Regulations, Sample Volumes and Turnaround Times for VMRD Assays

			SERUMS/LIQUIDS		*POWDERS*			
Regulation Satisfied	**Catalog Number**	**Description**	**Minimum Sample ***	**Recommended Sample**	**Minimum Sample**	**Recommended Sample**	**Assay Time**	**Turnaround Time**
9/CFR 113.53c (including 113.46 & 113.47)	9C-AOP-BOV	9CFR Compliant Testing of Animal Origin Product for Bovine Species	50 mL	100 mL	1.50 g	2.00 g	22 days	25-32 days
9/CFR 113.53c (including 113.46 & 113.47)	9C-AOP-POR	9CFR Compliant Testing of Animal Origin Product for Porcine Species	50 mL	100 mL	1.50 g	2.00 g	22 days	25-32 days
9/CFR 113.53d	9C-PT-POR	9CFR Compliant Testing of Porcine Trypsin, 28 day 113.53d Requirement	variable: at least 5.00 g in solution	variable: at least 5.00 g in solution	5.00 g	10.00 g	29 days	31-38 days
9/CFR 113.53a (including 113.28)	9C-MY-IN	Mycoplasma Detection Assay, 9CFR 113.28 with inhibition assy	10 mL	20 mL	0.25 g	5.00 g	28 days	31-38 days
9/CFR 113.53a (including 113.28)	9C-MY	Mycoplasma Detection Assay, 9CFR 113.28	10 mL	20 mL	0.25 g	5.00 g	28 days	31-38 days
9/CFR 113.53b (including 113.26)	9C-B&F	Sterility Assay of Animal Origin Products, 9CFR 113.26	25mL	30mL	1.25 g	5.00 g	14 days	16-23 days
9/CFR 113.27	9C-B&F-MSV	Sterility Assay of Virus Samples, 9CFR 113.27	4.5mL	5mL	0.25 g	1.00 g	14 days	16-23 days
9CFR 113.53c and 113.47 method	M9C-AOP-BOV	Virus Assay on Bovine cells using 113.47,53c method	24ml	48 ml	0.68 g	1.36 g	22 days	25-32 days
9CFR 113.53c and 113.47 method	M9C-AOP-BOV-BPYV	BPyV Virus Assay using 113.47,53c method	24mL	48 mL	0.68 g	1.36 g	22 days	25-32 days
9CFR 113.53c and 113.47 method	M9C-AOP-HAM-VES	Vesivirus Assay using 113.47,53c method	24 mL	48 mL	0.68 g	1.36 g	22 days	25-32 days

*Assumes testing on vero cells and on one other cell line; more sample will be required for additional cell lines.

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Regulation Satisfied	**Catalog Number**	**Description**	**Minimum Sample ***	**Recommended Sample**	**Minimum Sample**	**Recommended Sample**	**Assay Time**	**Turnaround Time**
CVMP/743/00-Rev.2 (2005) 4.3.3.1, 4.3.3.2, CHMP/BWP/1793/02 (2003) 7.3.1, 7.3.2, 7.3.3, EP 5.2.5	EM-AOP-BOV	Bovine Virus Assay EP 5.2.5; CVMP 4.3.3.1,2; CHMP 7.3.1,2,3	80 mL	150 mL	Call	Call	22 days	25-32 days
CVMP/743/00 (4.3.3.2), CHMP/BWP/1793/02 (7.3.3)	QUANT-AOP-BOV	Quick Test for BVD, IBR and PI3 by FA	25 mL	50 mL	Call	Call	10-22 da	13-26
CVMP/743/00 (4.3.3.3), CHMP/BWP/1793/02 (7.3.4)	SN-AOP-BOV-4	Beta SN Assay, 4 Bovine viruses, EMA CVMP 4.3.3.3 CHMP 7.3.4	4 mL	10 mL	Call	Call	7 days	7-13 days
CPMP/BWP/1793/02 (2003) 5.3.4	EMCT-AOP-BOV CT-AOP-BOV (standalone)	28 day EMA Comparative Titration (Serum Inhibitory Test) as required by CPMP	18 mL	30 mL	Call	Call	28 days	31-38 days
CVMP/743/00 (4.3.3.3), CHMP/BWP/1793/02 (7.3.4)	ALPHA-AOP-BOV	Alpha Neutralization / Bovine virus CVMP 4.3.3.3; CHMP 7.3.4	2 mL	5 mL	Call	Call	7 days	7-13 days
CVMP/743/00 (4.3.3.3), CHMP/BWP/1793/02 (7.3.4)	Optional: VR-AOP-BOV	Virus Reduction Serum Neutralization Assay for BVD	1 mL	5 mL	Call	Call	7 days	7-13 days
For Full EMA test			111 mL	200 mL	Call	Call	28 days	31-38 days
CVMP/743/00-Rev.2 (2005) 4.3.3.1, 4.3.3.2 (partial)	MEM-AOP-BOV-(VIRUS)	Stand alone EMA method test for a Bovine Virus In Animal Origin Product (Specify Virus)	18 mL	30 mL	Call	Call	22 days	31-38 days

*Assumes testing on vero cells and on one other cell line; more sample will be required for additional cell lines.

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Regulation Satisfied	**Catalog Number**	**Description**	**Minimum Sample ***	**Recommended Sample**	**Minimum Sample**	**Recommended Sample**	**Assay Time**	**Turnaround Time**
EP 2.6.7	EP-MY-IN	Mycoplasma Detection Assay in compliance with EP 2.6.7 with inhibition assay	124 mL	248 mL	6.50 g	13.00 g	28 days	31-38 days
EP 2.6.7 and USP <63>	EPUSP-MY	Mycoplasma Detection Assay, EP 2.6.7 & USP 63 w/o Inhibition	45 mL	50 mL	2.25 g	4.50 g	28 days	31-38 days
EP 2.6.7 and USP <63>	EPUSP-MY-IND	Myco Assay, EP2.6.7 & USP63 for indicator assay	4 mL	8 mL	0.50 g	1.00 g	9-11 days	14-21 days
EP 2.6.7 and USP <63>	EPUSP-MY-VS-IN	Myco Assay, EP2.6.7 & USP63 for Viruses w/ Inhibition	45 mL	90 mL	2.25 g	4.50 g	28 days	31-38 days
None, based on Barille paper	LVB-MY-B&A	Mycoplasma Detection Assay, Large Volume Barile Method	60 mL	120 mL	3.00 g	6.00 g	28 days	31-38 days
None, based on Barille paper	LVB-MY-B&A-IN	Mycoplasma Large Volume Barile Method with inhibition	160 mL	320 mL	8.00 g	16.00 g	28 days	31-38 days
PTC (1993) Agar and Broth Media Procedure (Part A), and Indicator Cell Culture Procedure (Part B)	PTC-MY	Mycoplasma Detection Assay, FDA Points to Consider, Complete	20 mL	40 mL	1.00 g	2.00 g	28 days	31-38 days
PTC (1993) Agar and Broth Media Procedure (Part A)	PTC-MY-B&A	Mycoplasma Detection Assay, FDA PTC Agar & Broth Procedure	15 mL	30 mL	0.75 g	1.50 g	28 days	31-38 days
NA	PTC-MY-B&A-IN	Stand alone EMA method test for a Bovine Virus In Animal Origin Product (Specify Virus)	40 mL	80 mL	2.00 g	4.00 g	28 days	31-38 days
PTC (1993) Indicator Cell Culture Procedure (Part B)	PTC-MY-IND	Mycoplasma Detection Assay, FDA PTC Indicator Cell	5 mL	10 mL	0.25 g	0.50 g	4-6 days	9-16 days
PTC (1993) Indicator Cell Culture Procedure (Part B)	PTC-MY-IND-MSV	Myco Detection Assay, FDA PTC for Viruses w/ Inhibition	10 mL	20 mL	0.50 g	1.00 g	4-6 days	9-16 days
USP <63>	USP-MY-IN	Mycoplasma Detection Assay, USP 63 With Inhibition Assay	124 mL	248 mL	6.50 g	13.00 g	28 days	31-38 days