipment

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Equipment inventory** | | | |
| 6.1 | Is there an equipment inventory? | | | |
| 6.2 | If yes or partial, is each equipment recorded with a paper or electronic equipment form? | X | | |
| | If yes or partial, does this form include: | | | |
| 6.3 | Name of the equipment? | | | |
| 6.4 | Serial number? | | | |
| 6.5 | Name and contact details of manufacturer (or local supplier)? | | | |
| 6.6 | Date of receipt? | | | |
| 6.7 | Date of first use? | | | |

| | | | | |
|---|---|---|---|---|
| 6.8 | Location in the laboratory? | | | |
| 6.9 | Condition (i.e. new, used)? | | | |
| 6.10 | Maintenance activities? | | | |
| 6.11 | Damage and repairs? | | | |
| 6.12 | The individual primarily responsible for this equipment? | | | |

**Equipment maintenance, calibration and monitoring**

| | | | | |
|---|---|---|---|---|
| 6.13 | Are results validated against reference materials and/or methods when new equipment is introduced? | | | |
| 6.14 | Is the equipment maintained in a safe working condition (including electrical safety)? | | | |
| 6.15 | Is there daily monitoring and recording of temperatures for temperature-dependent equipment? | X | | |
| 6.16 | Is the staff duly trained and authorized before first using equipment? | | | |

| | | | | |
|---|---|---|---|---|
| 6.17 | Do only authorized personnels use the equipment? | | | |
| 6.18 | Does the laboratory have a dedicated person in charge of the equipment (maintenance management, etc.)? | | | |
| 6.19 | Is a preventive maintenance programme in place? | | | |
| 6.20 | Does the laboratory have contracts with external maintenance and repair services? | | | |
| 6.21 | Are data from equipment maintenance recorded and used? | | | |
| 6.22 | Is there a defined protocol and time period for pipette calibration? | | | |
| 6.23 | Is calibration of other equipment performed and checked regularly (pH meter, spectrophotometer, etc.)? | | | |
| 6.24 | Are results validated against gold standards after equipment maintenance or repair? | | | |
| 6.25 | Are there user manuals for most of the equipment? | X | | |
| 6.26 | If yes, are these manuals available in the language commonly used by the staff? | X | | |

| | | | | | |
|---|---|---|---|---|---|
| 6.27 | Are there sufficient spare parts for quick repairs (lamps, fuses, filters, etc.)? | | | | |
| 6.28 | Is defective equipment (waiting for repair or obsolete to be removed) labelled appropriately? | | | | |
| 6.29 | Are procedures available for the disposal of equipment? | | | | |

| **List of FUNCTIONING and USABLE equipment** | Number | Is it registered? | Is it maintained (including calibration if applicable)? | Is it certified? |
|---|---|---|---|---|
| Atomic Absorption Spectrometer | | | | |
| Autoclave (clean) | | | | |
| Autoclave (dirty) | | | | |
| Automated microbial identification and susceptibility testing systems | | | | |
| Automatic pipette (other than micropipettes) | | | | |
| Basic scale | | | | |
| Beta and gamma (scintillation) counters | | | | |
| Binocular microscope | | | | |
| Biosafety Cabinet (BSC) class I | | | | |
| Biosafety Cabinet class II | | | | |
| Biosafety Cabinet class III | | | | |

| **List of FUNCTIONING and USABLE equipment** | Number | Is it registered? | Is it maintained (including calibration if applicable)? | Is it certified? |
|---|---|---|---|---|
| Blood culture automated incubator | | | | |
| Bunsen burner + gas bottle | | | | |
| Candle jar | | | | |
| Centrifuge, cooled | | | | |
| Centrifuge, simple | | | | |
| Chemistry analyser | | | | |
| CO2 incubator | | | | |
| Coagulometer | | | | |
| Colorimeter | | | | |
| Computer for laboratory work | | | | |
| Computer for office work | | | | |
| DNA automated extractor | | | | |
| Dry ice machine | | | | |
| Electrophoresis equipment | | | | |
| ELISA equipment (Washer/Incubator/Reader) | | | | |
| Flame photometer | | | | |
| Flow cytometer | | | | |

| **List of FUNCTIONING and USABLE equipment** | Number | Is it registered? | Is it maintained (including calibration if applicable)? | Is it certified? |
|---|---|---|---|---|
| Fluorescence microscope | | | | |
| Fluorimeter | | | | |
| Freezer -20°C | | | | |
| Freezer -70°C | | | | |
| Gas Chromatography with any detection system | | | | |
| Gel electrophoresis for nucleic acids and peptides | | | | |
| Glassware kit | | | | |
| Haematology automated analyser | | | | |
| Heated magnetic agitator | | | | |
| Haematocrit centrifuge | | | | |
| High Performance Liquid Chromatography with any detection system | | | | |
| Immunoassays automated analyser | | | | |
| Incubator | | | | |
| Lyophilizer | | | | |
| Manipulation box (chemical hood) | | | | |
| Mass Spectrometry (with or without Liquid Chromatography) | | | | |
| McFarland photometer | | | | |

| **List of FUNCTIONING and USABLE equipment** | Number | Is it registered? | Is it maintained (including calibration if applicable)? | Is it certified? |
|---|---|---|---|---|
| Media dispenser | | | | |
| Micropipette 1-5ml | | | | |
| Micropipette 20 µl | | | | |
| Micropipette 200- 1000µl | | | | |
| Micropipette 5- 50µl | | | | |
| Micropipette 50- 200µl | | | | |
| Oven | | | | |
| pH meter | | | | |
| Photographic equipment | | | | |
| Plexiglass screen | | | | |
| Precision scale | | | | |
| Printer for laboratory work | | | | |
| Printer for office work | | | | |
| Pulsed Field Gel Electrophoresis | | | | |
| Refrigerator | | | | |
| Rotary agitator | | | | |
| Semi-automated microbial identification or susceptibility testing systems | | | | |

| List of FUNCTIONING and USABLE equipment | Number | Is it registered? | Is it maintained (including calibration if applicable)? | Is it certified? |
|---|---|---|---|---|
| Slide dryer | | | | |
| Thermal cycler (Thermocycler, PCR Machine or DNA Amplifier), Conventional | | | | |
| Thermal cycler (Thermocycler, PCR Machine or DNA Amplifier), Real Time | | | | |
| Thin Layer Chromatography (with/without scanning device) | | | | |
| Turbidimeter | | | | |
| UV light table | | | | |
| UV/visible spectrophotometer | | | | |
| Vacuum pump | | | | |
| Vortex | | | | |
| Washing machine for glassware | | | | |
| Water distiller | | | | |
| Water bath | | | | |

**Comments**

## 7. Laboratory testing performance

*Reference number to be entered under "Discipline #" in the answer table below*

| Disciplines | # |
|---|---|
| Clinical chemistry | 1 |
| Haematology and haemostasis | 2 |
| Parasitology | 3 |
| Mycology | 4 |
| Bacteriology (except serology) | 5 |
| Virology (except serology) | 6 |
| Viral serology | 7 |
| Bacterial serology | 8 |
| Toxicology | 9 |
| Histopathology | 10 |
| Cytology | 11 |
| Human genetics | 12 |
| Transfusion medicine | 13 |
| Food testing (microbiology) | 14 |
| Food testing (chemicals and others) | 15 |
| Water testing | 16 |
| Veterinary testing | 17 |
| Environmental testing (air, soil) | 18 |
| Other | 19 |
| *Other:* | |

*Specimen to be entered under "Specimen type" in the answer table below*

| Specimen type |
|---|
| Blood |
| Stool |
| Urine |
| CSF |
| Sputum |
| Lymph nodes |
| Bone marrow |
| Pus |
| Pharyngeal/nasopharyngeal swab |
| Urethral/vaginal swab |
| Other |

**Enter all relevant tests performed in the laboratory (one test/line) and provide requested details for each test**

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | | | | **Frequency** | **Staff** | **SOPs** | | **Equipment** | | **Reagents/Test kits** | | **Quality Control** | | | **External Quality Assessment** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| e.g. | Cytobacteriological examination of urine | 5 | Urine | Microscopy, Gram, Culture | 45 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 4 | 4 | 1 | 1 | 2 |

| | | | | | Frequency | Staff | SOPs | | Equipment | | Reagents/Test kits | | Quality Control | | | External Quality Assessment | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| 7.1 | | | | | | | | | | | | | | | | | | |
| 7.2 | | | | | | | | | | | | | | | | | | |
| 7.3 | | | | | | | | | | | | | | | | | | |
| 7.4 | | | | | | | | | | | | | | | | | | |
| 7.5 | | | | | | | | | | | | | | | | | | |
| 7.6 | | | | | | | | | | | | | | | | | | |
| 7.7 | | | | | | | | | | | | | | | | | | |
| 7.8 | | | | | | | | | | | | | | | | | | |
| 7.9 | | | | | | | | | | | | | | | | | | |

| | | | | | Frequency | Staff | SOPs | | Equipment | | Reagents/Test kits | | Quality Control | | | External Quality Assessment | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| 7.10 | | | | | | | | | | | | | | | | | | |
| 7.11 | | | | | | | | | | | | | | | | | | |
| 7.12 | | | | | | | | | | | | | | | | | | |
| 7.13 | | | | | | | | | | | | | | | | | | |
| 7.14 | | | | | | | | | | | | | | | | | | |
| 7.15 | | | | | | | | | | | | | | | | | | |
| 7.16 | | | | | | | | | | | | | | | | | | |
| 7.17 | | | | | | | | | | | | | | | | | | |
| 7.18 | | | | | | | | | | | | | | | | | | |

| | | | | | Frequency | Staff | SOPs | | Equipment | | Reagents/Test kits | | Quality Control | | | External Quality Assessment | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| 7.19 | | | | | | | | | | | | | | | | | | |
| 7.20 | | | | | | | | | | | | | | | | | | |
| 7.21 | | | | | | | | | | | | | | | | | | |
| 7.22 | | | | | | | | | | | | | | | | | | |
| 7.23 | | | | | | | | | | | | | | | | | | |
| 7.24 | | | | | | | | | | | | | | | | | | |
| 7.25 | | | | | | | | | | | | | | | | | | |
| 7.26 | | | | | | | | | | | | | | | | | | |
| 7.27 | | | | | | | | | | | | | | | | | | |

Annex 2: LAT/Facility - Laboratory testing performance

| | | | | | **Frequency** | **Staff** | **SOPs** | | **Equipment** | | **Reagents/Test kits** | | **Quality Control** | | | **External Quality Assessment** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| 7.28 | | | | | | | | | | | | | | | | | | |
| 7.29 | | | | | | | | | | | | | | | | | | |
| 7.30 | | | | | | | | | | | | | | | | | | |
| 7.31 | | | | | | | | | | | | | | | | | | |
| 7.32 | | | | | | | | | | | | | | | | | | |
| 7.33 | | | | | | | | | | | | | | | | | | |
| 7.34 | | | | | | | | | | | | | | | | | | |
| 7.35 | | | | | | | | | | | | | | | | | | |
| 7.36 | | | | | | | | | | | | | | | | | | |

| | | | | | Frequency | Staff | SOPs | | Equipment | | Reagents/Test kits | | Quality Control | | | External Quality Assessment | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Test type/Name** | Discipline # | **Specimen type** | **Method/s and Instrument/s** | Average number of tests performed monthly | Is staff competent to perform the test? | Is SOP available for this test? | Is the SOP adequate/up-to-date? | Is equipment appropriate for this test? | Is equipment adequately maintained? | Are adequate reagents for this test available? | Are the reagents in-date? | Are IQC specimens included when performing this test? | Are IQC results acceptable? | Are corrective actions implemented if IQC results are not acceptable? | Does the laboratory participate in EQA for this test? | Are EQA results acceptable? | Are corrective actions implemented if EQA results are not acceptable? |
| 7.37 | | | | | | | | | | | | | | | | | | |
| 7.38 | | | | | | | | | | | | | | | | | | |
| 7.39 | | | | | | | | | | | | | | | | | | |
| 7.40 | | | | | | | | | | | | | | | | | | |

**Comments**

# 8. Facilities

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

## Infrastructure

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | What is the general condition of laboratory building and infrastructure? For the following questions, choose one of the following answers: 1.Good; 2.Medium; 3.Bad; 4.Non applicable | | | |
| 8.1 | Walls, floors and roofs? | | | |
| 8.2 | Windows and doors? | | | |
| 8.3 | Benches? | | | |
| 8.4 | Heating / air conditioner / ventilation? | | | |
| 8.5 | Lighting? | | | |
| 8.6 | Waste disposal? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Work conditions** | | | |
| 8.7 | Does the laboratory face electricity interruption (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable)? | | | |
| 8.8 | If applicable, do you have an emergency electric generator or other backup power source? | | | |
| 8.9 | Is key/sensitive equipment protected by a UPS (Uninterruptable Power Supply)? | | | |
| | *i.e. photometer/spectrophotometer, thermal cycler, BSC, or any other equipment that can be damaged by sudden interruptions in electricity* | | | |
| 8.10 | Does the laboratory face water shortages (1.Never; 2.Sometimes; 3.Regularly; 4.Non applicable)? | | | |
| 8.11 | Is the space allocated sufficient to perform the work without compromising the quality and safety of patients and personnel? | | | |
| 8.12 | Are work areas clean and well maintained? | | | |
| 8.13 | Is sample collection carried out in room(s) separated from the laboratory examination room(s)? | | | |
| 8.14 | Is there an effective separation between adjacent laboratory sections in which there are incompatible activities (e.g. nucleic acid extraction vs amplification)? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 8.15 | Are there designated rooms for specialized testing (TB, brucellosis, etc.)? | | | |
| 8.16 | If applicable, is there a negative pressure room? | | | |
| 8.17 | Are there appropriate storage areas? | | | |

**Comments**

# 9. Human resources

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Staff number** | | | |
| | *Number of:* | | | |
| 9.1 | *Managers/senior staff (postgraduate degree)* | | | |
| 9.2 | *Laboratory technologists or technicians (performing tests)* | | | |
| 9.3 | *Laboratory assistants/medical aides (not doing tests)* | | | |
| 9.4 | *Support/administrative staff* | | | |
| 9.5 | *Phlebotomists* | | | |
| 9.6 | *Other staff* | | | |
| 9.7 | *For other staff, please specify:* | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 9.8 | *Total number of persons working in the laboratory* | | | |
| 9.9 | Is the staff number adequate to undertake the required work? | | | |
| | If no or partial: | | | |
| 9.10 | Is trained manager/senior staff missing? | | | |
| 9.11 | Is technical staff missing? | | | |
| 9.12 | Is assistant/medical aide staff missing? | | | |
| 9.13 | Is support/administrative staff missing? | | | |
| 9.14 | Is phlebotomist missing? | | | |
| 9.15 | Is other staff missing? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 9.16 | *For other staff, please specify:* | | | |

**Qualifications**

| | | | | |
|---|---|---|---|---|
| 9.17 | Are qualifications, training and experience of staff recorded? | X | | |
| 9.18 | Are job descriptions defining qualifications and duties available? | X | | |
| 9.19 | Are lines of authority and responsibility clearly defined for all laboratory staff? | | | |
| 9.20 | Has a quality manager been designated? | | | |
| 9.21 | Does the staff have appropriate qualifications or competences to perform laboratory work? | | | |
| | If no or partial: | | | |
| 9.22 | Do managers/senior staff have appropriate qualifications or competences? | | | |
| 9.23 | Do laboratory technologists have appropriate qualifications or competences? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 9.24 | Do assistants/medical aides have appropriate qualifications or competences? | | | |
| 9.25 | Do support/administrative staff have appropriate qualifications or competences? | | | |
| 9.26 | Do phlebotomists have appropriate qualifications or competences? | | | |
| 9.27 | Do other staff have appropriate qualifications or competences? | | | |
| 9.28 | *For other, please specify:* | | | |

**Continuous education**

| | | | | |
|---|---|---|---|---|
| 9.29 | Is there a professional development programme in place for the staff? | | | |
| 9.30 | Is continuing education (training, workshop, conference, etc.) provided to staff members? | | | |
| 9.31 | Is "in-house" education (on-site training, journal club, etc.) provided to staff members? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 9.32 | Is there a library accessible by all staff in the laboratory? | | | |
| 9.33 | *Please list the educational activities in the last two years* | | | |

**Comments**

# 10. Biorisk management

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Biorisk management policy** | | | |
| 10.1 | Has a policy concerning the management of laboratory biorisk (biosafety and biosecurity) been written? | X | | |
| 10.2 | Does this policy clearly state the biorisk management objectives and commitment to improve biorisk management performance? | | | |
| 10.3 | Is the policy appropriate to the nature and scale of the risk associated with the facility and associated activities? | | | |
| | **Biorisk assessment and control** | | | |
| 10.4 | Have the hazards associated with proposed work been identified and documented? | X | | |
| 10.5 | Have the biorisks been assessed and categorized? | X | | |
| 10.6 | Are biorisk control measures described in an action plan? | X | | |
| 10.7 | Are biorisk control measures documented? | X | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Implementation and operation** | | | |
| 10.8 | Are roles and responsibilities related to biorisk management defined and documented? | X | | |
| 10.9 | Is a senior manager designated to oversee the biorisk management system? | | | |
| 10.10 | Has a biorisk management committee been established? | | | |
| 10.11 | Has a biorisk management advisor (or biological safety officer) been designated? | | | |
| 10.12 | Is this advisor providing advice and guidance on biorisk management? | | | |
| 10.13 | Has this advisor delegated authority to stop work if necessary? | | | |
| 10.14 | Does personnel have access to occupational health services? | | | |
| 10.15 | Has a facility manager been designated to manage facilities, containment equipement and buildings? | | | |
| 10.16 | Has a security manager been designated? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 10.17 | Has an animal care manager been designated, in case the laboratory handles animals? | | | |
| 10.18 | Are qualifications, experience and aptitudes relating to biorisk considered as part of the recruitment process? | | | |
| 10.19 | Is there mechanism/s to ensure that personnel is competent (e.g. successful completion of training, ability to perform tasks under supervision)? | | | |
| 10.20 | Is personnel regularly trained on biorisk management? | X | | |
| 10.21 | Is an up-to-date biological agent and toxin inventory established and maintained? | | | |
| 10.22 | Are desinfection and decontamination procedures implemented effectively? | | | |
| 10.23 | Are waste management procedures implemented effectively? | | | |
| 10.24 | Are personal protective equipment and clothing used appropriately? | | | |
| 10.25 | Can personnel access prophylactic or emergency treatment in case of exposure to contaminated materials? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 10.26 | Is a vaccination policy defined and implemented? | | | |
| 10.27 | Is behaviour of personnel safe (e.g. no mouth pipetting, no recaping of needles, no smoking, no food stored in working areas)? | | | |
| 10.28 | Are the facilities designed to allow to work in a safe and secure way? | | | |
| 10.29 | Is there a formal commissioning process of new facilities? | | | |
| 10.30 | Are equipments and elements of the physical plant that may impact on biorisk identified? | | | |
| | If yes or partial, are these equipments and elements: | | | |
| 10.31 | Correctly certified or validated, in line with the manufacturer or regulations' requirements? | | | |
| 10.32 | Correctly maintained? | | | |
| 10.33 | Are appropriate security measures in place to minimize potential unappopriate removal or release of biological agents (e.g. theft, earthquake, flood)? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 10.34 | Is access to sensitive information (e.g. inventory of agents and toxins) controlled by adequate policies and procedures? | | | |
| 10.35 | Are procedures for a safe and secure transport of culture, specimens, samples and other contaminated materials established? | | | |
| 10.36 | Are emergency plans available (e.g. in case of explosion, fire, flood, worker exposure, accident or illness, major spillage)? | X | | |
| 10.37 | Are emergency situation simulation exercices including security drills conducted at regular intervals? | | | |
| 10.38 | Are contingency measures planned in the event of an emergency or unforeseen event (e.g. power failure)? | X | | |
| 10.39 | Are biorisk documents and records controlled and managed as part of the laboratory document management system? | | | |
| 10.40 | Are accident/incident and nonconformities related to biorisk correctly managed (i.e. reported, recorded, investigated, and leading to preventive or corrective actions)? | X | | |
| 10.41 | Do planned inspection or audit/s include assessment of the biorisk management system? | | | |
| 10.42 | Is there a regular review of the biorisk management system? | | | |

**Comments**

# 11. Public health functions

*Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable*

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| | **Surveillance and response** | | | |
| 11.1 | Does the laboratory know the designated reference laboratories? | | | |
| 11.2 | Is the laboratory part of surveillance network/s for endemic communicable diseases (e.g. HIV, parasitic diseases, hepatitis)? | | | |
| 11.3 | *If yes, please specify:* | | | |
| 11.4 | Is the laboratory part of surveillance network/s for epidemic-prone diseases (e.g. measles, rotavirus, meningitis)? | | | |
| 11.5 | *If yes, please specify:* | | | |
| 11.6 | Is the laboratory part of surveillance network/s for non-communicable diseases (e.g. diabetes, cancer)? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 11.7 | *If yes, please specify:* | | | |
| 11.8 | Has the laboratory defined responsibilities in national preparedness and response to public health emergencies like outbreaks? | | | |
| 11.9 | *If yes, please specify:* | | | |
| 11.10 | Are specific instructions or guidelines for laboratory investigation of public health events available? | X | | |

**Specimens**

| | | | | |
|---|---|---|---|---|
| 11.11 | Does the laboratory receive specimens from the field during the investigation of public health events or public health surveys? | | | |
| 11.12 | Does the laboratory give advice on specimen collection and transport practices from the field during the investigation of public health emergencies? | | | |
| 11.13 | Does the laboratory have a stock of emergency laboratory sampling kits (personal protective equipment, sample collection material, transport media)? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 11.14 | Does the laboratory receive specimens or isolates from clinical laboratories for public health purpose (e.g. routine surveillance, outbreak investigation)? | | | |
| 11.15 | Does the laboratory refer specimens or isolates to reference laboratories for public health purpose (e.g. routine surveillance, outbreak investigation)? | | | |

**Reporting**

| | | | | |
|---|---|---|---|---|
| 11.16 | Is a list of notifiable diseases the laboratory must report available? | X | | |
| 11.17 | Is reporting to public health authorities established and implemented? | | | |
| 11.18 | If yes, is there a standardized form/document to report notificable diseases or other events? | X | | |
| 11.19 | Does the laboratory send aggregated data on a weekly or monthly basis to public health authorities? | | | |
| 11.20 | Does the laboratory send aggregated data on a weekly or monthly basis to reference laboratory(ies)? | | | |
| 11.21 | If applicable, is information provided to clinicians about AST patterns? | | | |

| | | Documents to be collected | 1; 2; 3; 4 | Provide here the answer to the open question/s and/or insert any additional information |
|---|---|---|---|---|
| 11.22 | If applicable, is information provided to epidemiologists about AST patterns? | | | |

**Comments**

# 12. Gap analysis

What are the biggest needs/weaknesses in the laboratory?

*Score from 0 (no gap) to 5 (high gap) for the points below and please provide comments for the area/s that display the biggest weaknesses (scores 4 and 5)*

| | | 0; 1; 2; 3; 4; 5 | Comments |
|---|---|---|---|
| 12.1 | Financial resources for laboratory activities | | |
| 12.2 | Human resources – qualifications and availability of suitable laboratory staff | | |
| 12.3 | Equipment adequacy | | |
| 12.4 | Equipment calibration and maintenance | | |
| 12.5 | Reagent and consumable quality | | |
| 12.6 | Reagent and consumable availability and delivery | | |

Annex 2: LAT/Facility - Gap analysis

| | | | |
|---|---|---|---|
| 12.7 | Specimen collection standardization and quality | | |
| 12.8 | Guidelines on laboratory practices | | |
| 12.9 | Transportation of specimens | | |
| 12.10 | Laboratory organization, service delivery structure | | |
| 12.11 | Regulatory framework | | |
| 12.12 | Data management | | |
| 12.13 | Laboratory safety or security | | |
| 12.14 | Quality assurance | | |

| | | | |
|---|---|---|---|
| 12.15 | Political commitment (national laboratory policies, budget, etc.) | | |
| 12.16 | Other | | |
| | *For other, please specify:* | | |

**Comments**

# Laboratory Facility Assessment Questionnaire Report

| General comments on the assessment | Conclusions and recommendations |
| --- | --- |
| | |

# Acronyms referred to in this document

| | |
|---|---|
| AST | Antimicrobial Susceptibility Testing |
| BSC | Biosafety Cabinet |
| CO2 | Carbon Dioxide |
| CSF | Cerebrospinal Fluid |
| DNA | Deoxyribonucleic acid |
| ELISA | Enzyme-linked immunosorbent assay |
| EQA | External Quality Assessment |
| HIV | Human Immunodeficiency Virus |
| HR | Human Resources |
| IQC | Internal Quality Control |
| ISO | International Organization for Standardization |
| IT | Information Technology |
| LIS | Laboratory Information System |
| NGO | Non-Governmental Organization |
| PCR | Polymerase Chain Reaction |
| TB | Tuberculosis |
| UPS | Uninterruptable Power Supply |
| UV | Ultraviolet |
| WHO | World Health Organization |