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RCPA
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GUIDELINE

Subject: **Pathology Testing Outside the Normal Request-Test-Report Cycle**
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Background

Pathology testing in Australia is performed in an environment described by the RCPA Guideline: The Pathology Request-Test-Report Cycle - Guidelines for Requestors and Pathology Providers. The usual components of this cycle are a request made by a medical practitioner, a test performed in an accredited laboratory and a report given to the requesting doctor who will then decide on appropriate further action. A pathologist or other employee of a pathology laboratory may play a role in all aspects of this cycle with advice on the appropriate test to use for the specific clinical situation and assistance in interpretation of the result, in addition to the roles in ensuring quality in sample handling, analysis and result transmission. Pathology testing may however be carried out in environments where these factors do not readily apply and this may have implications for the delivery of high quality laboratory testing. Some examples of such tests are the Non-Invasive Prenatal Test, Lyme disease and Genetic testing. Variations may occur in all components of the request-test-report cycle as follows:

1. **The Requesting Phase**
   While most pathology tests will be requested by, or on behalf of, a registered medical practitioner, some tests may also be requested by a wide range of people who are not registered medical practitioners. These may include those who are part of current medical services (such as nurses, dieticians, physiotherapists and dentists); alternative health practitioners including acupuncturists, homeopaths and chiropractors; and importantly patients themselves through direct-to-consumer (“DTC”) testing.

2. **The Testing Phase**
   While most pathology testing in Australia is performed in a laboratory accredited under the NATA/RCPA accreditation program, some testing can also occur in many environments outside the accredited laboratory setting. These may include other medical settings such as ward testing or general practice premises; in a patient’s home using point of care testing devices; in research organisations, often as part of establishing a new test or as part of a research program process; and in commercial laboratories without accreditation. The setting for some laboratory testing may be overseas and not generally answerable to Australian regulatory processes.

3. **The Reporting Phase**
   The test result may be returned to any of the requestors as indicated in (1) above, or forwarded to another person for assistance with interpretation. Appropriate interpretation of a pathology result requires knowledge of the patient as well as knowledge of the test.

The aim of the current Pathology structures and regulatory framework around the request-test-report cycle are, in brief, to ensure the right test is performed on the right patient to give the right answer which is interpreted correctly. The role of the pathologist and the accredited laboratory in the traditional setting are to ensure, as far as possible, that these goals are achieved. Similarly the current accreditation and supervision environment provides assurance that only appropriately requested, analysed and reported tests are offered and they are validated as being technically suitable for use.

When tests are used outside the standard request-test-report cycle, there is a professional requirement for the laboratory and for any involved medical practitioners to ensure that the testing

process leads to a beneficial outcome. Pathology testing, when done incorrectly or inappropriately, can result in significant risk or potential for adverse outcome for the patient in terms of incorrect, inaccurate or spurious diagnosis, initial costs, anxiety about the results and the time, invasiveness and costs of any follow-up testing. Inappropriate or improperly performed testing may also have consequences for the health system with the time and expense of further investigation of patients, when the initiating event is an abnormal finding of unknown significance or of inappropriate care provided in response to incorrect diagnosis.

Responsibilities of the key participants
Each participant (requestor, laboratory, and interpreter) must be aware of the limitations of the other participants in the cycle. For example if a laboratory is offering services directly to a patient, there is a greater responsibility to ensure the customer is provided with sufficient information prior to deciding to proceed with the test and to act appropriately in response to the test. Similarly if a requestor is using a non-accredited laboratory service there is a greater need to consider whether the test is going to benefit the patient and will be performed to a suitable quality.

Responsibility of the requestor
The requestor should ensure that:

- the test requested will be of clinical utility.
- the patient has given informed consent (including costs, possible follow-up processes).
- the selected laboratory is equipped and qualified to perform the test
  there are procedures in place to follow-up any unexpected results
- the patient should given the option of nominating their regular medical practitioner to receive copies of the results.

Responsibility of the laboratory
The laboratory should ensure the:

- provision of information on the clinical utility of the test is relevant to the requestor.
- technical validity of the result (including QC, QA, interferences etc).
- integrity of the data flow (result on the right patient).
- provision of interpretive support relevant to the interpreter.

Responsibility of the interpreter
To ensure he interpreter has sufficient knowledge of the:

- test to ensure correct interpretation
- patient to ensure correct interpretation.

Guidelines on the Clinical Validation and Demonstration of Clinical Utility of Assays Falling outside the Normal Request Test Report Cycle
In circumstances where testing is performed outside the normal test–request-report cycle the College strongly advocates the following Guidelines so as to minimize the risk of harm to patients.

1. Pathology tests should not be used for clinical management before they have been adequately validated both analytically and clinically, or that have yet to demonstrate clinical utility.
2. Criteria for clinical and diagnostic utility must meet the minimum standards required by regulatory bodies, such as the Therapeutic Goods Administration (TGA) and the National Pathology Accreditation Advisory Council (NPAAC). These requirements can be found at: Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (IVDs) (Fourth Edition 2018)

3. Multivariate Index Assays (MIA), may utilise for interpretation the patterns of measurement of multiple biomarkers, the details of which may not have been published due to proprietary or commercial interests. The obligations for clinical validation before diagnostic use of such proprietary assays is not obviated or lessened by the proprietary or commercial nature of such assays. These College Guidelines require that such assays must undergo the same rigour and demonstrate of technical and clinical validation as for any other IVD or diagnostic assay.