

PIP (Program Information for Participants)

The Australian National Quality Assurance Program (ANQAP) is coordinated at the State Government of Victoria – Bundoora Location, under DJPR (Department of Jobs, Precincts and Regions).

The main focus of the program is proficiency testing of assays used in quarantine, export certification and national disease control programs.

An Official Panel will typically consist of 6 samples with a mixture of Positive and Negative samples. Sample panels are forwarded to laboratories 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 laboratories. ANQAP uses its subcontractors to test all samples for homogeneity, quality and stability. All contractors chosen are NATA accredited or equivalent, where applicable.
- Various aspects of the proficiency testing scheme can from time-to-time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and ANQAP is responsible for this work.
- When a subcontractor has prepared the samples for ANQAP, they may be acknowledged in the report for that test.
- Test samples will be, as far as is technically possible, matrix samples of a similar type to those routinely analysed by most participating laboratories.
- The levels of target analytes in the samples distributed are selected to represent levels that would be measured by most participating laboratories.
- The results from all laboratories 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 laboratory will be allocated a confidential number. The identity and codes of all participating laboratories will be known only to ANQAP staff. Laboratories are advised by email of their confidential number at the beginning of the year's program. This laboratory identification is changed annually. 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. Individual reports will only display that specific laboratory's confidential number and all other laboratory confidential numbers will be removed. This will further ensure client confidentiality is maintained.

When an accredited body or regulatory authority requires the proficiency test results to be disclosed, where applicable, clients will be notified via email of the requirement prior to enrolment. If enrolment has already been processed, authorisation to release information will be sought from the client via email regarding this matter.

ANQAP Certificates of Participation

At the conclusion of the testing cycle, a Certificate of Participation will be issued to each participating laboratory, listing the tests participated in. This certificate will not list classification of results. For laboratories 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 laboratory received a classification for. Certificates will be mailed to the nominated contact at each laboratory as per the Enrolment Form.

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

All participants will be notified via email if ANQAP needs to alter the Test Timetable.

Enrolment

Registration

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

ANQAP is obliged to take all necessary steps to avoid/prevent collusion between laboratories or falsification of results as per ISO/IEC 17043. To meet the clause, ANQAP enrol each laboratory 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 laboratories before each new cycle. It is also available on the ANQAP website: www.anqap.com. Late enrolments can be accepted however a laboratory 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 delayed where payment is outstanding.

Cancellation of participation

If a laboratory wishes to cancel participation 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 laboratory wishes to cancel participation after the samples are dispatched, no refund or credit will be granted. ANQAP may seek feedback from a laboratory 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**

Laboratories will be advised via email once samples have been dispatched with tracking details. 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 laboratory 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.

Samples are forwarded at ambient air temperature. This method of transport and the mode of packaging has been validated by ANQAP and will not harm freeze dried samples for up to 14 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

Laboratories 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 the ANQAP to compare results, determine a consensus median and provide an accurate classification for each laboratory. Where an endpoint is not provided, the laboratory will only be classified according to their interpretation of the sample and a note of this will be specifically made on the report.

Laboratories 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. Laboratories 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 laboratory 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 may invalidate test results.

Reporting results

The current version of the **Result Reporting Form (QF 15 Result Reporting Form for Veterinary and QF 18 JD Result Reporting Form for JD Culture)** must be used. This will be sent to participants at the beginning of each testing cycle or as the documents are updated. Results can be reported electronically and emailed to ANQAP, or the form may be filled in by hand, scanned and emailed to ANQAP. Copies of these forms are also available on the ANQAP website, www.anqap.com.

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 laboratory 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 detail regarding method/reagents used, they will be automatically excluded from the statistical analysis. This has been communicated as a statement at the bottom of the relevant reporting forms.

Retests

ANQAP will calculate the result for each sample and an acceptable variation range (AVR). Laboratories reporting results outside the AVR will be required to retest. For tests that are classified on interpretation only, laboratories will be asked to retest if their reported interpretation differs from the consensus interpretation. A retest report will be forwarded to the laboratory. Retest results should be reported to ANQAP on the relevant **Result Reporting Form (QF15 or QF 18)**.

ANQAP Reports

ANQAP will not disclose any results prior to the distribution of Official Reports/Official Retest Reports/Official Final Retest Reports/General Reports. ANQAP will aim to issue a report to each participating laboratory within approximately three 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 also includes 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 be personalized and all other laboratory confidential numbers will be removed.

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, laboratories are asked to inform ANQAP as soon as possible. An amended report will be forwarded to the affected laboratory 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 AVR will be calculated from the median and the results should fall within this range. This forms the basis on which laboratories 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:

- ✓ Initial results submitted by this laboratory are satisfactory as they fall within the AVR range from the median.
- R Initial results submitted by this laboratory are outside the AVR from the median and retesting is required.

Retest results will be classified as:

- R✓ Retest results submitted by this laboratory are satisfactory as they fall within the AVR or match the consensus interpretation.
- Rm Retest results submitted by this laboratory demonstrate minor variation as results fall just outside the AVR according to the defined criteria; these results are acceptable however the minor variation is worthy of note.
- RU Retest results submitted by this laboratory are outside the AVR or disagree with the consensus interpretation and are unsatisfactory.

For those laboratories who do not report results on time as per 'Results Due' date on the **Test Timetable**, they will receive a "General Report" which will be issued on the same day as the standard reports in the usual format however this report will exclude late results and will not be addressed to the laboratory. This "General Report" will be issued to allow the late reporting laboratory to compare their results with the median and consensus interpretation reported by other laboratories for that round.

Where retest samples are not available for a particular panel, the laboratory will either be classified as **Satisfactory (✓)**, **Result Demonstrating Minor Variation (MV)** or **Result Unsatisfactory (U)** for each sample.

Interim Reports

ANQAP does not encourage the issuing of interim reports and they will not be readily available. Laboratories who require an interim report will need to put forward a strong business case which will be reviewed by the ANQAP management team. The outcome of the review will be communicated to the laboratory via email.

If an interim report is issued, the information in the report will only reflect the relevant laboratory results (i.e. the summary table of results for all participating laboratories will not appear on the report) and the laboratory will be classified according to their Interpretation only. In this case, the classification will be dependent on historical results rather than the standard classification where the median is taken into account. This report will not be NATA endorsed and therefore a statement regarding this will be noted on the report.

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

A laboratory may purchase an OOS panel, where available. The samples used in the OOS panel all undergo the same treatment and pre-screening 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 laboratory's classification, relevant historical test data will be used.

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

Laboratory Error Fee

If an Official Report is to be amended due to an error made by a Laboratory, e.g. transcription error or due to miscommunication by the Laboratory, that Laboratory will be issued a \$200.00 AUD invoice to cover the costs of amending and re-issuing the Official Reports. The \$200.00 AUD fee will be for 1 test. If multiple tests are impacted (multiple test rounds are to be amended), the \$200.00 AUD fee will be multiplied by the number of tests impacted. **Reports will not be amended under any circumstances if retest samples have been dispatched.**

It is the client's responsibility to check for transcription errors, that emails are being sent to the correct email address (Anqap.quality@ecodev.vic.gov.au), and to please keep in mind that ANQAP will send the client an email

confirming receipt of results. If the client 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.

Annual Report

Each year, following the completion of all testing, a full report is prepared and published on the ANQAP website: www.anqap.com. This report will include the participant's results for each round and the classification for each laboratory for each round. Confidentiality will be maintained by removing all confidential numbers and the report will not disclose participants details.

Determination of the Acceptable Variation Range (AVR)

CFT, MAT, HIT and VNT

The acceptable 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 are temporarily classified as

Retest Required (R) and the laboratory would be required to retest

Following retesting, the result will be classified as either:

- **Retest Result Satisfactory (R✓)** - result within the AVR
- **Retest Result Demonstrating Minor Variation (Rm)** - result within 3/8-3/128
- **Retest Result Unacceptable (RU)** - result $\leq 2/8$ - $\geq 4/128$

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 acceptable range 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 are classified as

Satisfactory (✓)

A negative result or a result of 1+ would be classified as

Retest Required (R) and the laboratory would be required to retest

Following retesting, the result would be classified as either:

- **Retest Result Satisfactory (R✓)** - result within the AVR
- **Retest Result Demonstrating Minor Variation (Rm)** - for result within 1+ - >3+
- **Retest Result Unacceptable (RU)** - for result outside the Rm

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 laboratories 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 take into account the previous testing history of the sample.

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

Participants are expected to complete all calculations following the method used and report to ANQAP 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 are temporarily classified as

Retest Required (R) and the laboratory would be required to retest

Following retesting, the result will be classified as either:

- **Retest Result Satisfactory (R✓)** - result within the AVR
- **Retest Result Demonstrating Minor Variation (Rm)** - result within range 40IU (2+@1/20) to 640IU (2+@1/320)
- **Retest Result Unacceptable (RU)** - result <40IU (2+@1/20) to >640IU (2+@1/320)

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 by at least two laboratories prior to use to establish an expected result range and to ensure the sample is 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 gives an unexpected result. This may be attributed by several factors:

- The sample may have deteriorated.
- The sample may have lost activity and the result fall 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 will be documented as a non-conformance and the sample will be removed from use. Affected laboratories 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 laboratories. The entire sample panel may also be re-issued to laboratories due to a major non-conformance of the panel.

Statistical Analysis

Where statistical analysis is appropriate, this will be done on two samples (split-level analysis). The samples must have results with only minor differences or an identical pair is used.

Outliers

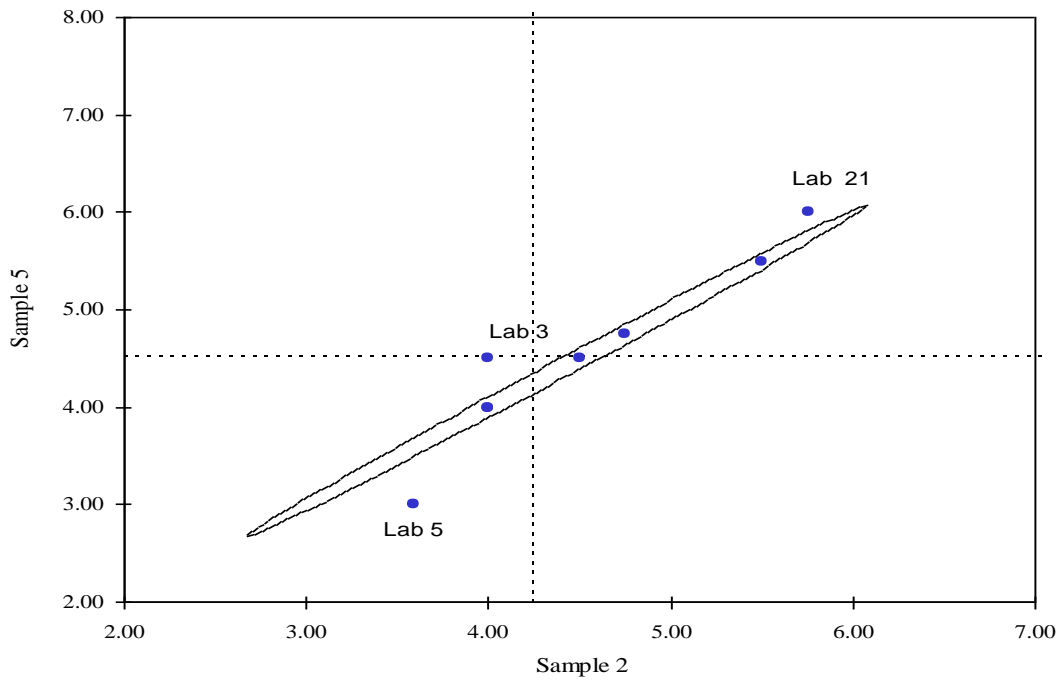
As ANQAP uses robust statistical analysis to classify a laboratory's results, the impact of gross outliers is minimal. If a laboratory has reported an initial result as a gross outlier, e.g. they have reported a result as Negative when the consensus was Positive or vice versa with the wrong interpretation, this result will be excluded from the Statistical Analysis. A comment will be made on **QF 17 Monthly Result Reporting Spreadsheet** and 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.

- Laboratories 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.

Youden Analysis for JD CFT
 JD CFT 2010 Statistical Analysis



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 laboratories.
- A Z-score greater than 3 ($Z > 3$ or $Z < -3$) identifies a result which demonstrates significant variation from other laboratories. 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.

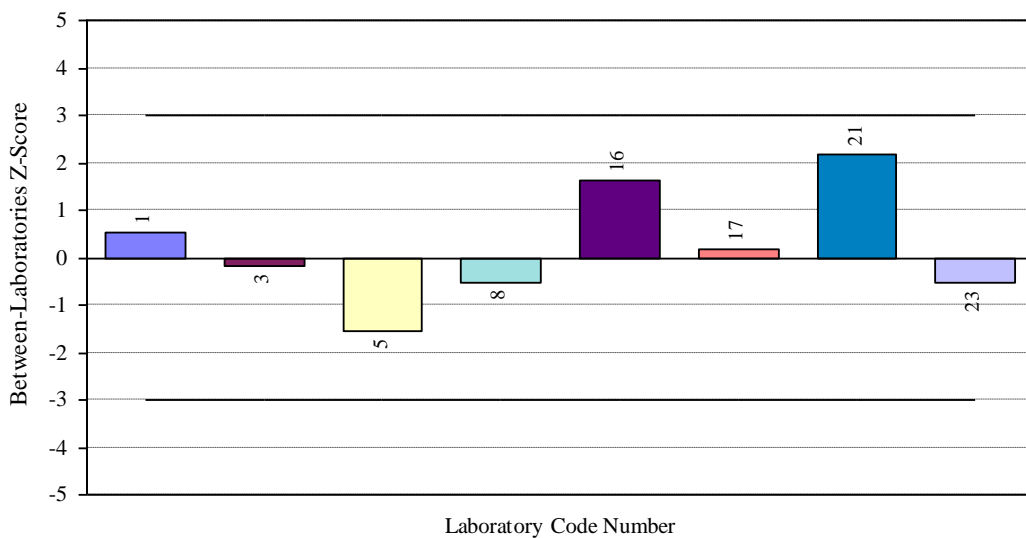
Z-score bar charts

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.

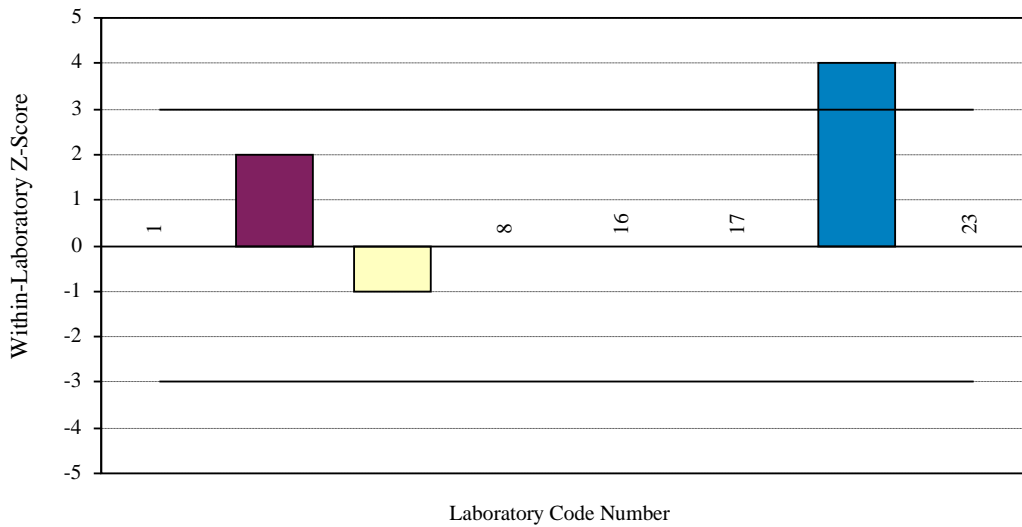
JD CFT Between-Laboratories Z-score bar chart

Analysis - Sample Pair 2 & 5



JD CFT Within-Laboratory Z-score bar chart

Analysis - Sample Pair 2 & 5



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 you notify ANQAP of any contact detail changes in a timely manner to ensure you receive the latest communication regarding our Proficiency Testing Scheme.

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 please contact us. This matter will be dealt with as soon as possible and be dealt with in total confidence.

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