Department of Primary Industries
Department of Regional NSW

Procedure - Use of point of care tests for prohibited matter

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Category:	Operations and Industry	Review date:	30 June 2025

Scope:

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This procedure should be read in conjunction with the Policy - Point of Care tests for prohibited matter in NSW, Management of animal biosecurity in NSW, Surveillance for diseases of animals and aquatic pests, Endemic diseases of animals, Prohibited matter pests and diseases of animals and Procedure - Reporting notifiable pests and diseases of animals and biosecurity events. Disease-specific procedures, exemption orders and prohibited matter permits should be consulted prior to the use of any point of care test (PoCT) for a prohibited matter for additional requirements related specific PoCTs

This procedure applies to all PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter in NSW. This includes any in vitro test developed for the diagnosis or screening for prohibited matter (listed in Schedule 2 of the Biosecurity Act 2015) where its intended use is at any location other than the State Veterinary Diagnostic Laboratory (SVDL). Note: PoCT containing prohibited matter as a reagent or control are outside the scope of this procedure. It is prohibited to develop, manufacture, import, distribute and use tests containing prohibited matter under the Act.

This procedure does not apply to any PoCT to be used to test for biosecurity matter other than prohibited matter. Operators of PoCT for biosecurity matter other than prohibited matter should make their own assessment of fitness for purpose and diagnostic value.

This procedure applies to all developers/ manufacturers of PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter.
This procedure applies to all operators of PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter. This includes government veterinarians, private veterinary practitioners and other staff who are authorised to investigate outbreaks of suspected notifiable diseases of animals and/or aquatic pests under the Biosecurity Act 2015, Local Lands Services Act 2013 and Veterinary Practice Act 2003, as well as any other class of persons specified in an exemption order or prohibited matter permit for a specific PoCT.

This procedure applies to domestic animals, animals held in captivity, and wildlife (free-living animals and feral animals). Diseases of animals include conditions caused by both infestation and

Sources: [Enter sources]

infection with disease agents, formerly referred to in animal biosecurity policies and procedures as ‘pests and diseases of animals.

Management of the biosecurity risk

Where a PoCT for prohibited matter has achieved Sub-committee on Animal Health Laboratory Standards (SCAHLS) or World Organisation for Animal Health (WOAH) accreditation or provisional recognition in NSW, its use may be allowed under a prohibited matter permit or exemption order. Misuse or misinterpretation of these tests and reporting of inaccurate test represents a significant biosecurity risk with implications for producers, vets, communities, and industries. PoCT for prohibited matter must be used by authorised, trained and competent operators, according to manufacturer and regulatory standards in order to minimise the risk of a biosecurity event occurring.

This procedure describes the minimum requirements for use of a POC tests for prohibited matter in NSW.

Biosecurity legislation summary

Biosecurity Duty
A person, other than an authorised officer, who owns or is caring for animals, or a person working in their professional capacity such as a veterinarian has a duty to immediately notify an authorised officer if they suspect, or are aware, that an animal is infested or infected with prohibited matter.

Disclosure of information
The collection, use and disclosure of information in accordance with this procedure, including any internal or external discussion or distribution of information, must be in compliance with the Privacy and Personal Information Protection Act 1998 or be exempted by the operation of section 387 of the Act.
Section 387 (2) of the Act provides authority for the disclosure of information about a person, without the consent of the person: to a public sector agency, or to any other person, but only if the disclosure is reasonably necessary for the purpose of exercising a biosecurity risk function.

Work health and safety

The Work Health and Safety Act 2011 places an obligation on the agency (NSW DPI and LLS) as a person conducting a business or Undertaking and workers to provide a safe and healthy workplace. Safe Work Method Statements that support activities included in this procedure must be used in identifying, assessing and controlling risks.

NSW DPI and LLS will work together to create a safe and supportive work environment when undertaking any activities for this procedure.

Roles and responsibilities:

- PoCT developer/distributor
    - Securing provisional recognition from NSW PoCT Working Group and NSW CVO.
    - Supplying kits that are fit for use upon leaving the supplier.
    - Supplying a clear operational procedure that includes:
        - intended use of the test including clinical circumstances and interpretation of results
        - sample collection and processing requirements
        - reagent storage
        - device calibration procedures
        - device use procedure
        - safety data sheets and safe handing practices for all samples, reagents, controls.
        - maintenance and troubleshooting procedures including device error messages and abnormal or unexpected results
        - result interpretation including critical alert limits and reference ranges
        - limitations of the use procedure including known interferences and limits of detection
        - Quality Control (QC) and External Quality Assurance (EQA) procedures and Quality Control Record Sheets
        - safe work practice and infection control information
        - requirements and processes for recording, storing and reporting results
    - Providing training in use of the device to approved operators and undertaking competency assessments. This training and assessment must occur before the operator commences using the PoCT. Depending on the timeframe for field validation, all staff performing PoCT must be reassessed for competence periodically. The interval between re-certification of competency will be dependent on the device type and frequency of use and may be varied if there is any deficiency in performance of PoCT at the testing location. Minimum intervals for re-certification are to be specified in the PoCT Validation Template for Provisional Recognition of PoCT for Prohibited Matter application for review by the NSW PoCT working group.
    - Training and competency assessment for PoCT operators should include:
        - demonstration of appropriate use of the device,
        - pre-analytical requirements including sample collection,
        - reagent storage requirements,
        - safe work and infection control practices,
        - the ability to identify results that fall outside of reference ranges,
        - device maintenance,
        - an understanding of Quality Control (QC) and Quality Assurance Program (QAP)
        - confidentiality of patient and client information
        - NSW General Biosecurity Duty
    - Maintaining records of training and competency assessment for a minimum of five (5) years and be supplied to an authorised officer upon request for the purposes of auditing or incident investigation.
    - Providing ongoing technical and clinical support for PoCT operators.
    - Reporting known or suspected issues that may alter the safety or quality of the PoCT to an authorised officer immediately. This includes use of PoCT for any purpose other than that stated in the exemption order or provisional matter permit.
    - Supporting NSW Government in management of the risks associated with PoCT for prohibited matter.
- PoCT user
    - Comply with all stipulations in the prohibited matter permit, the Policy PoCT for Prohibited Matter, manufacturer instructions and supplied operational protocols and procedures.

Sources: [Enter sources]

- Ensure they are trained and assessed as competent to use the test prior to conducting any testing.
- Report any suspicion or awareness of prohibited matter or a biosecurity event immediately per the relevant procedure/s including Procedure - Reporting notifiable pests and diseases of animals and biosecurity events. This must occur prior to performing a PoCT.
- Submit appropriate clinical samples for confirmatory testing to the state veterinary diagnostic laboratory.
- Manage all biosecurity risks associated with the PoCT result until confirmatory testing has been conducted, including:
    - maintaining confidentiality of the result,
    - appropriately mitigating work health and safety and public health risks
    - mitigating risks associated with property/animal health certification, animal movement and disease transmission or clinical decision making with high animal health/welfare impacts
- Report all PoCT results according to the Procedure - Reporting notifiable pests and diseases of animals and biosecurity events.
- Maintain accurate and complete records for all tests performed including:
    - animal, client and property identification data,
    - clinical presentation and justification for use of PoCT over (or in addition to) laboratory analysis
    - date, time and method of sample collection
    - date and time of PoCT use
    - validated result data, including the result or printout from the PoC instrument and any quality control/calibration results associated with testing
    - laboratory submission number and result from confirmatory testing
    - identity of PoCT operator and location where test occurred
    - the identification of the analyser or device
- Ensure there is a clinical governance framework in place that actively manages safety and quality risks in the delivery of PoCT that may include:
    - appointment of a PoCT testing supervisor for each organisation undertaking PoC testing, who is accountable for the conduct, quality and implementation of the tests being performed, and/or
    - development of a practice policy covering:
        - operational standards under the prohibited matter permit,
        - safe handling, storage and disposal of specimens, reagents and other consumables,
        - all aspects of device performance including calibration and internal quality control of the analytical and non-analytical characteristics in accordance with the Internal quality audit procedure and the Laboratory equipment maintenance and calibration procedure,
        - the process for escalating concerns regarding machine operation and maintenance, PoCT result validity and operator safety
        - the procedure for implementing test results in clinical decision-making with a risk-mitigation mindset
        - maintenance of records of patient results, staff training and reporting and Quality Control (QC) and Quality Assurance Program (QAP)

- NSW DPI Biosecurity and Food Safety and Local Land Services authorised officers
    - Notifications of suspected prohibited matter and concerns about PoCT result validity or test safety are managed per the Procedure - Reporting notifiable pests and diseases of animals and biosecurity events.
    - A record of results from PoCT and confirmatory testing will be maintained in an online, auditable case management system specified in the relevant prohibited matter procedure or

by the PoCT Working group as a condition of provisional recognition. PoCT results must be clearly distinguishable from results from confirmatory laboratory analysers.
    - Results from a PoCT will not be used for trade or property certification without direction from the DPI Species Coordinator or NSW CVO unless specified in the relevant prohibited matter procedure.
- NSW DPI PoCT working group
    - Notifications of concerns about PoCT result validity or test safety are investigated immediately and a recommendation is made to the NSW CVO regarding the prohibited matter permit on a risk-assessed basis.
    - Regular auditing and review processes are conducted to assess PoCT safety, validity and utility per the Procedure – Validation of PoCT for prohibited matter.

Definitions and acronyms:

- **CVO:** Chief Veterinary Offiver
- **PoCT:** Point of care test
- **LLS:** Local Land Services
- **DPI*:*** Department of Primary Industries
- **LHMS*:*** Livestock Health Management system
- **SCAHLS:** Subcommittee for Animal Health Laboratory Standards
- **NATA:** National Association testing Authorities
- **WOAH:** World Organisation for Animal Health
- **The Act:** NSW Biosecurity Act 2015

Documentation:

- Policy - Biosecurity collection, use and disclosure of information
- Policy - Information Security (IND-I-197)
- Policy – Code of Ethics and Conduct
- Procedure - Biosecurity collection, use and disclosure of information
- Policy - Point of Care tests for prohibited matter in NSW
- Policy - Management of animal biosecurity in NSW
- Policy - Surveillance for diseases of animals and aquatic pests
- Policy - Endemic diseases of animals
- Policy - Prohibited matter pests and diseases of animals
- Procedure- Biosecurity collection, use and disclosure of information
- Procedure - Reporting notifiable pests and diseases of animals and biosecurity events
- Procedure – Validation of Point of Care tests for prohibited matter.
- NSW PoCT Validation Template

Revision history:

Version	Date issued	Notes	By

Sources: [Enter sources]

1	15 November 2022	New policy developed in response to the Biosecurity Act 2015	Animal Biosecurity

Contact:

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Sources: [Enter sources]