Technical Note 37 — October 2014

Issued: June 2014, Reissued October 2014

Guidelines for Laboratory Accreditation of Massively Parallel Sequencing (Next Generation Sequencing)

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Purpose

This technical note is applicable to accredited facilities and those seeking accreditation for analysis which employs Massively Parallel Sequencing (MPS) (aka Next Generation Sequencing).

The Royal College of Pathologists, Australasia (RCPA) has prepared the *Guidelines for the Implementation of Massively Parallel Sequencing* which can be sourced from the following link: http://www.rcpa.edu.au/Library/College-Policies/Guidelines/Implementation-of-Massively-Parallel-Sequencing

The Guidelines primarily relate to facilities performing clinical human testing (Medical Testing facilities). It is expected that such facilities adopt the guidelines as good practice.

In lieu of any other appropriate documentation, these Guidelines should also be considered, as appropriate, by other facilities outside of a clinical human service performing MPS.

Scope of Services provided and accreditation

It is recognised that the extent of services offered by MPS can vary greatly between facilities. These range from the provision of a full MPS service to an interpretative and reporting service only with little or no testing or control over the testing activities.

The provision of an MPS service includes multiple variables that need to be tested and several parameters to be defined empirically. These are then incorporated into the specimen QC, library preparation, sequencing, bioinformatics analysis, interpretation and reporting pipeline to arrive at diagnostically acceptable levels of accuracy.

It is an iterative process and control of the process is required to fully understand the issues and to adjust the parameters at each stage to achieve the desired confidence limits.

After consultation with the Royal College of Pathologists of Australasia and the Medical Testing Accreditation Advisory Committee NATA has defined the limitations for which accreditation can be offered in this area. These are described below:

a) Accreditation can be sought by facilities that perform the entire MPS service.
b) Accreditation can be sought by facilities which offer a sequencing service to referring facilities.
c) Accreditation can be sought by facilities that sub-contract the sequencing service provided they have a documented procedure for selecting and evaluating referral facilities as documented in ISO 15189 *Medical Laboratories - requirements for quality and competence* and the relevant NPAAC requirements.
d) Accreditation cannot be sought by facilities who only offer interpretation and reporting services for MPS i.e. who sub-contract the sequencing and bioinformatics analysis.

Where any portion of the MPS service is sub-contracted the identity of the referral facility performing the sub-contracted work must be included in the test report.
The scope of accreditation will be defined to identify which elements of the MPS service each facility performs in house.

Further information

Any questions regarding this technical note may be directed to Andrew Griffin, Deputy Sector Manager – Life Sciences in the NATA Melbourne office on (03) 9274 8200, or by email at Andrew.Griffin@nata.com.au

Any questions regarding the *RCPA Guidelines for the Implementation of Massively Parallel Sequencing* should be directed to the RCPA.

AMENDMENTS
The table below provides a summary of changes made to the document with this issue.

Section	Amendment
Scope of Services provided and accreditation	Inclusion of the scope of MPS services for which NATA is able to offer accreditation.