

Supplemental III: Laboratory response checklist for infectious disease outbreaks

1. Laboratory investigation

1.1. Specimen collection and transportation: To support timely, coordinated laboratory investigation, identify and document specimen collection and transportation needs in advance, including:

- 1.1.1. Appropriate specimen types, volumes and amounts; to be reassessed as required
- 1.1.2. Appropriate specimen container(s) for transportation as per Risk Group classification
- 1.1.3. Detailed specimen container packaging and labeling instructions
- 1.1.4. Cold chain management requirements, i.e. temperature and timelines for shipping/arrival
- 1.1.5. Transportation of Dangerous Goods (TDG) documentation requirements
- 1.1.6. Preferred courier service recommendations in alignment with pathogen risk classification
- 1.1.7. Geographic considerations impacting the transportation of specimens and essential testing equipment and supplies for remote and isolated populations
- 1.1.8. Biosafety, biosecurity and infection control guidelines, protocols, equipment and supplies required to support specimen handling and processing within clinical, laboratory and field response settings, including:
 - 1.1.8.1. Personal protective equipment (PPE), specimen collection and transport materials (e.g. swabs, viral transport medium (VTM))
 - 1.1.8.2. Containment measures (e.g. biological safety cabinets) and decontamination methods
 - 1.1.8.3. Specimen retention, storage and disposal requirements
- 1.1.9. Additional documentation requirements and considerations within existing legislative and regulatory frameworks, including:
 - 1.1.9.1. Import and export permits
 - 1.1.9.2. Material transfer agreements between client and laboratory entities (e.g. to support distribution of reagents, controls, validation/proficiency panels)
 - 1.1.9.3. Alignment of specimen collection requirements with existing data sharing agreements
 - 1.1.9.4. Laboratory guideline, licensing and certification requirements relevant to the investigation of a new/emerging infectious agent (e.g. FDA, HC, HPTA, HPTR requirements)
 - 1.1.9.5. Emergency response assistance plans and protocols for transport (e.g. ERAP for Risk Group 4 pathogens, and engagement of Regional Response Coordinators)

- 1.1.10. Drafting of a specimen flow chart to guide collection and transport requirements

1.2. Laboratory testing: To support laboratory investigation efforts; review, develop, document and communicate evidence-based ID testing recommendations and protocols in collaboration with public health partners, with consideration of:

- 1.2.1. Diagnostic algorithm(s) to be used for laboratory confirmation of case investigations, to inform and/or align with the current ID case definition (which may be outbreak-specific)
- 1.2.2. Testing criteria and triaging protocols for high volume testing, using available knowledge of exposure history (e.g. close contact, travel history) and other risk factor information (e.g. pregnancy, hospitalization status)
- 1.2.3. Test Requisition Form (TRF) data field requirements, in alignment with the ID case definition to support timely and effective case management and public health response
- 1.2.4. Specimen acceptance and rejection criteria
- 1.2.5. Specimen retention and storage protocols (for diagnostic, surveillance and research purposes)
- 1.2.6. Quality control and standardization of laboratory testing methods and reporting processes within the context of a quality management system, including:
 - 1.2.6.1. Validation, verification and comparison of diagnostic laboratory test performance specifications; including sensitivity, specificity, accuracy and precision
 - 1.2.6.2. Implementation and use of Standard Operating Procedures (SOPs)
 - 1.2.6.3. Monitoring and assessment of laboratory test turn-around times (upon specimen receipt)
- 1.2.7. Test result reporting requirements, including:
 - 1.2.7.1. Use of standardized test result communication processes, report forms, and terminology
 - 1.2.7.2. Possible need to report 'preliminary' results prior to issuance of a final report
 - 1.2.7.3. Ability to support result reporting for submitted specimens vs. case investigations
- 1.2.8. Alignment and standardization of test methods and interpretation criteria across decentralized testing sites/jurisdictions to support accurate, consistent case reporting and surveillance efforts
- 1.2.9. Review and updating of testing-related processes and protocols to support evolving outbreak response requirements in keeping with current scientific evidence
- REVIEW COMPLETE - LABORATORY INVESTIGATION**

2. Laboratory response capacity and training

2.1. Laboratory response capability: To address laboratory response challenges specific to the ID threat, collaboratively assess the following with public health laboratory partners on an ongoing basis:

- 2.1.1. Laboratory capabilities for pathogen identification and characterization, including front-line screening and confirmatory testing methods at all jurisdictional levels (i.e. hospital, regional, provincial/territorial (P/T), state, national and international)
- 2.1.2. Availability of validated diagnostic testing methods (e.g. serological, molecular, subtyping, genomic, proteomic), including commercially available kits and lab-developed tests (LDTs)
- 2.1.3 Performance characteristics of currently used diagnostic test methods, including sensitivity, specificity, turn-around times, and throughput using current platforms
- 2.1.4. Requirement to develop and validate LDTs where external capacity does not exist, or is not reliably accessible during an outbreak
- 2.1.5. Decentralized diagnostic testing capabilities and potential for technology transfer to improve national laboratory response capacity, dependent upon magnitude and duration of response
- 2.1.6. Access to testing by at-risk and under-served populations, including the need to pursue alternate testing strategies to support geographically remote and/or isolated populations (e.g. use of point-of-care testing approaches, enhanced community engagement models)
- 2.1.7. Ongoing availability of critical equipment and reagents via established vendors and supply chains
- 2.1.8. Availability of essential laboratory supplies via local, regional and national emergency stockpiles (e.g. PPE, swabs, reagents)
- 2.1.9. Requirement to coordinate the sourcing of laboratory supplies via multiple vendors, with a particular focus on domestically produced supplies (e.g. specimen collection devices and containers, laboratory disposables, chemicals/reagents)
- 2.1.10. Capacity to support ongoing clinical validation activities as needed to verify the quality of all laboratory supplies, particularly when dealing with multiple and/or frequently changing vendors due to supply chain continuity issues
- 2.1.11. Ability to acquire specimens from the international community to support the development of diagnostic tools to detect novel pathogens emerging in international settings

2.2 Surge capacity and training: To support flexible, scalable and timely laboratory response to ID threats, dynamically assess requirements related to the following surge capacity considerations:

- 2.2.1. ID-related scientific expertise and technical response capacity amongst current staff

- 2.2.2. Availability of laboratory space, biocontainment facilities, testing equipment and consumables (e.g. biological safety cabinets, autoclaves, dedicated PCR workstations, testing platforms, reagents, extraction kits, PPE, swabs, VTM)
- 2.2.3. Identification of available 'surge capacity' positions that can be internally mobilized and/or cross-trained to mitigate workload issues across various laboratory response functions (e.g. via organization-wide, response-oriented personnel inventory and surge mobilization processes)
- 2.2.4. Cross-training needs and priorities (e.g. core competencies, testing and equipment proficiencies, data entry/management skills to support high volume reporting)
- 2.2.5. Standardized approaches for training and documentation of personnel proficiencies (e.g. testing methods; data collection, analysis and interpretation)
- 2.2.6. Engagement of dedicated Emergency Operations Centre (EOC) support to enhance response capacity within an Incident Command System (ICS)
- 2.2.7. Identification of funding constraints, and opportunities to access emergency funding mechanisms
- 2.2.8. Alternative approaches to work-shift scheduling to increase available person-hours during heightened response periods
- 2.2.9. Explore options for strategic short and long-term staffing of positions with in-demand skill sets (scientific, technical and program support) to address capacity shortfalls due to increased workloads, alternate work arrangements, and anticipated EID illness/self-isolation requirements
- 2.2.10. Mobile laboratory capacity to support ID outbreak field response requirements, both domestically and internationally
- 2.2.11. Laboratory test throughput assessment, including the identification of any bottlenecks
- 2.2.12. Available technologies with the potential to facilitate surge capacity development, including:
 - 2.2.12.1. Alternate testing platforms to increase testing throughput
 - 2.2.12.2. Training videos, e.g. to demonstrate specimen collection requirements
 - 2.2.12.3. Web-based information exchange and data sharing tools and platforms
- 2.2.13. Risk mitigation planning to address operational vulnerabilities observed during all phases of the laboratory response effort
- 2.2.14. Participation in preparedness assessment exercises (including joint simulations) with interjurisdictional, interdisciplinary public health partners involved in coordinated ID response (e.g. epidemiologists, physicians, field investigators); typically during inter-outbreak periods
- REVIEW COMPLETE - LABORATORY RESPONSE CAPACITY AND TRAINING**

3. Laboratory surveillance and data management

3.1. Laboratory-based surveillance and data management: To support timely and integrated laboratory-based ID surveillance activities, key considerations are as follows:

- 3.1.1. Assess the current surveillance status of the ID at all jurisdictional levels including the existence of, or requirement for:
 - 3.1.1.1. An established case definition to support case investigation and confirmation using laboratory and epidemiological criteria within the current outbreak context
 - 3.1.1.2. Alignment of case confirmation criteria between reporting jurisdictions to ensure national consistency of case counts, reporting, surveillance and response efforts
 - 3.1.1.3. Reporting/notification processes for suspected and/or confirmed cases at each jurisdictional level (subnational, national, international (e.g. IHR reporting obligations))
 - 3.1.1.4. Dedicated, site-based laboratory liaison personnel to support real-time reporting of laboratory-generated intelligence and surveillance data, to inform public health response activities (e.g. daily, national lab-confirmed case reporting by jurisdiction; % positive tests for populations of interest; changes to laboratory testing algorithms, specimen acceptance criteria)
 - 3.1.1.5. Surveillance systems/platforms capable of supporting timely ID detection, reporting, outbreak monitoring and development of risk models within the current response context
 - 3.1.1.6. Information management and information technology (IM/IT) support for data transfer pipelines and bioinformatics tools needed to acquire and analyze genomic (e.g. whole genome sequencing (WGS)) and other 'omics' data
- 3.1.2. Identify laboratory-based surveillance considerations related to ID case/outbreak detection, confirmation, characterization, monitoring and reporting, including:
 - 3.1.2.1. Current knowledge of ID epidemiology, natural history and ecology to inform laboratory testing strategies and triage recommendations
 - 3.1.2.2. Monitoring and classification of laboratory investigations in alignment with established case definition criteria (e.g. suspect case under investigation, probable positive case, laboratory-confirmed case, not a case/discarded)
 - 3.1.2.3. Key laboratory and epidemiological data elements necessary to inform laboratory investigation processes, including triaging of specimens, diagnostic algorithm selection, result interpretation, data linkage, and case classification and confirmation efforts (e.g. unique case identifiers, test history, symptom onset date, travel history, other risk factors, etc.)
 - 3.1.2.4. Data linkage and integration requirements to support timely surveillance and response, e.g.:
 - linkage of specimens and associated test result(s) with the case under investigation
 - linkage of laboratory and epidemiological case data held by separate public health jurisdictions
 - linkage of confirmed cases with a given outbreak, or outbreak source

- 3.1.2.5. Laboratory-confirmed case review, verification, monitoring and reporting processes
- 3.1.2.6. Molecular epidemiology/public health genomics approaches to support ID strain surveillance, outbreak characterization and source attribution
- 3.1.2.7. Feasibility of using web-based tools and public health informatics platforms to support timely, secure information sharing and linkage of case investigation data from disparate public health sources
- 3.1.2.8. Design and development of surveillance reports to support ongoing laboratory-based monitoring, assessment and reporting of ID outbreak information, e.g.:
 - Monitoring the status of laboratory investigation processes (real-time)
 - Laboratory-confirmed case counts (e.g. cumulative totals, new cases/unit time)
 - Final classification of laboratory investigations across target populations (e.g. % positive tests vs. total tests performed, % laboratory-confirmed)
 - Distribution of laboratory-confirmed cases using available data (i.e. by age, sex, geography, exposure history, other risk categories (e.g. healthcare workers (HCW), race/ethnicity))
 - Molecular epidemiology of the outbreak (e.g. case linkage, source attribution)
 - Estimation of lab-based indicators to monitor and assess surveillance performance (e.g. timeliness, laboratory-based ID investigation rates, data quality and completeness)
- 3.1.2.9. Legislative context and agreements relevant to interjurisdictional sharing of information and data to support ID laboratory investigation activities (e.g. MLISA, IHR)
- 3.1.3. Align laboratory test requisition form TRF data fields with the ID case definition to support effective surveillance and response, with consideration of the following key data field types:
 - 3.1.3.1. **Submitting laboratory/client contact information** to support result reporting and other communication to inform clinical decision-making
 - 3.1.3.2. **Unique identifiers** to enable non-nominal, interjurisdictional linkage of laboratory result(s) with the case under investigation to support accurate case classification, reporting, clinical decision-making, surveillance and response
 - 3.1.3.3. **Geolocator information** for the case under investigation, as jurisdictionally relevant (e.g. city, reporting health region, province/territory/state, country, postal code, forward sortation area (i.e. three-digit postal code))
 - 3.1.3.4. **Clinical, epidemiological and laboratory fields** needed to support triaging of high priority specimens, appropriate test algorithm selection and result interpretation; as well as case confirmation, targeted surveillance and reporting (e.g. test history, travel/exposure history, immunization history, pregnancy, hospitalization status, symptomatic vs. asymptomatic, other enhanced risk group information)
 - 3.1.3.5. **Date fields** needed to support diagnostic algorithm selection, test result interpretation, and to estimate laboratory-based surveillance indicators (i.e. symptom onset, specimen collection, specimen receipt, test result and case reporting dates)
- 3.1.4. Assess laboratory information management system (LIMS) data flow requirements, and implement LIMS processes to support ID investigation, surveillance and response, including:

- 3.1.4.1. Standardized approaches to the documentation and monitoring of test requisition, specimen tracking, data entry/review, data linkage and result reporting processes
- 3.1.4.2. Terminology standardization, mapping of data flows, and definition of data retention/life cycle requirements
- 3.1.4.3. 'Chain of custody' documentation requirements for high-profile laboratory investigation and result reporting (e.g. microbial forensics)
- 3.1.4.4. Development of customized queries to support ongoing surveillance and response
- 3.1.4.5. Summary report generation to facilitate monitoring, assessment and reporting of laboratory-based ID surveillance and outbreak response activities
- 3.1.4.6. Use of web-based tools and platforms to support test requisition and reporting, as well as timely interjurisdictional linkage of case investigation data
- 3.1.5. Dynamically assess and address operational vulnerabilities impacting overall response and reporting efforts, including:
 - 3.1.5.1. External communication and interjurisdictional reporting challenges
 - 3.1.5.2. Interjurisdictional differences in laboratory testing algorithms and result interpretation
 - 3.1.5.3. Changes to interjurisdictional confirmed case definitions that may impact surveillance
 - 3.1.5.4. Data linkage issues impacting accuracy and timeliness of case counting and reporting
 - 3.1.5.5. Challenges in the collection of enhanced 'risk group' data to support timely laboratory investigation, as well as epidemiological analysis of ID impacts specific to at-risk populations
- REVIEW COMPLETE – LABORATORY RESPONSE CAPACITY AND TRAINING**

4. Interjurisdictional engagement and communication

4.1. Interjurisdictional engagement and communication: To support coordinated public health stakeholder engagement and consistent messaging of laboratory information, develop a strategic communication strategy incorporating the following considerations:

- 4.1.1. Accessibility of current ID laboratory response information to the public and to public health professionals via:
 - 4.1.1.1. Web-based content and social media tools
 - 4.1.1.2. A 24-hour emergency contact number that provides urgent access to laboratory support services

- 4.1.1.3. A public-facing 'Guide to Laboratory Services', including specimen and test requisition requirements
- 4.1.1.4. Laboratory testing recommendations and guidance documents to support decision-making by clinical and public health partners
- 4.1.1.5. Alerting and notification processes that simultaneously disseminate time-sensitive information to interjurisdictional public health decision-makers
- 4.1.2. Engagement of external laboratory partners, public health networks and interjurisdictional working groups involved in the coordination of ID public health response, including:
 - 4.1.2.1. Physician networks and committees responsible for clinical guideline development
 - 4.1.2.2. Public health laboratory and epidemiology partners, and interjurisdictional networks responsible for developing consensus case definitions, and coordinating public health surveillance and intervention activities
 - 4.1.2.3. Biosafety networks and partners involved in the development of biosafety guidelines
 - 4.1.2.4. Policy makers responsible for evidence-based policy development and implementation to support public health action
- 4.1.3. Strengthened mechanisms for collaboration and information sharing with public health partners and networks to enable:
 - 4.1.3.1. Evidence-based development of laboratory and clinical recommendations and guidelines, and public health surveillance and intervention strategies
 - 4.1.3.2. Consistent public health messaging of specimen collection and testing guidelines and recommendations for identified at-risk groups
 - 4.1.3.3. Alignment of ID case definitions used at multiple jurisdictional levels, including international case definitions where feasible
 - 4.1.3.4. Consensus regarding laboratory-confirmed case inclusion and exclusion criteria
 - 4.1.3.5. Accurate and consistent case classification, counting and reporting in fulfillment of P/T, state, national and international surveillance requirements
 - 4.1.3.6. Updating of publicly available web-based content to support coordinated laboratory response efforts and evidence-based public health decision-making
- 4.1.4. Review and revision of external communication and reporting processes to address:
 - 4.1.4.1. Challenges impacting the timeliness of external reporting of ID cases and test results to inform clinical decision-making and public health action
 - 4.1.4.2. Inconsistencies and interjurisdictional differences in testing algorithms, result interpretation, case confirmation and surveillance processes

- 4.1.4.3. Required changes to test reporting algorithms and information sharing methods
- 4.1.4.4. Data sharing and linkage issues impacting timeliness of confirmed case reporting
- 4.1.5. Event-specific internal communication and reporting structures and mechanisms needed to support coherent, effective information sharing and public health messaging, including:
 - 4.1.5.1. Identification of a lead subject matter expert (SME) responsible for scientific oversight of ID-specific laboratory response efforts (e.g. field deployment activities, participation in targeted research and surveillance studies)
 - 4.1.5.2. A 'single-window' point of contact responsible for coordinating the receipt and distribution of event-specific information within the organization (e.g. EOC support)
 - 4.1.5.3. Appropriate routing mechanisms for external requests received within the organization (e.g. public health stakeholder requests for information, outbreak support, media-related communications, etc.)
- REVIEW COMPLETE – INTERJURISDICTIONAL ENGAGEMENT AND COMMUNICATION**

5. Research and ethics

5.1. Research requirements and ethical considerations: To advance scientific research in support of public health action, consider the following laboratory-related issues in collaboration with public health partners:

- 5.1.1. ID-specific applied and basic research requirements and priorities, e.g.:
 - 5.1.1.1. Pathogen identification and characterization studies (phenotypic, genomic, proteomic)
 - 5.1.1.2. Diagnostic and confirmatory reference test method development
 - 5.1.1.3. Participation in the rapid assessment/validation of critical testing supplies, methods and platforms, e.g. via public health/private industry collaborations
 - 5.1.1.4. Immunity-related ID research, including host immune response (nature and duration) and population-level seroprevalence studies
 - 5.1.1.5. Transmission studies to identify and characterize primary routes of infection, with particular consideration of at-risk groups and populations
 - 5.1.1.6. Development of risk models using the best available evidence, including predictive models to inform public-health decision-making
 - 5.1.1.7. Field studies, vector competency studies
 - 5.1.1.8. Vaccine and other medical countermeasure development and assessment

- 5.1.1.9. Applied biosafety research with a focus on timely knowledge translation
- 5.1.1.10. Public health surveillance studies requiring research ethics approval
- 5.1.2. Clear differentiation between applied public health research projects that will require research ethics approval, and routine laboratory-based pathogen investigation, characterization and surveillance activities that are integral to timely public health response
- 5.1.3. Prioritization of research-associated testing activities within the context of available laboratory capacity and resources to support broader public health response (e.g.: participation in EID response task forces, networks and other multi-disciplinary research initiatives)
- 5.1.4. Ethical, safety and environmental requirements relevant to investigation of the ID agent using the proposed methods and study design(s)
- 5.1.5. Patient consent requirements having the potential to impact laboratory testing for public health research purposes
- 5.1.6. Available mechanisms to address consent-related concerns (e.g. development/updating of patient consent and test requisition forms)
- 5.1.7. Procurement requirements and availability of relevant animal models and vectors
- 5.1.8. Research Ethics Board (REB) approval requirements (human and animal), including coordination of multiple REB approval processes to support interjurisdictional collaboration
- 5.1.9. Authorship and intellectual property considerations associated with interjurisdictional collaboration and publication
- 5.1.10. Requirements for timely analysis and publication of research findings to inform public health decision-making
- 5.1.11. Ongoing review and re-assessment of ID research priorities (applied and basic) within the context of current scientific evidence and evolving ID response requirements
- 5.1.12. Identification of strategic partnerships and funding opportunities to advance research objectives
- 5.1.13. Maintenance of REB approval status for ongoing research projects

- REVIEW COMPLETE – RESEARCH AND ETHICS**