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Proficiency Testing Laboratory Quality Assessment in Chile

Submitted by: Chile

APEC CHINA 2014

Food Safety Cooperation Forum Partnership Training Institute Network Proficiency Testing Workshop
Beijing, China
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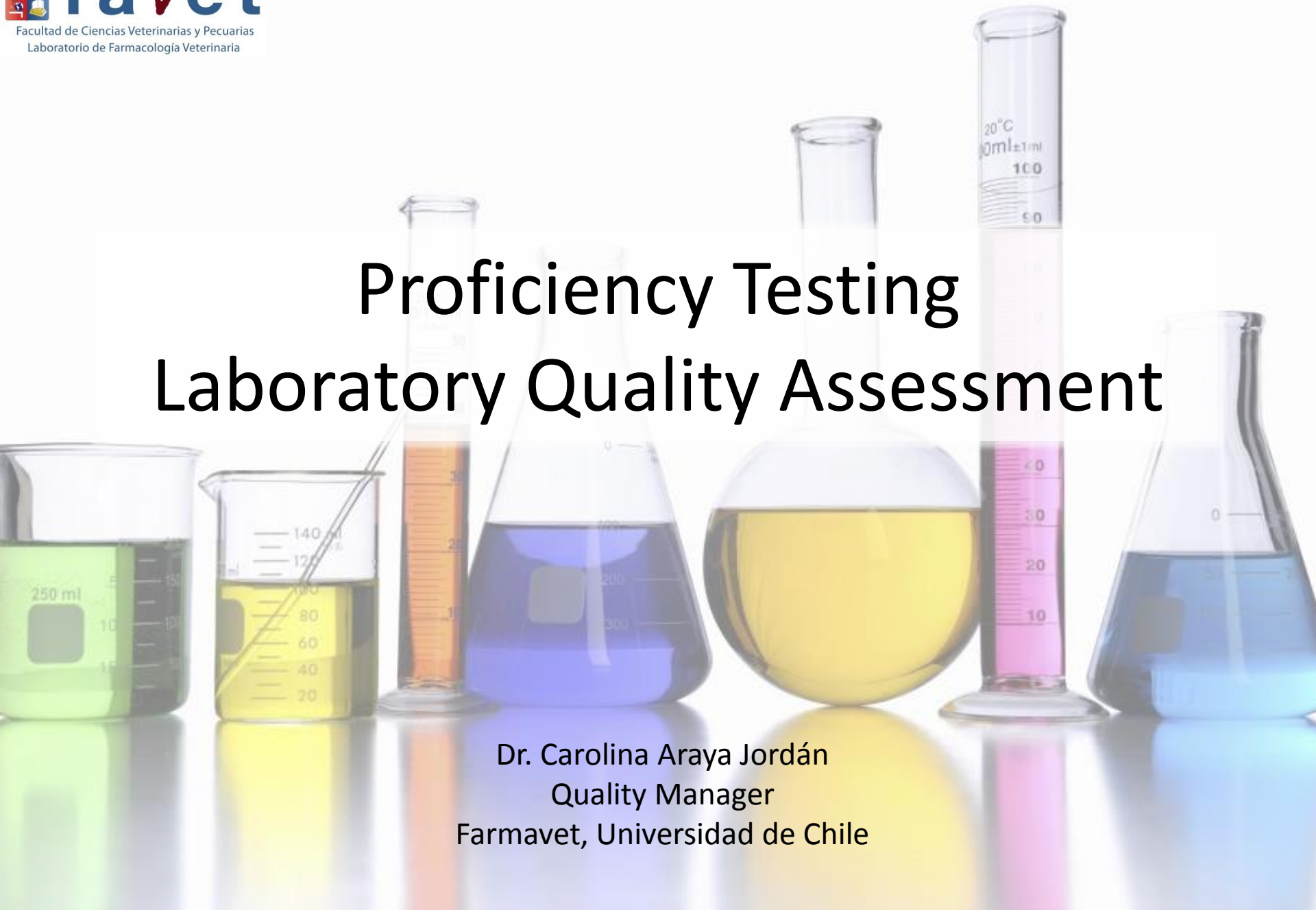
Proficiency Testing
Laboratory Quality Assessment



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ISO 17025

5.9: *Assuring the quality of test and calibration results*

- **Use of CRMs and/or RMs**
- **Proficiency-testing**
- **Replicate tests**
- **Retesting**
- **Correlation of results for different characteristics**

ISO

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Proficiency-testing

- ISO 17043 (definition 3.7): “Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons”
- Independent assessment of the technical performance of a laboratory, necessary to assure the validity of measurements.

WHY?

BECAUSE

- ✓ Measurements give rise to inaccuracies, technically known as “errors”. Errors arise because of unavoidable variation in the chemical procedure employed to make the measurement.
- ✓ The measurement of chemical concentration requires far more complicated procedures than typical physical measurements such as length or time

- So, even though our analytical methods are validated, participation in proficiency testing is a MUST.

ISO Requirement

Method inaccuracies

How is our performance evaluated?

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z-score

- A score of zero implies a perfect result. This will happen quite rarely even in perfectly competent laboratories.
- Laboratories complying with the PT will commonly produce scores falling between - 2 and 2. **They might expect to produce a value somewhat outside this range occasionally, roughly about one time in twenty (Questionable results).**
- A score outside the range from –3 to 3 would be very unusual for a laboratory operating under quality standards, so the cause of the event should be investigated and remedied (Corrective Action).

What does z-score implies?

- Satisfactory z-score does not only give information on the good performance of the analytical system.
- Treatment of PT samples is a complex chain of events, comprising every aspect of laboratory management and technical experience.

What does z-score implies?

- Selection of PT
- Reception of sample
- Treatment of sample
- Technical staff
- Laboratory equipment use and calibration (scales, pHmeter, micropipettes, shakers, centrifuges)
- Reagent quality
- Certified Reference Material quality
- Quality controls
- Instruments calibration (HPLC, GC)
- Integration software
- Analyst qualification
- Data treatment
- Reporting results

PT Result

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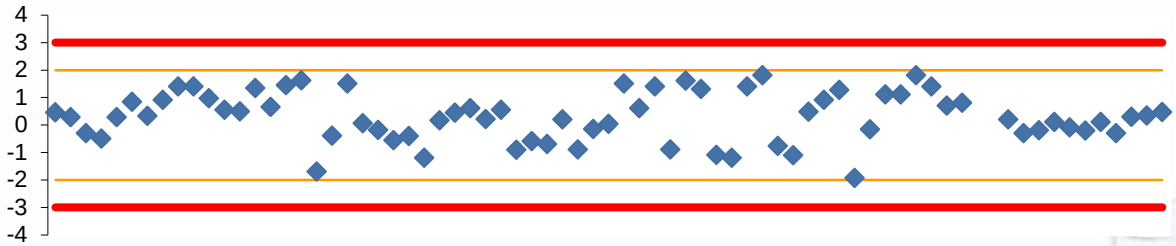

Satisfactory z-score

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- Laboratory's Quality System is well functioning
- Satisfactory technical performance

A single laboratory would typically produce z-scores covering the range –2 to +2: the following set [0.6, -0.8, 0.3, 1.7, 0.7, -0.1] would be typical. The small ups and downs between the scores do not indicate a change in performance – they arise by chance. So 1.9 is not 'worse' than 0.2: it does not indicate deterioration in performance.

Interpretation

- Official Laboratory for National Fisheries Service (SERNAPESCA): National Residues Control Plan for antibiotics and contaminants (salmon, trout, aquaculture products)
- Service Laboratory for National Agricultural Service (SAG): National Residues Control Plan for antibiotics and contaminants (pig, poultry, bovines, ovines and honey)
- **Accredited under international regulation ISO 17025, since 2002.**

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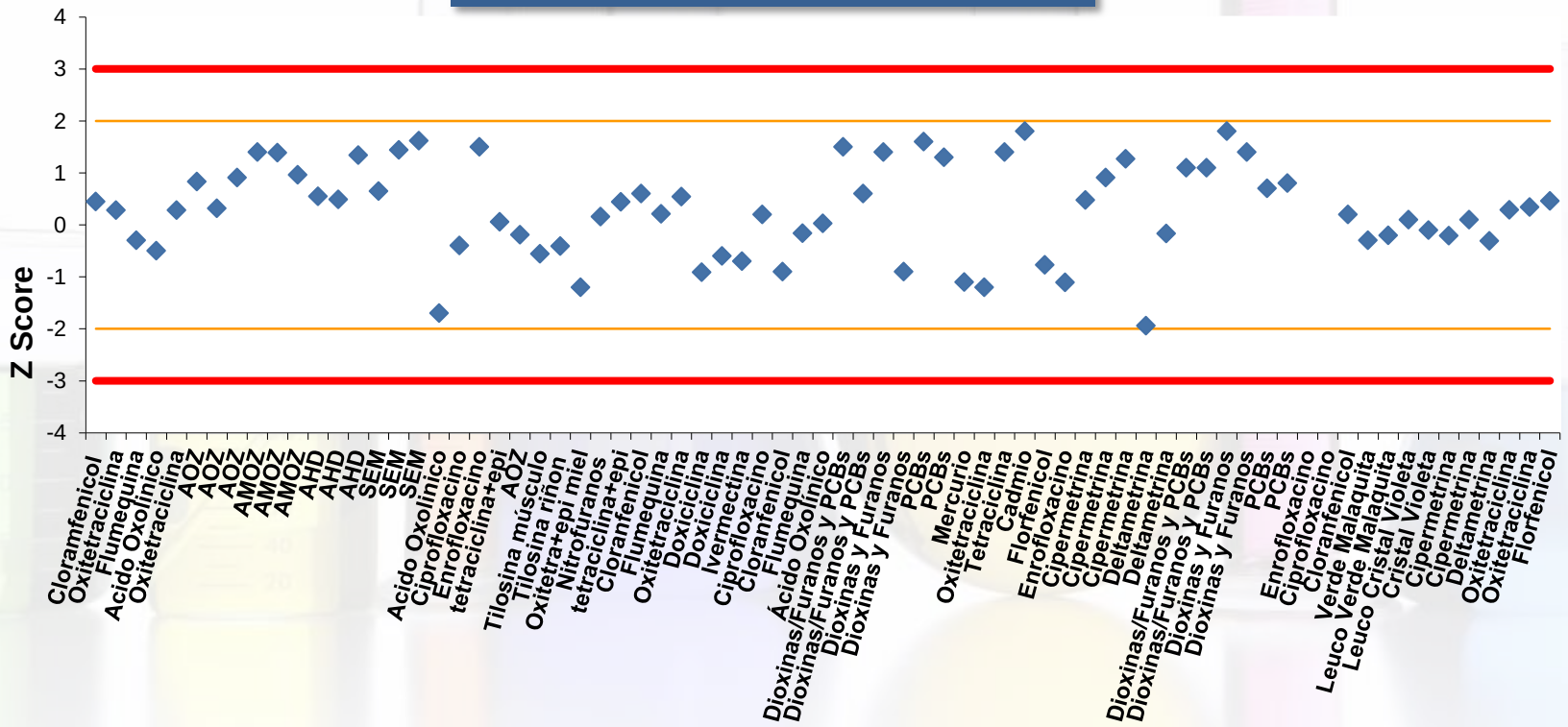

- Satisfactory z-score guarantees lack of systematic errors?
  - Small systematic errors can still allow for satisfactory z-score, and the only way to detect them is to analyze consecutive PT for the same analite.
  - Consecutive performance scores, for the same parameter, which have the same bias sign against the assigned value, should be evaluated.

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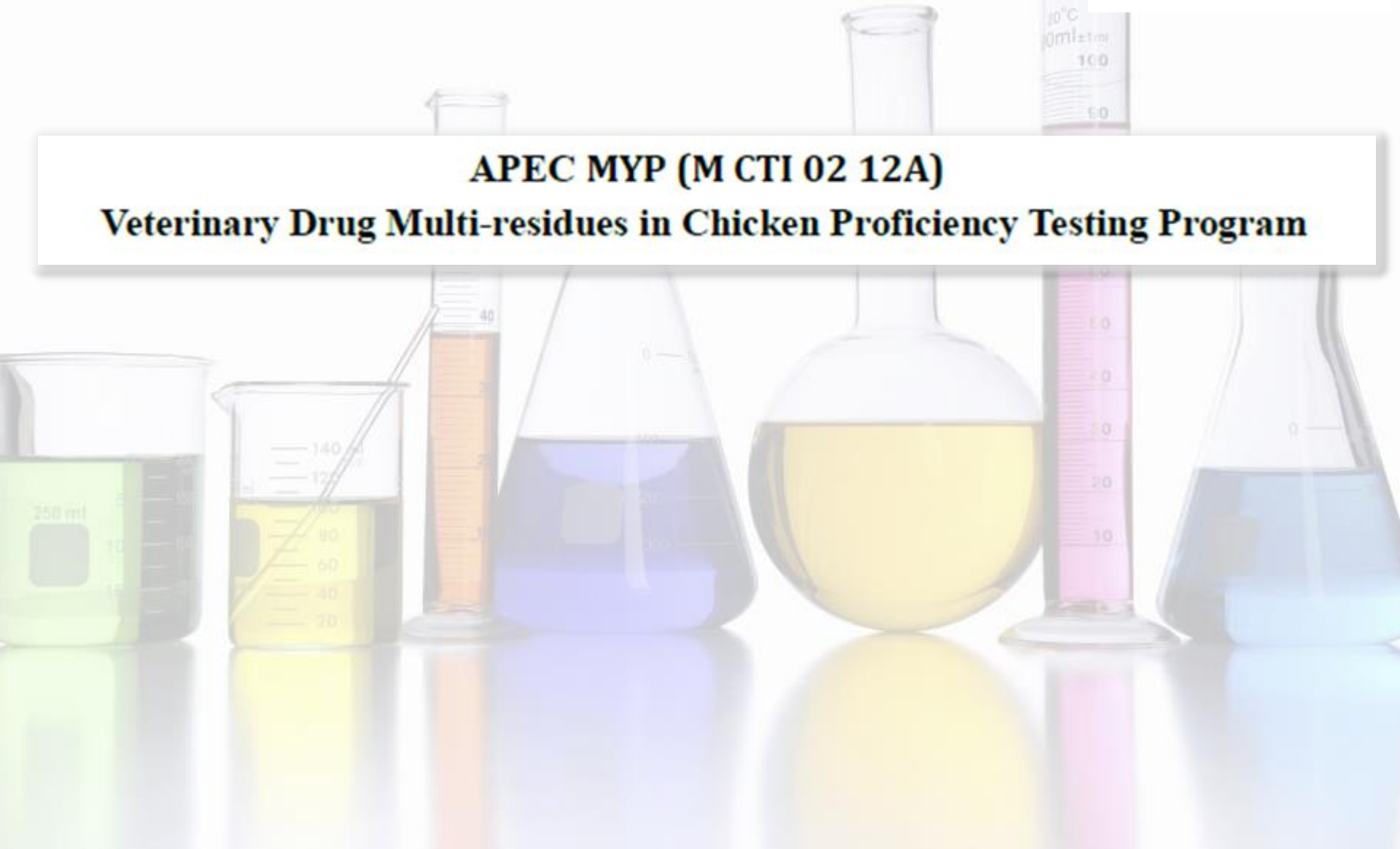
APEC MYP (M CTI 02 12A)

Veterinary Drug Multi-residues in Chicken Proficiency Testing Program



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Veterinary Drug Multi-residues in Chicken Proficiency Testing Program

Table 1 Reported Results of Residue of AOZ

lab code	Sample A					Sample B					Method or instrument
	Testing results in duplicate (μg/kg)		Mean value (μg/kg)	Recovery (%)	Z-Score	Testing results in duplicate (μg/kg)		Mean value (μg/kg)	Recovery (%)	Z-score	
	1	2				1	2				
APEC FSCF-MYP-001	20.500	20.000	20.300	98.300	6.20	9.510	9.330	9.420	98.300	5.42	LC-MSMS
APEC FSCF-MYP-002	9.000	10.000	9.500	/	1.61	5.000	6.000	5.500	/	1.74	LC-MSMS
APEC FSCF-MYP-006	7.030	7.020	7.030	100.000	0.56	3.860	3.860	3.860	100.000	0.20	LC-MSMS
APEC FSCF-MYP-007	3.680	3.430	3.560	97.200	-0.92	2.180	2.170	2.180	97.200	-1.37	LC-MSMS
APEC FSCF-MYP-009	5.588	5.755	5.652	80.200	-0.03	3.207	3.229	3.218	90.000	-0.40	LC-MSMS
APEC FSCF-MYP-010	3.190	3.630	3.410	104.820	-0.98	2.020	2.400	2.210	104.820	-1.34	LC-MSMS
APEC FSCF-MYP-013	2.630	2.590	2.610	/	-1.32	1.710	1.810	1.760	/	-1.77	LC-MSMS
APEC FSCF-MYP-016	3.200	2.800	3.000	108.000	-1.16	1.800	1.700	1.750	126.000	-1.78	LC-MSMS
APEC FSCF-MYP-017	6.900	5.500	6.200	/	0.20	2.800	2.300	2.600	/	-0.98	LC-MSMS
APEC FSCF-MYP-018	7.700	7.800	7.800	112.000	0.88		4.700	4.700	112.000	0.99	LC-MSMS
APEC FSCF-MYP-019	2.040	2.010	2.030	40.400	-1.57	3.240	2.370	2.810	40.400	-0.78	LC-MSMS
APEC FSCF-MYP-021	3.960	3.770	3.870	74.400	-0.79	5.460	5.550	5.500	74.400	1.74	LC-MSMS
APEC FSCF-MYP-022	5.588	5.600	5.594	<90-110>	-0.05	3.544	3.524	3.534	<90-110>	-0.10	LC-MSMS
	5.790	5.792	5.791	<90-110>	0.03	3.605	3.992	3.799	<90-110>	0.15	LC-MSMS
APEC FSCF-MYP-025	6.590	6.570	6.580	99.000	0.37	3.760	3.920	3.840	99.000	0.19	LC-MSMS
APEC FSCF-MYP-026	5.400	5.200	5.300	88.000	-0.18	3.100	3.000	3.000	88.000	-0.60	LC-MSMS
APEC FSCF-MYP-027	7.520	7.290	7.400	107.000	0.71	4.210	4.140	4.180	107.000	0.50	LC-MSMS
APEC FSCF-MYP-028	0.800	0.740	0.770	7.800	-2.11	0.510	0.470	0.490	8.200	-2.96	LC-MSMS
APEC FSCF-MYP-029	6.013	5.999	6.006	91.100	0.12	3.799	3.702	3.751	91.100	0.10	LC-MSMS
APEC FSCF-MYP-030	5.870	5.880	5.880	97.600	0.07	3.700	3.790	3.750	97.600	0.10	LC-MSMS

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Veterinary Drug Multi-residues in Chicken Proficiency Testing Program

Table 2 Reported Results of Residue of AMOZ

lab code	Sample A					Sample B					Method or instrument
	Testing results in duplicate (μg/kg)		Mean value (μg/kg)	Recovery (%)	Z-Score	Testing results in duplicate (μg/kg)		Mean value (μg/kg)	Recovery (%)	Z-score	
	1	2				1	2				
APEC FSCF-MYP-002	1.900	2.100	2.000	/	**1.02**	0.900	1.100	1.000	/	**0.98**	LC-MSMS
APEC FSCF-MYP-006	2.000	2.000	2.000	101.000	**1.02**	1.000	1.000	1.000	101.000	**0.98**	LC-MSMS
APEC FSCF-MYP-007	1.130	1.040	1.080	88.000	**-0.83**	0.460	0.510	0.485	88.000	**-0.94**	LC-MSMS
APEC FSCF-MYP-009	1.745		1.745	85.600	**0.51**	0.885	0.852	0.868	87.800	**0.49**	LC-MSMS
APEC FSCF-MYP-010	1.260	1.180	1.220	108.580	**-0.55**	0.530	0.730	0.630	108.580	**-0.40**	LC-MSMS
APEC FSCF-MYP-013	0.750	0.860	0.805	/	**-1.38**	0.385	0.409	0.397	/	**-1.27**	LC-MSMS
APEC FSCF-MYP-016	0.500	0.600	0.550	108.000	**-1.90**	<0.5	<0.5	<0.5	126.000	/	LC-MSMS
APEC FSCF-MYP-017	2.000	1.600	1.800	/	**0.62**	0.590	0.510	0.550	/	**-0.70**	LC-MSMS
APEC FSCF-MYP-018	2.100	2.000	2.100	99.000	**1.22**		0.990	0.990	99.000	**0.94**	LC-MSMS
APEC FSCF-MYP-019	1.020	0.895	0.956	45.000	**-1.08**	0.780	0.676	0.729	45.000	**-0.03**	LC-MSMS
APEC FSCF-MYP-021	<1	<1	<1	108.000	/	1.480	1.580	1.520	108.000	2.92	LC-MSMS
APEC FSCF-MYP-022	1.484	1.539	1.512	<90-110>	**0.04**	1.018	0.997	1.008	<90-110>	**1.01**	LC-MSMS
	1.508	1.486	1.497	<90-110>	**0.01**	1.017	1.078	1.048	<90-110>	**1.16**	LC-MSMS
APEC FSCF-MYP-025	1.500	1.480	1.490	80.000	**-0.01**	0.670	0.660	0.670	80.000	**-0.25**	LC-MSMS
APEC FSCF-MYP-026	1.800	2.000	1.900	100.000	**0.82**	0.700	0.800	0.800	100.000	**0.23**	LC-MSMS
APEC FSCF-MYP-027	1.630	1.640	1.640	104.000	**0.29**	0.637	0.669	0.653	104.000	**-0.31**	LC-MSMS
APEC FSCF-MYP-028	0.190	0.170	0.180	11.100	-2.64	0.140	0.140	0.140	0.000	-2.23	LC-MSMS
APEC FSCF-MYP-029	1.501	1.470	1.485	100.000	**-0.02**	0.743	0.748	0.746	100.000	**0.03**	LC-MSMS
APEC FSCF-MYP-030	1.360	1.340	1.350	96.800	**-0.29**	0.680	0.740	0.710	96.800	**-0.10**	LC-MSMS

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Veterinary Drug Multi-residues in Chicken Proficiency Testing Program

Table 6 Reported Results of Residue of Ciprofloxacin

lab code	Sample A					Sample B					Method or instrument
	Testing results in duplicate (μg /kg)		Mean value (μg /kg)	Recovery (%)	Z-Score	Testing results in duplicate (μg /kg)		Mean value (μg /kg)	Recovery (%)	Z score	
	1	2				1	2				
APEC FSCF-MYP-001	84.000	94.000	89.000	102.000	0.33	681.000	585.000	633.000	102.000	3.77	LC-MSMS
APEC FSCF-MYP-002	64.000	74.000	69.000	/	-0.67	470.000	490.000	480.000	/	0.93	LC
APEC FSCF-MYP-003	97.848	92.246	95.047	68.900	0.63	526.206	511.715	518.961	68.900	1.65	LC-MSMS
APEC FSCF-MYP-007	84.700	80.100	82.400	101.000	0.00	411.000	437.000	424.000	101.000	-0.11	LC-MSMS
APEC FSCF-MYP-009	31.046	29.569	30.310	85.400	-2.59	82.491	80.087	81.290	75.400	-6.49	LC-MSMS
APEC FSCF-MYP-010	59.270	65.570	62.420	103.160	-0.99	396.570	457.630	427.100	103.160	-0.06	LC-MSMS
APEC FSCF-MYP-013	105.000	97.300	101.000	80.800	0.92	417.000	394.000	406.000	/	-0.45	LC-FLD
APEC FSCF-MYP-014	136.000	142.000	139.000	96.000	2.81	813.000	742.000	777.000	96.000	6.45	LC-MSMS
APEC FSCF-MYP-015	90.460	90.440	90.450	/	0.40	432.880	421.800	427.340	/	-0.05	LC-MSMS
APEC FSCF-MYP-016	71.200	72.400	71.800	91.400	-0.53	528.000	532.000	530.000	91.400	1.86	LC-MSMS
APEC FSCF-MYP-017	85.100	82.000	83.600	94.000	0.06	419.500	440.600	430.100	94.000	0.00	LC-MSMS
APEC FSCF-MYP-019	48.000	49.300	48.600	53.500	-1.68	338.000	336.000	337.000	53.500	-1.73	LC-MSMS
APEC FSCF-MYP-020	58.000	59.200	58.600	91.000	-1.18	309.000	313.000	311.000	91.000	-2.21	LC-MSMS
APEC FSCF-MYP-022	74.999	72.029	73.514	74.450	-0.44	418.998	471.946	445.472	74.450	0.29	LC-MSMS
	76.964	77.713	77.339	74.450	-0.25	434.622	426.542	430.582	74.450	0.01	LC-MSMS
APEC FSCF-MYP-023	102.276	95.974	99.100	91.450	0.83	483.165	500.997	492.110	91.450	1.15	LC-MSMS
APEC FSCF-MYP-024	89.500	91.900	90.700	/	0.41	472.000	426.000	449.000	/	0.35	LC-MSMS
APEC FSCF-MYP-025	229.000	266.000	248.000	105.000	8.22	1523.000	1268.000	1396.000	105.000	17.96	LC-MSMS
APEC FSCF-MYP-026	46.000	53.000	50.000	72.000	-1.61	319.000	309.000	314.000	72.000	-2.16	LC-MSMS
APEC FSCF-MYP-027	68.400	81.900	75.200	109.000	-0.36	421.000	438.000	430.000	109.000	0.00	LC-MSMS
APEC FSCF-MYP-028	103.000	101.000	102.000	2.000	0.97	413.000	429.000	421.000	3.800	-0.17	LC-MSMS
APEC FSCF-MYP-029	86.000	83.000	84.500	96.600	0.10	432.000	433.000	432.500	96.600	0.04	LC-MSMS
APEC FSCF-MYP-030	60.000	63.900	62.000	111.000	-1.01	290.000	251.000	271.000	111.000	-2.96	LC-MSMS

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Table 3 Reported Results of Residue of Sulfamethoxazole

lab code	Sample A					Sample B					Method or instrument
	Testing results in duplicate (μg/kg)		Mean value (g/kg)	Recovery (%)	Z-Score	Testing results in duplicate (μg/kg)		Mean value (g/kg)	Recovery (%)	Z-score	
	1	2				1	2				
APEC FSCF-MYP-001	34.900	32.800	33.900	102.000	1.02	194.000	183.000	189.000	102.000	1.66	LC-MSMS
APEC FSCF-MYP-002	32.000	38.000	35.000	/	1.21	135.000	150.000	142.500	/	0.00	LC-MSMS
APEC FSCF-MYP-006	37.100	30.500	33.800	75.700	1.00	147.000	124.000	135.000	75.700	-0.27	LC–UV detector
APEC FSCF-MYP-007	38.500	39.400	39.000	63.800	1.90	167.000	161.000	164.000	83.700	0.77	LC–UV detector
APEC FSCF-MYP-009	29.310	31.930	30.620	78.980	0.45	141.420	140.130	140.780	79.480	-0.06	LC-MSMS
APEC FSCF-MYP-010	19.250	16.070	17.660	92.500	-1.79	93.470	91.530	92.500	92.500	-1.79	LC-MSMS
APEC FSCF-MYP-015	38.520	38.660	38.590	/	1.83	160.440	161.730	161.090	/	0.66	LC-MSMS
APEC FSCF-MYP-017	26.300	23.500	24.900	103.000	-0.54	92.500	100.400	96.500	103.000	-1.64	LC-MSMS
APEC FSCF-MYP-018	28.900	29.500	29.200	97.000	0.21	157.000	154.000	156.000	97.000	0.48	LC-MSMS
APEC FSCF-MYP-019	13.400	14.700	14.000	103.500	-2.42	102.000	99.000	100.000	103.500	-1.52	LC-MSMS
APEC FSCF-MYP-022	27.395	27.860	27.628	83.900	-0.06	140.768	141.671	141.220	83.900	-0.05	LC-MSMS
	27.338	27.204	27.271	83.900	-0.13	140.418	146.065	143.242	83.900	0.03	LC-MSMS
APEC FSCF-MYP-023	32.358	32.248	32.300	57.600	0.74	113.634	105.628	109.600	57.600	-1.18	LC-MSMS
APEC FSCF-MYP-024	30.800	33.200	32.000	/	0.69	150.000	152.000	151.000	/	0.30	LC-MSMS
APEC FSCF-MYP-025	20.800	23.200	22.000	101.000	-1.04	306.000	329.000	318.000	101.000	6.27	LC-MSMS
APEC FSCF-MYP-026	26.000	30.000	28.000	99.000	0.00	176.000	156.000	166.000	99.000	0.84	LC-MSMS
APEC FSCF-MYP-027	24.800	26.400	25.600	108.000	-0.42	129.000	134.000	132.000	108.000	-0.38	LC-MSMS
APEC FSCF-MYP-028	26.200	27.000	26.600	2.600	-0.24	147.000	146.000	147.000	0.700	0.16	LC-MSMS
APEC FSCF-MYP-029	20.000	20.000	20.000	96.500	-1.38	108.000	109.000	108.500	96.500	-1.22	LC-MSMS

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Veterinary Drug Multi-residues in Chicken Proficiency Testing Program

Table 5 Reported Results of Residue of Sulfaquinoxaline

lab code	Sample A					Sample B					Method or instrument
	Testing results in duplicate (μg /kg)		Mean value (μg /kg)	Recovery (%)	Z-Score	Testing results in duplicate (μg/kg)		Mean value (μg /kg)	Recovery (%)	Z score	
	1	2				1	2				
~~APEC FSCF-MYP-001~~	~~1008.000~~	~~970.000~~	~~989.000~~	~~105.000~~	~~0.00~~	~~311.000~~	~~330.000~~	~~320.000~~	~~105.000~~	~~1.81~~	~~LC-MSMS~~
APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS
APEC FSCF-MYP-007	910.000	998.000	954.000	95.200	-0.11	230.000	220.000	225.000	95.200	0.15	LC–UV detector
APEC FSCF-MYP-009	789.360	816.320	802.840	98.130	-0.57	199.710	186.980	193.340	97.680	-0.40	LC-MSMS
APEC FSCF-MYP-010	589.310	515.590	552.450	117.910	-1.34	126.160	135.050	130.600	117.910	-1.49	LC-MSMS
APEC FSCF-MYP-014	1150.000	932.000	1040.000	72.000	0.16	247.000	285.000	266.000	72.000	0.87	LC-MSMS
APEC FSCF-MYP-015	871.790	876.140	873.960	/	-0.35	238.110	231.540	234.820	/	0.33	LC-MSMS
APEC FSCF-MYP-017	1088.500	1034.200	1061.400	98.000	0.22	206.600	196.700	201.700	98.000	-0.25	LC-MSMS
APEC FSCF-MYP-018	1030.000	1040.000	1040.000	100.000	0.16	238.000	232.000	235.000	100.000	0.33	LC-MSMS
APEC FSCF-MYP-019	85.700	80.500	83.100	109.500	-2.78	199.000	189.000	194.000	109.500	-0.39	LC-MSMS
APEC FSCF-MYP-022	1019.240	1028.300	1023.770	86.250	0.11	219.140	213.130	216.135	86.250	0.00	LC-MSMS
	1028.994	1013.887	1021.441	86.250	0.10	211.152	217.869	214.511	86.250	-0.03	LC-MSMS
APEC FSCF-MYP-023	999.800	1010.626	1005.200	43.500	0.05	155.902	160.940	158.400	43.500	-1.01	LC-MSMS
APEC FSCF-MYP-024	1050.000	1130.000	1090.000	/	0.31	238.000	243.000	240.500	/	0.42	LC-MSMS
APEC FSCF-MYP-025	207.000	286.000	247.000	101.000	-2.28	84.500	124.000	104.000	101.000	-1.95	LC-MSMS
APEC FSCF-MYP-026	1129.000	1310.000	1220.000	97.000	0.71	290.000	266.000	278.000	97.000	1.08	LC-MSMS
APEC FSCF-MYP-027	222.000	222.000	222.000	99.000	-2.35	111.000	59.700	85.300	99.000	-2.28	LC-MSMS
APEC FSCF-MYP-028	156.000	158.000	157.000	1.300	-2.55	877.000	919.000	898.000	4.700	11.89	LC-MSMS
APEC FSCF-MYP-029	644.000	653.000	648.500	92.900	-1.05	134.000	136.000	135.000	92.900	-1.41	LC-MSMS

Non satisfactory results?

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- As a basic principle, laboratories should always investigate unsatisfactory results (z-score>|3|)
- For questionable results (|2|<z-score<|3|), laboratories can establish a criteria for launching an investigation, considering for example:
  - 2 consecutive questionable performance scores
  - A given number of consecutive satisfactory results, but with the same bias sign against the assigned value.

Non satisfactory results?

APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

Corrective Action

Preventive Measure

- Every unsatisfactory result must be faced with a full investigation and a Corrective Action.
- Questionable results must be analyzed over time, in case the same inaccuracy happens in future tests, and in search for trends.
- However, individual questionable results should be analyzed using the laboratory's Preventive Measure procedure.
- The key to both procedures is the Root Cause Investigation

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

Root Cause Investigation

- Clerical error:
  - Reporting problem (units, format)
  - Sample tracking
  - Interpretation
- Technical problem:
  - Sample preparation
  - Equipment failure
  - Calibration
  - Sample storage
- Problem related to the PT scheme:
  - Matrix difference between PT and routine samples
  - Parameter concentration outside the scope of laboratory methods
  - Lack of stability or homogeneity

Causes for poor performance

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

- Two samples, same matrix, same analite, different concentration
- Questionable results
- Root cause investigation
  - Clerical error?
  - Technical problem?
  - PT scheme?

SAME CONDITIONS

Root Cause Investigation

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

PT Scheme

- ✓ Matrix difference between PT and routine samples
- ✓ Analite concentration outside the scope of application of the method
- ✓ Inappropriate peer group

Causes for poor performance

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

PT Scheme

- ✓ When choosing a PT, if possible, concentration levels in the PT samples should be within the validated range of concentration in the laboratory.
- ✓ Reporting results outside this range, can increase inaccuracies of the method.

Causes for poor performance

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

- Validated range of concentrations in Farmavet for Sulphonamides:

5 ppb → 200 ppb

- Concentration levels for Sulfaquinoxaline above validated range.
- There is no information regarding analite behavior at this concentration level (Linearity of the calibration curve)
- Inaccurate results

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APEC FSCF-MYP-002	1250.000	1350.000	1300.000	/	0.95	370.000	400.000	385.000	/	2.94	LC-MSMS

Preventive Measure

- ✓ Check estimated concentration levels of PT test
- ✓ Validate additional calibration curves (higher concentration levels) for PT samples outside our scope
- ✓ Not reporting results outside the method's application scope

Effectiveness

- ✓ Blind sample analysis
- ✓ Additional PT participation for the questioned analite