

## **ATTACHMENT VII**

## SUMMARY

The Australian National Quality Assurance Program for veterinary diagnostic testing aims to establish quality assurance in 21 laboratories in Australia and New Zealand. Not all of the participating laboratories perform all of the tests.

This is achieved by designating national reference antisera for each test and attempting to ensure standard methods are used in all laboratories in line with the Australian Standard Diagnostic Techniques for Animal Diseases. Each laboratory is assessed on the result it provides for the reference standards, plus a number of unknown antisera for each test. The results reported for the unknown antisera are statistically analysed.

In Phase 1, which was completed in March 1991, four tests were evaluated. In Phase 2, completed in September 1992, the same four tests and eight additional tests were evaluated. In Phase 3, completed in October 1992, the twelve tests evaluated in Phase 2 and an additional 13 tests were evaluated. Phase 4, completed in May 1994, involved the 25 tests examined in Phase 3 and an additional 9 tests. Phase 5, completed in January 1995, evaluated the same 34 assays as Phase 4 with the exception of the Bluetongue complement fixation test which was replaced by the *Brucella ovis* ELISA. Phase 6, 1995, evaluated the same 34 assays as Phase 5. Phase 7, 1996, increased to 35 serological assays with the inclusion of the EBL ELISA. Since Phase 4 ANQAP has extended to include non-serological quality assurance programs such as the culture and identification of *Mycobacterium bovis*. Two new quality assurance programs have been included in the annual Phase 8 ANQAP evaluation, these include Footrot gelatin gel interlaboratory testing and the culture and identification of *Mycobacterium paratuberculosis*. All three programs are included in this report. Future expansion of the program in Phase 9 testing 1998 will include interlaboratory testing of Avian Influenza AGID, Newcastle Disease Virus HI, Rabbit Calicivirus Virus Disease ELISA, Myxoma ELISA and milk EBL ELISA.

This report includes the proficiency testing results for 38 assays evaluated in Phase 8 including *M. bovis* culture, *M. paratuberculosis* culture and Footrot gelatin gel. Phase 8 testing began in January 1997 and concluded in January 1998.

The procedure for classifying results was introduced in Phase 6 and developed further in Phase 7. Phase 8 was the first evaluation in which results were formally classified based on the ANQAP quality procedure QP0010 'Endorsement of Laboratories for Export Testing through Interlaboratory Proficiency Testing via ANQAP'. Laboratories reporting acceptable results were listed on the ANQAP Endorsed List of Laboratories which was published every quarter and distributed to SCAHLS, ANQAP participants and Chief Veterinary Officers.

The following statistical breakdown can be concluded from the Phase 8 classification of results:

The total number of evaluations required during Phase 8 was 269. In 183 of these evaluations (68%), results were within the acceptable variation range (AVR) from the consensus mean values and were classified as acceptable (✓). These figures are comparable to the Phase 7 evaluation where 73% of results fell within the AVR. Those laboratories which reported results outside the AVR were required to retest. Generally, all but three laboratories reported results which fell within the AVR or one dilution of the AVR limits on retesting, and were classified as acceptable or demonstrating minor variation. Only 3 of the 269 evaluations demonstrated significant variation due to decreased sensitivity, where positive results were consistently interpreted as negative. Laboratory 3 was not endorsed for the Akabane SNT, laboratory 13 was not endorsed for the BT AGID and laboratory 14 was not endorsed for the BVD AGID. In an internal

investigation each laboratory identified the cause of the decreased sensitivity and implemented improved procedures accordingly. Two laboratories attributed the loss of sensitivity to internal reagents and one laboratory identified a discrepancy in the interpretation method between the ASDT and their laboratory procedure. All three laboratories reported acceptable results on re-endorsement testing and were subsequently included on the ANQAP Endorsed List of Laboratories for the three tests.

The SNT and MAT demonstrated the largest variation with approximately 50% of laboratories requiring retesting. Serious concerns were identified with the Aino, Akabane SNT and all three MAT. The large between laboratory variation appears to be caused by variation in methodology and reagents. These issues will be addressed in the review of the ASDT and an SNT review by ANQAP in Phase 9. Results submitted for the AGID demonstrated the least variation with 81% results acceptable on original testing. The ELISA demonstrated only minor variation with 72% results acceptable on original testing.

Overall only 1% of the evaluations in Phase 8 were not initially endorsed, with 99% of laboratory results classified as acceptable or demonstrating minor variation on original or retesting.

The details and summary of the quality assurance testing for *M.bovis*, *M.paratuberculosis* and Footrot Gelatin Gel are included in the final chapter of this report.

## BRUCELLA ABORTUS COMPLEMENT FIXATION TEST ASSAY

Thirteen laboratories participated in the *B.abortus* CFT proficiency testing for Phase 8. Individual laboratory results for each of the five samples are tabulated below.

Lab	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Antisera	Antigen	Class.
1	4/4	3/8	4/4	-ve	1/16	Not supplied	Not supplied	✓
2	2/8	2/16	4/8	-ve	1/32	In-house	In-house	✓
3	4/8	2/16	4/8	-ve	3/32	In house	Weybridge	✓
4	1/8	4/8	3/8	-ve	2/16	In-house	CSL16771851	✓
6	4/4	4/8	4/8	-ve	4/16	ANQAP	In house	✓
7	4/4	2/8	1/8	-ve	2/16	In house	Antifix	✓
9	2/16	1/32	4/16	-ve	1/64	In-house	In-house	R
11	-ve	3/4	2/4	-ve	3/8	In-house	RM 36M421	R
12	1/8	2/8	2/8	-ve	4/16	Batch 56 P4441	01 RM	✓
13	4/4	3/8	1/8	-ve	1/16	Wagga	CSL01671901	✓
14	4/4	3/8	2/8	-ve	4/16	In-House	CSL	✓
16	3/16	2/32	-ve	3/4	2/16	Not supplied	Not supplied	R
17	2/8	3/8	1/8	-ve	4/16	In-house	CSL	✓
CM	2/8	4/8	1/8	Negative	3/16	*	*	*
<b>Retest results</b>								
9	1/8	2/8	1/8	-ve	3/16	In-house	In-house	R✓
11	2/4	2/8	*	*	*	In-house	RM 36M421	R✓
16	2/8	4/8	4/16	-ve	2/16	Not supplied	Not supplied	Rm

RM-Rhone Merieux

### Result Summary

#### Sample 1:

The consensus mean result for Sample 1 was 2/8 with an AVR of 2/4 to 2/16. Ten of the thirteen laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 reported results well above the AVR for all other positive samples and was asked to retest the entire panel. The retest result of 1/8 which is within the AVR and was classified as (R✓), retest result acceptable. Laboratory 11 reported a negative result for the positive Sample 1 and was asked to retest. A 2/4 retest result was within the AVR and classified as (R✓) retest results acceptable. Laboratory 16 reported a 3/16 result, above the AVR, and was asked to retest. The 2/8 retest result is identical to the consensus mean value and was classified as (R✓) retest results acceptable.

#### Sample 2:

The consensus mean result for Sample 2 was 4/8 with an AVR of 4/4 to 4/16. Ten of the thirteen laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 reported a result of 1/32 which falls above the AVR and was asked to retest. On retesting, Laboratory 9 reported 2/8 which is within the AVR and was classified as (R✓), retest results acceptable. Laboratory 11 reported a result of 3/4, below the AVR, and was asked to retest. The 2/8 retest result was within the AVR and was classified as (R✓), retest results acceptable. Laboratory 16 reported a result of 2/32 which is above the AVR and was asked to retest. On retesting they reported a result of 4/8 which is identical to the consensus mean and was classified as (R✓), retest results acceptable.

*Sample 3:*

The consensus mean result for Sample 3 was 1/8 with an AVR of 1/4 to 1/16. Eleven of the thirteen laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 reported a result of 4/16 which falls above the AVR and was asked to retest. On retesting, Laboratory 9 reported 1/8 which was identical to the consensus mean and classified as (R✓), retest results acceptable. Laboratory 16 reported a negative result for the positive sample and was asked to retest. A 4/16 retest result was above the AVR but within one dilution of the upper AVR limit, and was classified as (Rm), retest results demonstrating minor variation.

*Sample 4:*

The consensus mean result for Sample 4 was negative. Twelve of the thirteen laboratories reported a negative interpretation and were classified as acceptable (✓). Laboratory 16 reported a result of 3/4 and was asked to retest. On retesting lab 16 reported a negative reaction and was classified as (R✓), retest results acceptable.

*Sample 5:*

The consensus mean result for Sample 5 was 3/16 with an AVR of 3/8 to 3/32. Twelve of the thirteen laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 reported a result of 1/64 which falls above the AVR and was required to retest. A retest result of 3/16 was identical to the consensus mean and was classified as (R✓), retest results acceptable.

**Phase 8 *B.abortus* CFT - Transformed Results table**

Lab Code	Transformed Results		Between-Lab Z-Score	Within-Lab Z-Score
	Sample 1	Sample 3		
1	2.00	2.00	-1.35	-0.67
2	2.50	3.00	1.35	0.67
3	3.00	3.00	2.25	-0.67
4	2.25	2.75	0.45	0.67
6	2.00	3.00	0.45	2.02
7	2.00	2.25	-0.90	0.00
9	3.50	4.00	4.95 §	0.67
11	0.00	1.50	-5.85 §	3.37 §
12	2.25	2.50	0.00	0.00
13	2.00	2.25	-0.90	0.00
14	2.00	2.50	-0.45	0.67
16	3.75	0.00	-1.80	-10.79 §
17	2.50	2.25	0.00	-1.35

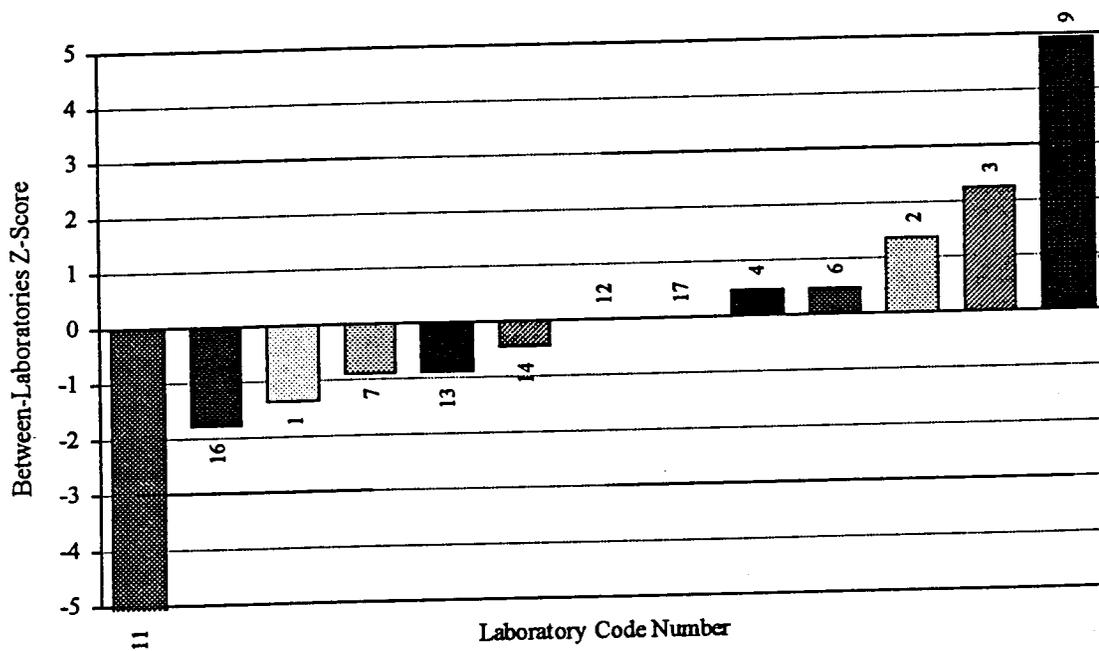
The between-laboratories and within-laboratory z-scores are for the related pair, samples 1 and 3.

§ denotes an outlier, i.e. |z-score| > 3.

Phase 8 *B.abortus* CFT - Summary Statistics table

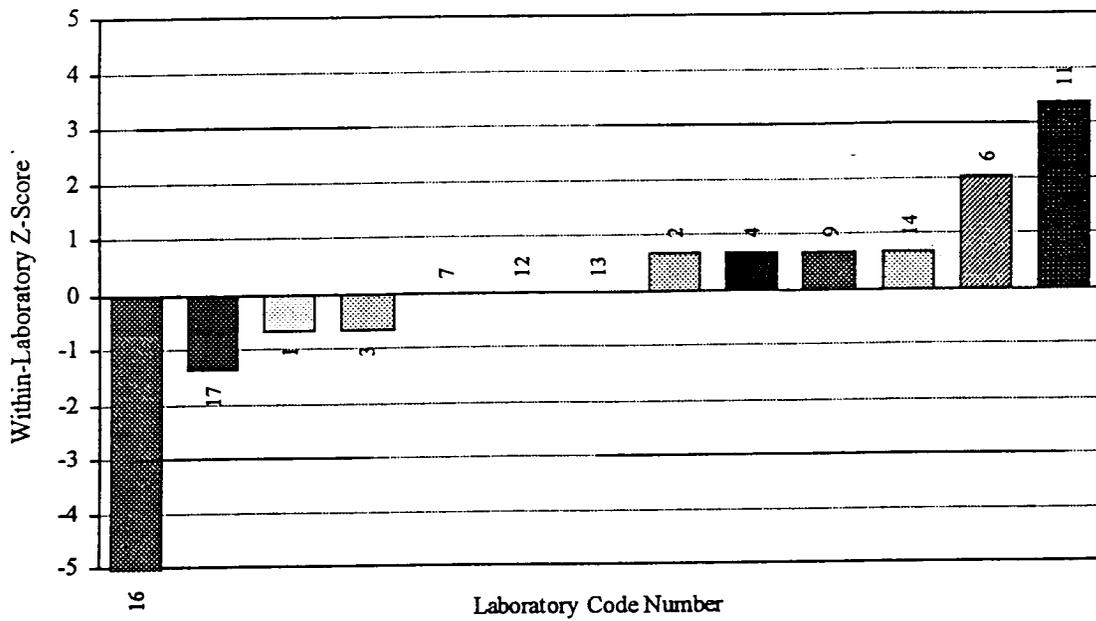
Statistic	Sample 1	Sample 3
No. of Results	13	13
Median	2.250	2.500
Normalised IQR	0.371	0.556
Robust CV	16.5%	22.2%
Minimum	0.00	0.00
Maximum	3.75	4.00
Range	3.75	4.00

*B.abortus* CFT - Between Laboratories Z-Score Bar Chart for Sample Pairs 1 & 3



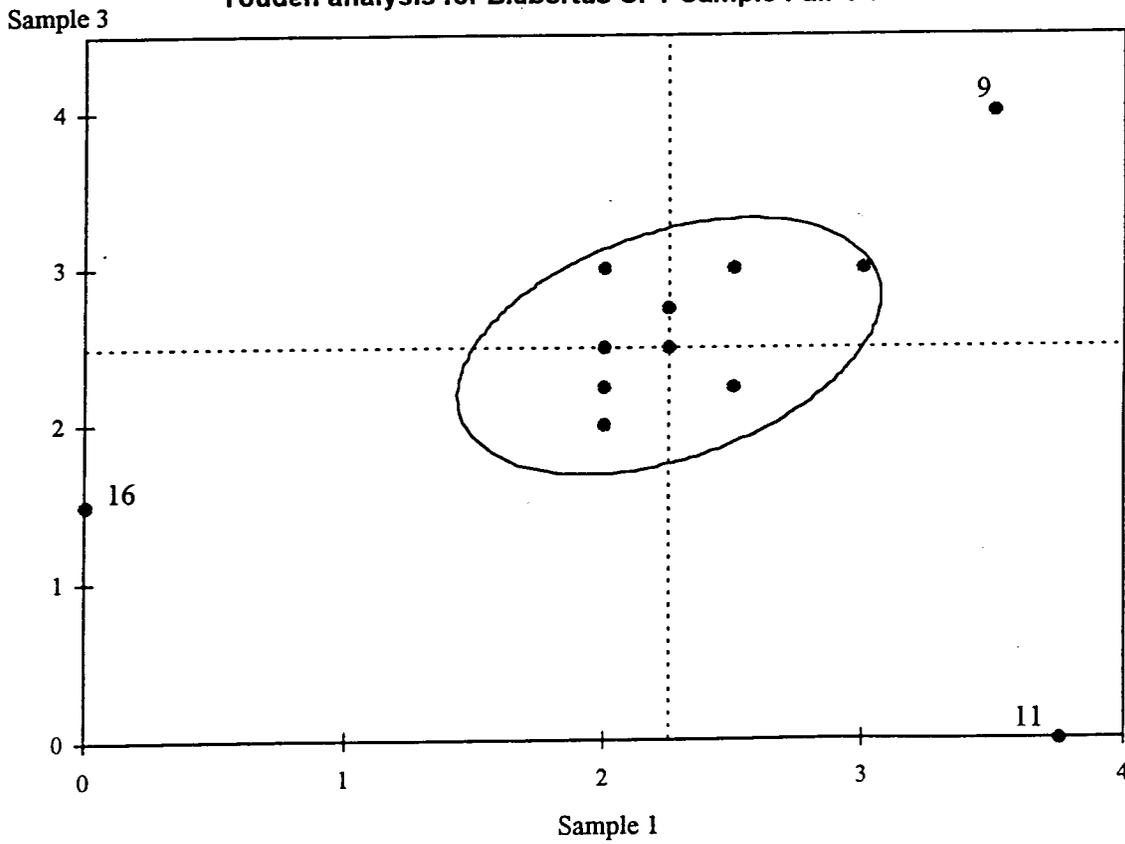
Laboratory 9 has a Between-Lab z-score of 4.95.  
 Laboratory 11 has a Between-Lab z-score of -5.85.

*B.abortus* CFT - Within Laboratory Z-Score Bar Chart for Sample Pairs 1 & 3



Laboratory 16 has a Within-Lab z-score of -10.79.

Youden analysis for *B.abortus* CFT Sample Pair 1 & 3



Lab 7 and Lab 13 are represented by one plot

### Statistical Summary

Three laboratories were identified as outliers. Laboratory 9 was identified as a between laboratory outlier with a z-score of 4.95 indicating increased sensitivity. Laboratory 11 was identified as a between and within laboratory outlier indicating decreased sensitivity and too large a difference between the sample pair. Laboratory 16 has been identified as a within laboratory outlier due to the extreme difference between the sample pair.

### Youden Summary

Three laboratories were plotted outside the Youden diagram in various quadrants. Laboratory 9 and 11 are in the upper right and lower left quadrant indicating systematic error. Laboratory 9 position in the upper section indicates increased sensitivity while in contrast lab 11 position indicates decreased sensitivity. Laboratory 16 is plotted on the 0 Sample 3 line indicating a negative result for the positive sample. Its position in the lower right quadrant indicates minor random error.

### Conclusion

Three of the ten laboratories (23%) evaluated in Phase 8 reported results outside the AVR and required retesting. Each of these laboratories, 9, 11 and 16, have been identified as outliers with a z score greater than 3 or -3. Laboratory 9 and 11 have been identified as between laboratory outliers, indicating large variation between their results and the other participating laboratories. The positive 5 z score for laboratory 9 indicating results of a greater magnitude than all other results while the negative 6 z score of lab 11 indicates significantly lower results. As well as being a between lab outlier laboratory 11 has been identified as a within laboratory outlier. The positive 3 within z score indicates the difference between the two samples to be much larger than acceptable. For example, Samples 1 and 3 are samples with similar titres, 2/8 and 1/8 respectively. Laboratory 11 however has reported results which are very different, a negative result for Sample 1 and a 2/4 result for Sample 2. Laboratory 16 also reported very different results for what are very similar samples, a 3/16 and a negative result. For this reason laboratory 16 was also identified as a within-lab outlier, where the difference within the two results is too large. The between and within lab bar chart show lab 9 and 11; and 16 and 11 plotted off the chart as outliers.

The labs which reported results outside the AVR do not appear to be using the same reagents, hence no particular antigen can be connected with the increased or decreased sensitivity. All three labs reported results closer to the expected values on retesting which also decreases the chance of a systematic reagent problem. Laboratories 9 and 11 which were demonstrating increased and decreased sensitivity respectively, both reported results which fell within the AVR on retesting and were classified as retest acceptable. Laboratory 16, which unfortunately failed to disclose their antigen source, reported results which were above the AVR for samples 1, 2, 4 and 5, but below the AVR for Sample 3. On retesting lab 16 reported acceptable results for samples 1, 2, 4 and 5 but now reported results above the AVR for Sample 3. It appears that lab 16 may have 'switched' Samples 3 and 4 when tested originally, a random operator error. The remaining ten laboratories employ various reagents including CSL, Rhone Merieux, CVL and in-house preparations.

Laboratory 11 also demonstrated decreased sensitivity when it was tested twelve months ago. This lab was one of the two labs which was required to retest in Phase 7. In both Phase 7 and 8 lab 11 reported decreased sensitivity on original testing but acceptable results on retesting. It appears that lab 11 may be developing a trend of lower results which are being identified and then rectified for ANQAP testing. Laboratory 11 should carefully monitor the conduct of the BB CFT and ensure the trend does not continue. With only two labs retesting in Phase 7 and three retesting in Phase 8 it appears the accuracy and precision of the BB CFT may have decreased slightly in the last twelve months.

Overall twelve of the thirteen laboratories were classified as acceptable on original or retesting. Laboratory 16 demonstrated significant random error on original testing by reporting a negative result for a positive sample and a positive result for a negative sample. On retesting lab 16 was able identify the correct positive and negative interpretations but reported Sample 3, which was negative on first testing, as 4/16 which now falls above the AVR. Lab 16 was classified as demonstrating minor variation on retesting.

All laboratories were endorsed for the BB CFT and were listed on the ANQAP Endorsed List of Laboratories.

## BRUCELLA ABORTUS ROSE BENGAL PLATE TEST

Eleven laboratories participated in the B.abortus RBPT evaluation for Phase 8. Original and retest results are tabulated below.

Lab	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Antisera	Antigen	Class
1	-ve	1+	1+	-ve	2+	In-house	CSL 63201	R
2	-ve	2+	1+	-ve	2+	In-house	RM 26E351	R
3	1+	2+	3+	-ve	2+	VIAS	CVL 252	✓
6	-ve	1+	1+	-ve	3+	ANQAP	RM26E751	R
7	1+(2+)	2+	2+	-ve	3+	VIAS	CVL 252	✓
9	2+	2+	1+	-ve	3+	In-house	CVL 251	✓
11	1+	2+	3+	-ve	4+	In-house	RM 26E751	✓
12	1+	2+	2+	-ve	3+	N/A	Sanofi Pasteur	✓
13	1+	2+	2+	-ve	3+	CSL #42201	CVL 252	✓
14	1+	1+	1+	-ve	3+	ANQAP	CVL	✓
17	-ve	1+	1+ (2+)	-ve	3+	In-house	CSL	R
C.M	1+	2+	2+	Negative	3+	*	*	*
<b>Retest Results</b>								
1	+/-	*	*	*	*	In-house	CSL 63201	R✓
2	1+	*	*	*	*	In-house	RM 26E351	R✓
6	1+	*	*	*	*	ANQAP	Sanofi Pasteur	R✓
17	1+	*	*	*	*	In-house	CSL	R✓

### Result Summary

#### Sample 1:

The consensus mean result for Sample 1 was 1+ with an AVR of +/- to 2+. Seven of the eleven laboratories reported low positive results and were classified as acceptable (✓). Laboratories 1, 2, 6 and 17 reported a negative result and were asked to retest. A retest result of 1+ was reported by labs 2, 6 and 17 while lab 1 reported a +/- result. These results are now within the AVR and have been classified as retest result acceptable (R✓).

#### Sample 2:

The consensus mean result for Sample 2 was 2+ with and AVR of 1+ to 3+. All Laboratories reported results within the AVR and are classified as acceptable (✓).

#### Sample 3:

The consensus mean result for Sample 3 is 2+ with and AVR of 1+ to 3+. All Laboratories reported results within the AVR and are classified as acceptable (✓).

#### Sample 4:

All Laboratories reported Sample 4 as negative and are classified as acceptable (✓).

#### Sample 5:

The consensus mean result for Sample 5 was 3+ with and AVR of 2+ to 4+. All Laboratories reported results within the AVR and are classified as acceptable (✓).

### Conclusion

Seven of the eleven laboratories (64%) reported results which were classified as acceptable on original testing for all interlaboratory samples. Only four laboratories reported results outside the AVR for one of the five samples. As with most serological assays the variation noted was at the low positive/trace level with all four labs demonstrating decreased sensitivity with a negative result. On retesting three of the laboratories, labs 2, 6 and 17, found Sample 1 to be a low positive at 1+. Laboratory 1 is still demonstrating minor decreased sensitivity and found Sample 1 as a trace reaction.

All Laboratories have reported using the ASDT for the B.abortus RBPT. Laboratory 6, however, deviated slightly from the ASDT on original testing by rocking the test plate for more than the recommended 4 minutes (ASDT, Bovine Brucellosis, Rose Bengal Plate Test, pg 12). At the recommended 4 minutes the positive reference antisera (Ref #1) was still negative. Laboratory 6 then read all result after 6 minutes when the Reference result gave a 2+ reaction. Even after 6 minutes lab 6 still found Sample 1 to be negative although the consensus mean value was positive at 1+. Due to the decreased sensitivity laboratory 6 sourced a new antigen and retested results. Using Sanofi Pasteur RBPT antigen lab 6 found Sample 1 to be 1+ using the ASDT. Only one other laboratory used the Sanofi antigen, this laboratory, lab 12, reported acceptable results for all samples. On original testing two laboratories used the CSL antigen which appears to be out of date. Both laboratories demonstrated decreased sensitivity reporting Sample 1, a 1+ positive, as negative. On retesting however a +/- and 1+ reaction were obtained. Three laboratories used the Rhone Merieux antigen with only one of them reporting Sample 1 as 1+. Laboratory 6 changed to Sanofi while lab 2 retested with Rhone Merieux and reported acceptable results. Five laboratories employ the CVL Weybridge antigen and all found Sample 1 as positive and were acceptable on original testing.

Overall the B.abortus RBPT demonstrated variation at the low positive/trace level. The negative and high positive samples demonstrated excellent results with very little variation. The B.abortus RBPT appears to have improved from the previous Phases, all laboratories were requested to retest in Phase 7 and only four laboratories were retested in Phase 8. 100% of labs using the CSL and 60% of labs using the Rhone Merieux antigen demonstrated decreased sensitivity. Retest results using these reagents however did fall within the AVR. All laboratories using the CVL and Sanofi antigen reported acceptable results.

All laboratories were endorsed for the B.abortus RBPT and were listed on the ANQAP Endorsed List of Laboratories.

## BRUCELLA ABORTUS SERUM AGGLUTINATION TEST

Eight laboratories took part in B. abortus SAT interlaboratory testing. Original and retest results are tabulated below.

Lab	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Antisera	Antigen	Class
1	33.5 IU	40 IU	46.5 IU	20 IU	93 IU	In-house	CSL 016771851	R
3	23 IU	40 IU	40 IU	-ve	93 IU	In-house	CVL-Wb 133	✓
6	27 IU	47 IU	53 IU	-ve	106 IU	ANQAP	In-house	✓
7	27 IU	40 IU	40(47) IU	-ve	93(80)IU	*	CSL 0167-71801	✓
9	49 IU	88 IU	93 IU	32 IU	186 IU	In-house	In-house	R
11	27 IU	40 IU	80 (93)IU	20 IU	93(106)IU	NSW 20081	CVL-Wb B135	R
12	47 IU	53 IU	53 IU	-ve	106 IU	*	RM 56P44101	✓
14	40(47) IU	53 IU	53 IU	23 IU	212(186)IU	In-house	CVL, UK	R
C.M	34 IU	53 IU	53 IU	-ve	106 IU	*	*	*
<b>Retest Results</b>								
1	*	*	*	23.25 IU	*	In-house	CSL 016771851	✓
9	40 IU	67 IU	53 IU	23 IU	134 IU	In-house	In-house	R✓
11	*	*	*	23 IU	*	NSW 20081	CSL-Wb B135	✓
14	*	*	*	20 IU	106 IU	In-house	CVL, UK	R✓

RM-RhoneMerieux      Wb-Weybridge

### Result Summary

#### Sample 1:

The consensus mean result for Sample 1 was 34IU with an AVR of 23IU to 47IU. Seven of the eight laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 reported a 49IU result which falls above the AVR and was asked to retest. A retest result of 40IU fell within the AVR was classified as (R✓), retest results acceptable.

#### Sample 2:

The consensus mean result for Sample 2 was 53IU with an AVR of 40IU to 80IU. Lab 9 was the only lab to report results outside the AVR with 88IU. A retest result of 67IU fell within the AVR and was classified as (R✓), retest results acceptable.

#### Sample 3:

The consensus mean result for Sample was 53IU with an AVR of 40IU to 80IU. Lab 9 was the only lab to report results outside the AVR with 93IU. A retest result of 53IU fell within the AVR and was classified as (R✓), retest results acceptable.

#### Sample 4:

Four labs reported equal to or greater than 20IU for Sample 4 and four labs reported a negative result. To investigate repeatability the four labs which reported a reaction were asked to retest. All reported similar results at approximately 23IU which would be interpreted as negative or inconclusive. Lab 9 reported a significantly lower result on retesting and was classified as retest result acceptable (R✓). All labs other than lab 9 were classified as acceptable (✓).

#### Sample 5:

The consensus mean result for Sample 2 was 106IU with an AVR of 80IU to 160IU. Six of eight laboratories reported results within the AVR and were classified as acceptable (✓). Laboratory 9 and 14

reported results above the AVR and were asked to retest. Both results fell within the AVR and were classified as (R✓), retest results acceptable.

### Conclusion

One of the eight laboratories demonstrated significant variation for all five samples. Laboratory 9, which employs its own in-house antigen, demonstrated systematic variation in the form of increased sensitivity. Systematic variation is indicative of reagent or methodology problems and in most cases affects all test samples. When retested lab 9 reported results within the AVR for all five samples. The same methodology and reagents were used in the subsequent testing with the only difference in the original and retesting testing being the dilutions used. On original testing laboratory 9 used half the reagents, and hence half the required sera, in an effort to report three replicate results with a small volume of sera supplied. If carried out correctly however this should not affect the final result. On retesting laboratory 9 reported acceptable results and appears to have rectified the original systematic variation identified on original testing. The original systematic variation may have been the result of the initial dilution of the original test sample. In the previous Phase 7 evaluation laboratory 9 also demonstrated slight increased sensitivity on original testing but acceptable on retesting. In general laboratory 9 has been asked to retest due to systematic error on a number of testing occasions during the Phase 8 evaluation. There appears to be a trend in reporting results consistently above or below the consensus value on original testing and reporting acceptable retest results. Laboratory 9 should implement a system to monitor the sensitivity of a test and ensure any loss of control is identified internally, and not just in the next ANQAP evaluation. This can be achieved by introducing a calibrated control, preferable a low positive which is more sensitive to change, and recording its result for every test run in a control chart.

Only one other lab reported variation in the SAT testing. Lab 14, which employs a CVL antigen, reported Sample 5 above the AVR but results within the AVR for Samples 1, 2, 3 and 4. It appears that laboratory 14 experienced random variation. Unlike systematic variation random error is indicative of technical error and affects only a small number of samples in a test. The effect on each sample is different and unpredictable. Lab 14 retested using the same methodology and reagents and reported a result identical to the consensus mean value. The CVL antigen was also used by two other labs which reported acceptable results on original testing.

Three other antigen sources were identified in Phase 8 testing. Results reported with the Rhone Merieux and CSL antigens were acceptable on original testing. Laboratory 6 also reported acceptable results with an in-house antigen.

In Phase 7 testing two laboratories reported results outside the AVR. As mentioned above lab 9 was one of the two. Lab 7 was the other lab to report increased sensitivity and random variation. Results reported by lab 7 were well within the AVR and acceptable in this evaluation. Lab 7 has demonstrated an improvement in the SAT in the last twelve months. Overall the BB SAT is demonstrating the similar variation as identified in Phase 7.

All labs were included on the Endorsed List of Laboratories for the Phase 8 evaluation.