PIP (Program Information for Participants)

The Australian National Quality Assurance Program (ANQAP) is coordinated by the State Government of Victoria – Bundoora location.

The main focus of the program is proficiency testing of assays used in quarantine, export certification and national disease control programs. Enrolment into the program is open to all veterinary/animal health testing laboratories who have the capability to test the samples in-house.

An Official Panel will typically consist of 6 samples with a mixture of Positive and Negative samples. Sample panels are forwarded to participants as per the **Test Timetable** schedule. ANQAP aims to provide a high-quality service by:

- Selecting test samples that are homogeneous and stable, to minimise result variability within and between participants. ANQAP uses its subcontractors to test all samples for homogeneity and stability. All subcontractors chosen are NATA accredited or equivalent, where applicable, and ANQAP takes responsibility for this work.
- When a subcontractor has prepared the samples for ANQAP, they may be acknowledged in the report for that service.
- Test samples will be, as far as is technically possible, matrix samples of a similar type to those routinely analysed by most participants.
- The levels of target analytes in the samples distributed are selected to represent levels that would be measured by most participants.
- The results from all participants are collated and evaluated, and reports prepared.
- Statistical analysis of the results will be undertaken where practicable and applicable.

Confidentiality

To protect the identity of participating laboratories, each participant will be allocated a Confidential Number. The identity and confidential number of all participants will be known only to ANQAP staff. At the commencement of every Proficiency Testing Scheme (PTS), participants are advised of their confidential number by email. A participant's confidential number is randomly allocated and therefore will change every year. All results for participants will be identified by confidential numbers, except for LEADDR reports or where the client has authorised the publication of their identity.

Confidential participant information will be provided to an accrediting body/regulatory authority upon request.

ANQAP Certificates of Participation

At the conclusion of the PTS, a Certificate of Participation may be issued to a participating laboratory upon request. The certificate will list the tests that the participant reported results for however the certificate will not list the classification of results. For participants who did not report results by the due date or who did not report any results, their certificate will not list the round/test which they were not classified for. The certificate will only list those tests in which the participant received a classification for. Certificates will be emailed to the nominated contact/s as stipulated on the participant's Enrolment Form.

Tests included in the program – refer to the **Test Timetable**.

Test Timetable amendments will be communicated to all participants via email and the website: https://www.anqap.com/.

Program Fees

Refer to Enrolment Form for Program Fees.

Enrolment

Registration

The ANQAP systems are set-up, and the program is run in such a way that each participant receiving test panels are counted as a separate organisation/laboratory. This helps to cover ANQAPs running costs, costs of transport, etc. Therefore, each participant must be enrolled as a separate client and the associated costs are applied.

ANQAP is required to take all necessary steps to avoid/prevent collusion between participants or falsification of results as per ISO/IEC 17043. To meet the clause, ANQAP enrol each participant separately, therefore avoiding/preventing collusion and falsification as much as possible to the best of ANQAP's control. Where collusion or falsification is suspected, the ANQAP management team will meet to discuss the issue and how to proceed with an appropriate action. A **CAR** (**Corrective Action Report**) will be raised to document the sequence of events and the outcome. This information will not be made public unless the ANQAP management team deem otherwise.

Enrolment paperwork is forwarded to interested participants before the commencement of each new cycle. It is also available on the ANQAP website. If a participant wishes to enrol in the ANQAP Proficiency Testing Program, they will need to complete the Enrolment Form via the link in the enrolment invitation email or via the link on the ANQAP website: https://www.anqap.com/.

Late enrolments can be accepted however a participant may be too late to be included in some of the scheduled tests. Invoices are payable within 30 days from the date of invoice. Sample dispatch and/or reports may be withheld where payment is outstanding.

Cancellation of participation

If a participant wishes to cancel their enrolment in the program, a partial refund may be possible if samples have not been dispatched. Notification of cancellation of participation must be in writing. If the participant wishes to cancel enrolment after the samples have been dispatched, no refund or credit will be granted. ANQAP may seek feedback from a participant that withdraws from the program.

ANQAP may request the return of a sample however it will only be accepted if the sample is in its original state that it was sent. If not, the participant should discard it as per their procedure.

Scheduled Testing

*Sample dispatch - refer to the **Test Timetable***

Once samples have been dispatched, tracking details will be emailed to participants. They are asked to notify ANQAP when they receive their samples. If the samples have been lost or damaged during transit, a new sample panel will be reissued where stock levels permit. Each sample will be clearly labelled with the test name, sample number and the nature of the sample, where applicable. The sample panels will be accompanied by a **Specimen Advice Form (SAF)**. The SAF details the sample storage and processing requirements. The participant must follow these instructions otherwise the panel/samples may be compromised in which case the panel/samples may no longer be valid to use in the test.

Majority of samples are forwarded at ambient air temperature. This method of transport and the mode of packaging have been validated by ANQAP and will not harm freeze dried samples for up to 28 days. However, ANQAP suggests samples are stored as per SAF until required for testing.

Please note that ANQAP reserves the right to refuse requests for samples at their own discretion.

Testing

Participants should treat the ANQAP samples as routine diagnostic specimens and test each sample according to their Standard Operating Procedure method by a single operator. Tests that require titration of samples must be taken out to read the endpoint for any positive samples identified. This is necessary for ANQAP to compare results, determine a consensus median and provide an accurate classification for each participant. Where an endpoint is not provided, the participant will only be classified according to their interpretation of the sample and a note of this will be made on the report.

Participants must have testing capabilities for the tests that they are enrolled in. The samples must be tested in-house and not subcontracted to another laboratory for testing. Participants who routinely subcontract tests that they are enrolled in must notify ANQAP of such practices prior to submission of results. Subcontracted results will not be analysed, and the participant will not receive a classification for that test panel. Results should be treated in confidence by participant laboratories. ANQAP's sample validation procedures only cover ANQAP's sample processing, transport and storage methods and not anyone else's methods. Therefore, subcontracting the testing to another laboratory will invalidate test results.

Reporting results

The current version of the **Result Reporting Forms** (**QF 15 Result Reporting Form** for Veterinary and **QF 81 JD Culture Result Reporting Forms** for JD Culture) must be used. These are distributed to participants at the beginning of each PTS and are also available on the ANQAP website: https://www.anqap.com/. Results must be reported electronically and emailed to ANQAP. Where applicable, ANQAP will perform **decimal point rounding to 2 decimal places**.

Results should be reported:

- **on time - late results will not be accepted under any circumstances**
- in a legible hand or typed to avoid transcription errors
- including details of the method used, copies of methods, the assay operator, the participant acronym and confidential number, cut-off limits, raw and calculated results including mean/median of replicate results where appropriate and interpretation of results (positive/negative). Any sample or test problems should also be described.

Results should be reported as they would be for routine diagnostic samples. Where participants have not provided the full details regarding method/reagents/kits used, they will be automatically excluded from the statistical analysis.

Retests

Retest samples and replacement samples are no longer available. If a participant is classified as "Minor Variation" or "Unacceptable" for a sample/s, they may be able to purchase an "Out of Schedule" sample/s to assist with troubleshooting, depending on stock availability. Participants will only have one opportunity to test and report results for each test panel after which time one "final report" will be issued for each test panel.

ANQAP Reports

Official Reports

ANQAP will not disclose any in-round results prior to the distribution of Official Reports. ANQAP will aim to issue a report to each participant within approximately eight weeks of the results due deadline. Separate reports will be prepared for each test and will indicate whether the testing was satisfactory or unsatisfactory. The report will also include a summary table of results (Collated Results Table) from all participating laboratories and where appropriate will also include test statistics (generally ELISA, CFT, VNT and HIT with sufficient participant numbers using the same kit/reagents or test method): split-level analysis will be carried out on two samples. The reports will not be personalized.

ANQAP makes every effort to avoid transcription errors however participants are requested to check that their results are entered correctly. Should any errors be identified, participants are asked to inform ANQAP as soon as possible. An amended report will be forwarded to the affected participants as soon as practicable. This report will supersede the previously issued report and will be labelled as "Amended Report". Participants are encouraged to contact ANQAP to discuss reports if further clarification is required or if they disagree with the report in any way.

On submission of all results, a median value will be calculated for each sample, if applicable. For many of the tests monitored, an acceptable variation range (AVR) will be calculated from the median and the results should fall within this range. This forms the basis on which participants are classified for each test. Tests reported as positive or negative will not have an AVR and results will be assessed on correct interpretation.

Results will be classified as:

✓ Results submitted by the participant are satisfactory as they fall within the AVR range from the median.

MV Results submitted by the participant demonstrate minor variation as results fall just outside the AVR according to the defined criteria; these results are acceptable however the minor variation is noteworthy.

U Results submitted by the participant are outside of the AVR or disagree with the consensus interpretation and are unsatisfactory.

For those participants who do not report results on time as per 'Results Due' date on the **Test Timetable**, they will receive the same report as all other participants however they will not receive a classification for the test round and a comment will be made on the report regarding the "Participant not reporting results by the due date".

Interim Reports

ANQAP will issue an "Interim Report" within two weeks of the "Results Due Date" listed on the **Test Timetable**. This report will not be NATA Accredited as the "expected classification results" will be displayed rather than the in-round test results (current Official Round results). The expected classification results will be derived from historical test results (including homogeneity, quality, stability, out of schedule, other) for each sample. The expected classification result for each sample should not differ from the current Official Round consensus classification. The interim report will not include results (AVR, median) from the current round and will only display the expected classification for each sample (i.e. Positive or Negative). The interim report should act as a guide for participants to use to self-assess their performance and implement prompt corrective action where applicable. The Official Reports will be distributed after the Interim reports.

Out of Schedule (OOS) Panels and Out of Schedule (OOS) Reports

A participant may purchase an OOS panel, where available. The samples used in the OOS panel all undergo the same treatment and validation testing requirements as the Official Panel samples. The OOS samples have been prepared in the same manner as the Official Panel samples and have been validated for both Homogeneity and Stability.

OOS reports are prepared in a similar fashion to the Official Panel reports. The OOS reports are not NATA endorsed and therefore the NATA emblem or other associated comments and statements will not be noted on the report. The reason for this is because instead of using the median and AVR to determine a participant's classification, relevant historical test data will be used.

If you would like further information regarding the OOS Panels or Reports, please contact ANQAP.

Determination of the Acceptable Variation Range (AVR)

U < MV < AVR < Median > AVR > MV > U

CFT, MAT, HIT and VNT

The acceptable variation range for the CFT, MAT, HIT and VNT is a dilution factor either side of the median value.

Example: A CFT median value of 3/32. The AVR is 3/16 to 3/64.

Results falling within this range will be classified as
Satisfactory (✓)

Results falling outside the AVR but are one dilution factor either side of the AVR will be classified as
Minor Variation (MV) - result within 3/8-3/128

Results falling outside the AVR and more than one dilution factor either side of the AVR will be classified as
Unacceptable (U) - result ≤2/8 - ≥ 4/128

AGID and RBPT

The AVR for AGID and RBPT result is one grading on either side of the median value. The exception to this is where the Consensus Median (CM) value calculated for the sample is a low positive, such as 1+. The AVR cannot include a non-positive value, thus the AVR will be identified as 1+ to 2+.

Example: An AGID median value of 3+. The AVR is 2+ to >3+.

Results falling within this range will be classified as
Satisfactory (✓)

Results of more than two scores below or above the median value will be classified as
Minor Variation (MV) – result of 1+

Results falling outside the AVR and more than one score either side of the AVR will be classified as
Unacceptable (U)

ELISA and PCR

The ELISAs included in the program will follow different methods and will vary in the interpretation of positive and negative results. ANQAP will report and classify participants based on the consensus interpretation, which will be positive or negative for most ELISAs. Some tests may also include ranges such as low/high positive, doubtful, suspicious and inconclusive ranges. In determining the consensus interpretation, ANQAP may also consider the previous test history of the sample.

To be classified as **Satisfactory**, a participant will be expected to report a positive interpretation for a positive sample and a negative interpretation for a negative sample for both ELISA and PCR tests.

Participants are expected to complete all calculations following the method used and report the interpretation, raw OD values and any further calculations (percent inhibition, ELISA Units and ELISA ratio, CT values for PCR).

SAT

The AVR for the SAT is a dilution factor either side of the median.

Example: An SAT median of 160 IU (2+ at 1/80). The AVR is 80 IU (2+ at 1/40) to 320 IU (2+ at 1/160).

Results falling within this range will be classified as
Satisfactory (✓)

Results falling outside the AVR but are one dilution factor either side of the AVR will be classified as
Minor Variation (MV) - result within range 40IU (2+@1/20) to 640IU (2+@1/320)

Results falling outside the AVR and more than one dilution factor either side of the AVR will be classified as
Unacceptable (U) – result <40IU (2+@1/20) to >640IU (2+@1/320)

Statistical Analysis

Where statistical analysis is appropriate, this will be performed on two samples (split-level analysis). The samples must have results with only minor differences (within AVR as stated above) or an identical pair is used. A participant's classification will not be dependent on the outcome of the Statistical Analysis.

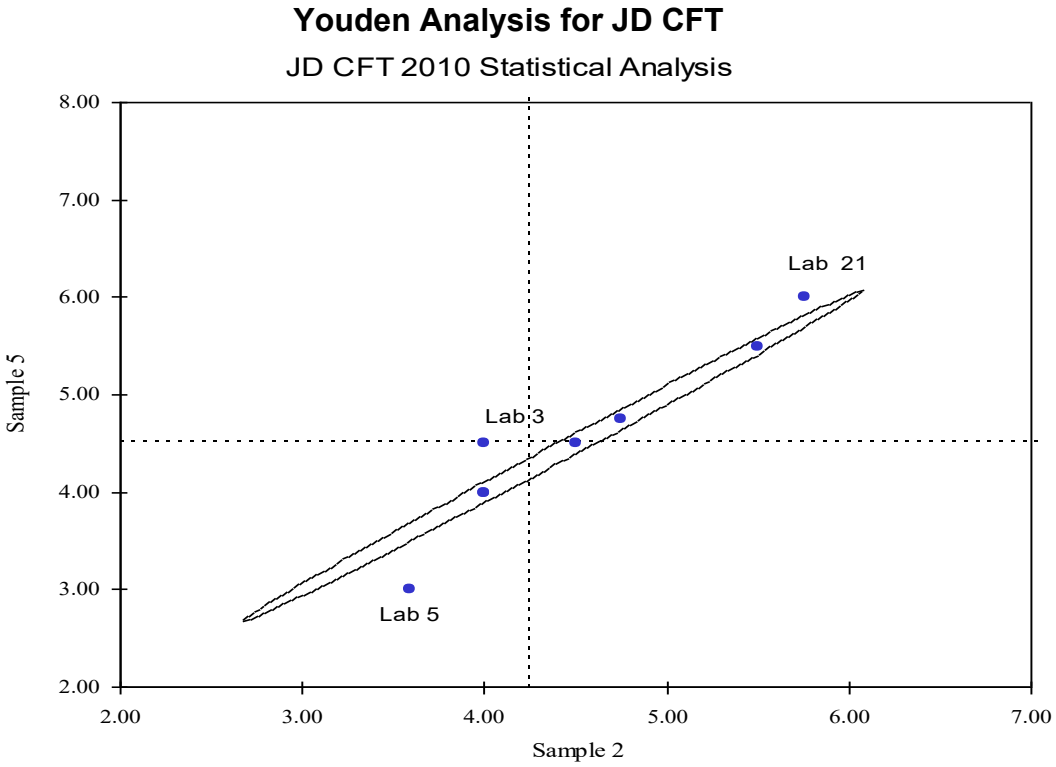
Outliers

As ANQAP uses robust statistical analysis to classify a participant's results, the impact of gross outliers is minimal. If a participant has reported a result as unsatisfactory, e.g. they have reported a result as Negative when the consensus was Positive or vice versa with the wrong interpretation, this result will be excluded from the Statistical Analysis. A comment will be made on the **Report Form**/**LEADDR Report Form** as to why the result was excluded from Statistical Analysis.

Youden plot

A Youden plot shows the result of one sample as a function of the result of the other sample in a sample pair. The Youden plot gives an idea of the dominating sources of error in the results. The Youden plot is relevant for sample pairs in which two almost identical samples with only minor difference (split-level samples) are distributed.

- Participant's with results in the upper left or lower right-hand corner of the diagram have results dominated by random error and little systematic variation.
- Laboratories with results in the upper right or lower left-hand corner of the diagram have results dominated by systematic error.
- An ellipse along the axis indicates results have been significantly affected by random variation for one of the samples.



Z-scores

Z-scores (Z) are calculated using the robust summary statistics (median and normalised Interquartile Range). For each pair of results, two Z-scores are obtained - a between-laboratories Z-score and a within-laboratory Z-score. The values are tabulated in a results table which are then graphically represented in bar charts. Two charts are generated, one for the between-laboratories Z-score and another for the within-laboratory Z-score.

Results are plotted in order of magnitude. Lines at +3 and -3 are included so that outliers can be clearly identified.

- A Z-score close to zero means that a result agrees well with the other participants.
- A Z-score greater than 3 (Z >3 or Z <-3) identifies a result which demonstrates significant variation from other participants. These results are identified as outliers.

Z-scores also provide information on the type of variation.

Between-laboratories Z-scores are based on the sum of the results and describe the variation between all laboratory results (reproducibility). A between-laboratories outlier indicates results that demonstrate significant variation from the other laboratories.

- Positive between-laboratories Z-scores indicate results are above the median value. An outlier with a positive >3 Z-score indicates significant increased sensitivity.
- Negative between-laboratories Z-scores indicate results are lower than the median value. An outlier with a negative <-3 indicates significant decreased sensitivity.

Within-laboratory variation is based on the difference between the sample pair and describes the variation within a laboratory (repeatability). A within laboratory outlier indicates variation between the individual results submitted by that laboratory and low precision.

- Positive within laboratory Z-scores indicates the difference between the laboratory's sample pair is overestimated.
- Negative within laboratory Z-scores indicates the difference between the laboratory's sample pair is underestimated or has estimated the difference to be in the opposite direction to the median difference.

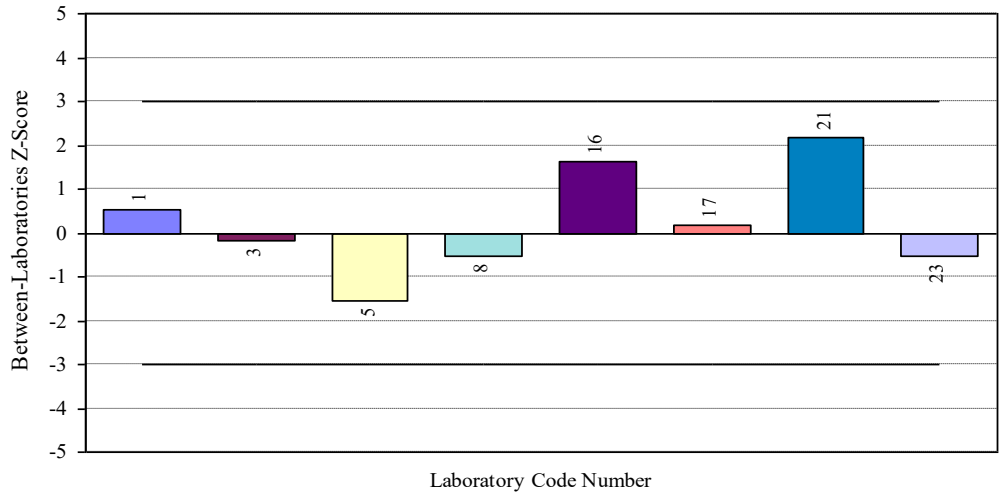
Z-score bar charts

The Z-score results are graphically represented in Z-score bar charts. Two bar charts are generated, a between-laboratories bar chart and a within-laboratory bar chart. Laboratories can use these charts to visually compare their performance relative to the other laboratories.

Lines at +3 and -3 are included so that outliers can be clearly seen on the bar charts as the bars extend over the cut off lines.

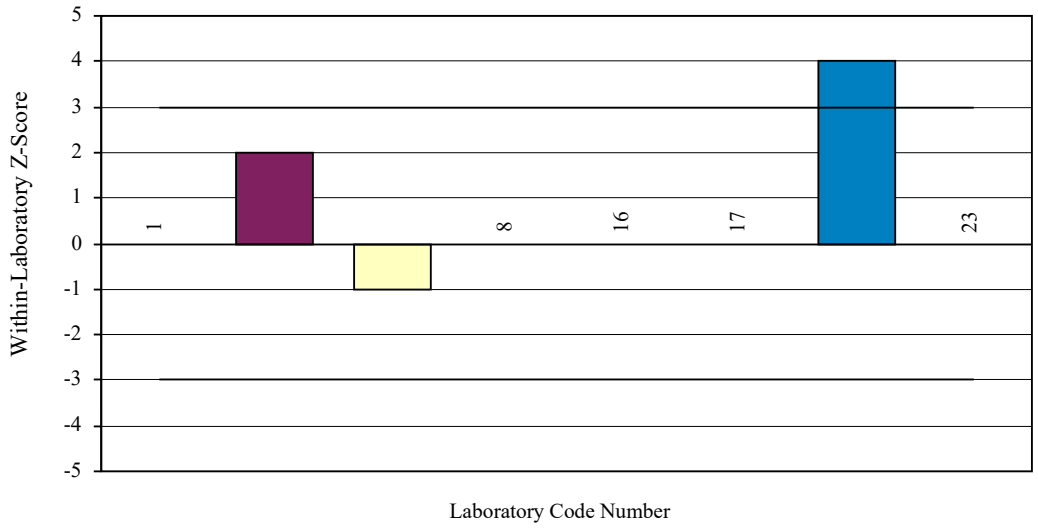
JD CFT Between-Laboratories Z-score bar chart

Analysis - Sample Pair 2 & 5



JD CFT Within-Laboratory Z-score bar chart

Analysis - Sample Pair 2 & 5



Non-Conforming Results

The National Coordinator is responsible for the management of non-conformances and for ensuring that problems are corrected, affected parties are notified and that review of procedures is undertaken to avoid further non-conformances.

The samples selected for use in the Official Panel are tested prior to use to establish an expected result range and to ensure the samples are appropriate for use. Testing is also done to ensure homogeneity and stability of the samples. Despite this thorough screening of samples, there may occasionally be a sample which produces an unexpected result. This may be attributed to one or many factors:

- The sample may have deteriorated.
- The sample may have lost activity and the result falls outside the fit-for-purpose cut off limits for a test.
- The sample may demonstrate bi-modal distribution patterns in its result. i.e. half the laboratories will report a result and the other half may report another result.
- The sample may be inappropriate for statistical evaluation.

When a sample produces an unexpected result, this may be documented as a non-conformance, and the sample may be removed from use. Affected participants will be informed via the report that the sample has not performed as expected and results for that sample will not be used in classifying participants. The entire sample panel may also be re-issued to participants if a major non-conformance of the panel has been identified.

Participant Error Fee

If an Official Report is to be amended due to an error made by a participant, e.g., transcription error or due to miscommunication by the participant, that participant will be issued a $450.00 AUD invoice to cover the costs of amending and re-issuing the Official Report. The $450.00 AUD fee will be for 1 test. If multiple tests are impacted (multiple test rounds are to be amended), the $450.00 AUD fee will be multiplied by the number of tests impacted.

It is the participant's responsibility to check for transcription errors, that emails are being sent to the correct email address (Anqap.quality@agriculture.vic.gov.au), and to please keep in mind that ANQAP will send the participant an email confirming receipt of results. If the participant does not receive this email in a timely manner, then it is very likely that ANQAP did not receive the results. If this is the case, please contact ANQAP immediately.

Complaints and Appeals Policy

Feedback, appeals and complaints may be received via email or by a participant filling in the **QF 21 Customer Feedback Form** (available via ANQAP website). The National Coordinator will investigate the issue/feedback and will be responsible for liaising with the complainant if further information/clarification is required.

An ANQAP management team meeting may be conducted to discuss the issue/feedback, the root cause and determine the most appropriate course of action. Formal records may be kept via the **CAR** or **IOR** system to track and record the actions taken to resolve the issue. Resolutions and corrective actions should be reviewed by an independent person to uphold impartiality, e.g. a request could be made to the Quality Unit to review the **CAR/IOR**.

Progress reports may be provided to the participant. Upon completion of the investigation, the National Coordinator will communicate the outcome of the investigation to the complainant, if applicable.

It is important to treat these events as learning opportunities and therefore not to discriminate or prejudice the complainant.

ANQAP values all client/participant feedback. The National Coordinator has overall responsibility for ensuring complaints are handled appropriately and promptly.

Any changes in the proficiency testing scheme design or operation will be promptly communicated to all participants. This communication will typically include email correspondence for traceability purposes. Please ensure that you notify ANQAP of any contact detail changes in a timely manner to ensure you receive the latest communication regarding our Proficiency Testing Scheme/s.

Contact Details

ANQAP actively seeks and welcomes your feedback. If there are any issues with reporting or your assessment of performance, or any other issue or feedback, please don't hesitate to contact us. This matter will be dealt with as soon as possible and be dealt with in complete confidence.

National Coordinator:

Ms Rose Kursun
Australian National Quality Assurance Program (ANQAP)
AgriBio Centre, La Trobe University Campus
5 Ring Road, Bundoora, Victoria, 3083 Australia.

Quality/Technical Officer:

Mr Batuhan Ozdemir
Histology, Veterinary Laboratory Services
AgriBio Centre, La Trobe University Campus
5 Ring Road, Bundoora, Victoria, 3083 Australia.

ANQAP e-mail: anqap.quality@agriculture.vic.gov.au

ANQAP website: https://www.anqap.com/

* This document is updated on a regular basis. For the most recent updated version, please refer to the ANQAP website.