

# **Testing Services**

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On behalf of the whole VMRD team, thank you for your business! VMRD was founded with the goal of bringing better tests to you, our customers. Better tests yield better diagnoses, better relationships, better outcomes, better bottom lines, and better days.

Our products and services team members strive every day to accomplish the better test goal. If we ever fail to achieve this goal, please do not hesitate to contact any member of the VMRD team, including me personally, so that we can make it right. That is the way we would want to be treated, and we will do our best to treat you that way.

May you have only good days at the bench!

Soli Deo gloria,

Ethan Adams, CEO











## INTEGRITY

In keeping with our company values of doing unto others as we would have them do unto us, we test your samples with the same care and diligence that we apply to our own samples. You want results quickly, but you also need to make sure that your product is free of adventitious agents and that the regulatory testing requirements have been satisfied. We keep both things in mind as we work with your sample and are constantly improving our processes.

# QUALITY

VMRD testing is performed by highly qualified staff to current Good Laboratory Practices (cGLP, 21CFR §58). We are continually investing in our quality management system that encompasses all aspects of our testing services. We are currently registered to ISO 9001:2015 and offer ISO 17025:2017 accredited testing. Our laboratory currently operates in a USDA licensed facility. Our assays are internally validated or verified to provide the best possible sensitivity for the detection of adventitious agents. We welcome customer audits and look forward to hosting you and/or your company's representative.

# EXPERIENCE

We have more than 34 years of business experience and over 50 years of combined laboratory testing experience. We have optimized and refined our methods, bench records, and reporting for maximum accuracy and acceptability to regulatory officials. We have accessioned over 6500 test articles, published more than 13,000 final reports and worked with over 90 customers within the last 6 years. This experience allows us to offer a wide range of regulatory and custom testing suited to each customer's needs.

### CONVENIENCE

Our assay offerings are geared toward providing one-stop testing, saving you time and money. Sample submission, test selection, and result reporting are facilitated through a secure online portal providing easy, self-service access to current and previous test results. Our dedicated sales staff are always available to assist with any inquiries and our Study Directors are happy to consult on any technical matters.

# **VIRUS TESTING**

VMRD Testing Services offers several validated or verified assays to evaluate a wide range of test articles for extraneous viruses as specified in various regulations and/or guidance documents including:

- USDA-APHIS 9 CFR
- CVMPICHMP

MC MC

FM

- European Medicines Agency (EMA)
  European Pharmacopeia (EP) monographs
  United States Pharmacopeia (USP) monographs

Contact us today to find out more!

# **BOVINE RAW MATERIAL TESTING**

ATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LEM
EST ARTICLE TYPE: ANIMAL	ORIGIN PRODUCT		
C-AOP-BOV/VERO*	Bovine Virus Assay I 9 CFR 113.53(c)	50 mL or 2 grams	22 days
C-AOP-BOV/VERO-17025	Bovine Virus Assay   9 CFR 113.53(c) ISO 17025:2017 accredited assays	50 mL or 2 grams	22 days
9C-AOP-BOV	Modified Bovine Virus Assay (virus specific)	30 mL or 1 gram	22 days
9C-AOP-BOV-BPyV	BPyV Virus Assay	50 mL	22 days
9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
M-AOP-BOV/VERO†	Bovine Virus Assay   EP 5.2.5; CVMP 4.3.3.1,2; CHMP 7.3.1,2,3	100 mL	22 days
EM-AOP-BOV	Modified Bovine Virus Assay (virus specific)	50 mL	22 days
N-AOP-BOV	Serum Neutralization, Bovine Viruses I CVMP 4.3.3.3; CHMP 7.3.4	5 mL	7 days
R-AOP-BOV	Virus Reduction - Serum Neutralization Assay	5 mL	7 days
LPHA-AOP-BOV	Serum Neutralization, Bovine Virus I CVMP 4.3.3.3; CHMP 7.3.4	5 mL	7 days
UANT-AOP-BOV	Sample Ultracentrifugation & BVD quantification CVMP 4.3.3.2, CHMP 7.3.3	35 mL	7 days
-AOP-BOV (BVD, HAD/Giemsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
ell-Viability	Test for determination of the viability of cells after TA exposure	30 mL	≥21 days
ID-BOV-IGG	Bovine IgG identification by RID of Bovine Origin Product	Call/Email	2-3 days
OP-GPA-5D	Growth Promotion Assay - Two Cell Lines/5 Day Method	25 mL	5 days

Additionally (to cGLP standards)

- Custom Validation Projects
- Non-clinical laboratory studies
- Other *in vitro* virology custom assays
  Master Seed Bank (cells and/or virus) production and accompanying regulatory testing

### ENGTH

## BOVINE RAW MATERIAL TESTING CONTINUED

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENGTH
TEST ARTICLE TYPE: CELL L	INE**		
9C-CL-BOV-PT1 and/or PT2*	Bovine Virus Assay of Bovine Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days PT1 22 days PT2
M9C-CL-BOV	Modified Bovine Virus Assay of Bovine Cell Line	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line, MA-104 cells	Call or Email	22 days
M9C (or MEM)-CL-MON-PRRS	PRRS Virus Assay of Cell Line, MARC cells	Call or Email	22 days
EM-CL-BOV-PT1 and/or PT2‡	Virus Assay of Bovine Cell Line I EP 5.2.4 — Viruses to be specified by customer	Call or Email	22 days PT1
			22 days PT2
TEST ARTICLE TYPE: MASTE	R SEED VIRUS***		
9C-MSV-BOV	Bovine Virus Assay of Master Seed Virus I 9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-BOV	Modified Bovine Virus Assay of Master Seed Virus	2 x 1 mL	22 days
EM-MSV-BOV	Bovine Virus Assay of MSV I EP 04/2013:0062, 2-1-3-2-6	Call or Email	22 days
VT-MSV-BOV	Virus Titration of Virus Stock to Determine TCID <sub>50</sub> /mL	2 vials	7 days
ncludes all 9 CFR Bovine viruses with optional virus tests: VSV, BLV, IBR/BHV-		isa) and Hemadsorption.	
Part 2 of cell line testing = testing cell	original cell line and testing for species appropriate adventitious agents lysates of grown cell line (VMRD or by company) on intended target specie and species of origing growth protocol before submission. Contact Account Manager for Cell Line intake Form.	n	

\*\*\*MSV's must have an accompanying neutralizing anti-sera and neutralization protocol. Contact Account Manager for MSV intake form.

All 9 CFR assays (9C-), including modified 9 CFR assays (M9C-), employ the methodologies outlined in 9 CFR 113.46 and 113.47.

All EM assays (EM-), including modified EM assays (MEM-) employ the methodologies outline in EP 5.2.5 as well as 9 CFR 113.46 and 113.47.

Please allow 3-5 business days for final report review and release. This includes final review by the assigned study director and Quality Assurance audit of the bench records.

# PORCINE RAW MATERIAL TESTING

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENGT
TEST ARTICLE TYPE: ANIMAL	ORIGIN PRODUCT		
9C-AOP-POR/VERO*	Porcine Virus Assay   9 CFR 113.53c	50 mL or 2 grams	22 days
M9C-AOP-POR	Modified Porcine Virus Assay (virus specific)	25 mL or 1 gram	22 days
9C-PT-POR	PPV Virus Assay of Porcine Trypsin I 9 CFR 113.53d	5 grams	28 days
M9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
M9C (or MEM)-AOP-MON-PRRS	PRRS Virus Assay using MARC cells	50 mL or 2 grams	22 days
EM-AOP-POR/VERO	Porcine Virus Assay I EP 5.2.5	50 mL or 2 grams	22 days
MEM-AOP-POR	Modified Porcine Virus Assay (virus specific)	50 mL or 2 grams	22 days
SN-AOP-POR	Serum Neutralization Assay, Porcine Viruses	5 mL	7 days
ALPHA-AOP-POR	Serum Neutralization, Porcine Viruses	5 mL	7 days
QUANT-AOP-POR	Ultracentrifugation of Porcine Product & PPV Quantification	25 mL or 1 gram	7 days
LT-AOP-POR (BVD, HAD/Geimsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
TEST ARTICLE TYPE: CELL LII	NE**		
9C-CL-POR-PT1 and/or PT2*	Porcine Virus Assay of Porcine Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days PT1 22 days PT2
M9C-CL-POR	Modified Porcine Virus Assay of Porcine Cell Line	Call or Email	22 days
EM-CL-POR-PT1 and/or PT2*	Virus Assay of Porcine Cell Line I EP 5.2.4 $-$ Viruses to be specified by customer	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line using MA-104 cells	Call or Email	22 days
M9C (or MEM)-CL-MON-PRRS	PRRS Virus Assay of Cell Line using MARC cells	Call or Email	22 days
TEST ARTICLE TYPE: MASTER	SFED VIBUS***		
9C-MSV-POR	Porcine Virus Assay of Master Seed Virus   9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-POR	Porcine Virus Assay of MSV (virus specific)	2 x 1 mL	22 days
EM-MSV-POR	Porcine Virus Assay of MSV (Virus specific) Porcine Virus Assay of MSV   EP 04/2013:0062, 2-1-3-2-6	2 x 1 mL	22 days 22 days
VT-MSV-POR	Virus Titration of Virus Stock to Determine TCID <sub>50</sub> /mL	2 vials	7 days
vi wover on	Vitas intation of vitas otoek to beteinine rold <sub>50</sub> /me	L VIGIO	, uays

M9C-CL-POR	Modified Porcir
EM-CL-POR-PT1 and/or PT2*	Virus Assay of
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assa
M9C (or MEM)-CL-MON-PRRS	PRRS Virus Ass

ILSI ANNOLL ITFL. ANNWAL			
9C-AOP-POR/VERO*	Porcine Virus Assay   9 CFR 113.53c	50 mL or 2 grams	22 days
M9C-AOP-POR	Modified Porcine Virus Assay (virus specific)	25 mL or 1 gram	22 days
9C-PT-POR	PPV Virus Assay of Porcine Trypsin I 9 CFR 113.53d	5 grams	28 days
M9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
M9C (or MEM)-AOP-MON-PRRS	PRRS Virus Assay using MARC cells	50 mL or 2 grams	22 days
EM-AOP-POR/VERO	Porcine Virus Assay I EP 5.2.5	50 mL or 2 grams	22 days
MEM-AOP-POR	Modified Porcine Virus Assay (virus specific)	50 mL or 2 grams	22 days
SN-AOP-POR	Serum Neutralization Assay, Porcine Viruses	5 mL	7 days
ALPHA-AOP-POR	Serum Neutralization, Porcine Viruses	5 mL	7 days
QUANT-AOP-POR	Ultracentrifugation of Porcine Product & PPV Quantification	25 mL or 1 gram	7 days
LT-AOP-POR (BVD, HAD/Geimsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
TEST ARTICLE TYPE: CELL LI	NE**		
9C-CL-POR-PT1 and/or PT2*	Porcine Virus Assay of Porcine Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days PT1 22 days PT2
M9C-CL-POR	Modified Porcine Virus Assay of Porcine Cell Line	Call or Email	22 days
EM-CL-POR-PT1 and/or PT2*	Virus Assay of Porcine Cell Line I EP 5.2.4 — Viruses to be specified by customer	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line using MA-104 cells	Call or Email	22 days
M9C (or MEM)-CL-MON-PRRS	PRRS Virus Assay of Cell Line using MARC cells	Call or Email	22 days
TEST ARTICLE TYPE: MASTER	SEED VIRUS***		
9C-MSV-POR	Porcine Virus Assay of Master Seed Virus I 9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-POR	Porcine Virus Assay of MSV (virus specific)	2 x 1 mL	22 days
EM-MSV-POR	Porcine Virus Assay of MSV   EP 04/2013:0062, 2-1-3-2-6	2 x 1 mL	22 days
VT-MSV-POR	Virus Titration of Virus Stock to Determine TCID <sub>50</sub> /mL	2 vials	7 days

Optional virus tests: PCV1, PCV2, PCMV, PIV/SIV, PRCV, PRV, VSV, SVA \*\*, \*\*\*, \*See page 5

# ATH

\*Viruses tested by FA for 9 CFR and EM include: BVD, REO, RAB, PAV, PPV, TGE, PHEV. Non-specific viral testing includes: Cytopathic Effect (Giemsa) and Hemadsorption.

# EQUINE RAW MATERIAL TESTING

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENGTH
TEST ARTICLE TYPE: ANIMAL	ORIGIN PRODUCT		
9C-AOP-EQU/VERO*	Equine Virus Assay I 9 CFR 113.53(c)	50 mL or 2 grams	22 days
M9C-AOP-EQU	Modified Equine Virus Assay (virus specific)	25 mL or 1 gram	22 days
M9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
EM-AOP-EQU/VERO	Equine Virus Assay   EP 5.2.5	50 mL or 2 grams	22 days
MEM-AOP-EQU	Modified Equine Virus Assay (virus specific)	50 mL or 2 grams	22 days
SN-AOP-EQU	Serum Neutralization Assay, Equine Viruses	5 mL	7 days
LT-AOP-EQU (BVD, HAD/Giemsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
TEST ARTICLE TYPE: CELL LI	NE**		
9C-CL-EQU-PT1 and/or PT2*	Equine Virus Assay of Equine Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days PT1 22 days PT2
M9C-CL-EQU	Modified Equine Virus Assay of Equine Cell Line	Call or Email	22 days
EM-CL-EQU-PT1 and/or PT2*	Virus Assay of Equine Cell Line I EP 5.2.4 — Viruses to be specified by customer	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line using MA-104 cells	Call or Email	22 days
TEST ARTICLE TYPE: MASTER	SEED VIRUS***		
9C-MSV-EQU	Equine Virus Assay of Master Seed Virus I 9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-EQU	Modified Equine Virus Assay of Master Seed Virus	2 x 1 mL	22 days
VT-MSV-EQU	Virus Titration of Virus Stock to Determine $\text{TCID}_{50}/\text{mL}$	2 vials	22 days

\*Viruses tested by FA include: BVD, REO, RAB, EHV, EAV. Non-specific viral testing includes: Cytopathic Effect (Giemsa) and Hemadsorption. Optional virus tests: NA \*\*, \*\*\*, \*See page 5

# CANINE RAW MATERIAL TESTING

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENG
TEST ARTICLE TYPE: ANIMAL	ORIGIN PRODUCT		
9C-AOP-CAN/VERO*	Canine Virus Assay I 9 CFR 113.53(c)	50 mL or 2 grams	22 days
M9C-AOP-CAN	Modified Canine Virus Assay (virus specific)	50 mL or 2 grams	22 days
M9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
EM-AOP-CAN	Canine Virus Assay I EP 5.2.5	50 mL or 2 grams	22 days
MEM-AOP-CAN	Modified Canine Virus Assay (virus specific)	50 mL or 2 grams	22 days
SN-AOP-CAN	Serum Neutralization Assay, Canine Viruses	5 mL	7 days
LT-AOP-CAN (BVD, HAD/Giemsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
TEST ARTICLE TYPE: CELL LI	NE**		
9C-CL-CAN-PT1 and/or PT2*	Canine Virus Assay of Canine Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days PT1 22 days PT2
M9C-CL-CAN	Modified Canine Virus Assay of Equine Cell Line	Call or Email	22 days
EM-CL-CAN-PT1 and/or PT2 <sup>‡</sup>	Virus Assay of Canine Cell Line I EP 5.2.4 — Viruses to be specified by customer	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line using MA-104 cells	Call or Email	22 days
TEST ARTICLE TYPE: MASTER	SEED VIRUS***		
9C-MSV-CAN	Canine Virus Assay of Master Seed Virus   9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-CAN	Modified Canine Virus Assay of Master Seed Virus	2 x 1 mL	22 days
VT-MSV-CAN	Virus Titration of Virus Stock to Determine TCID <sub>50</sub> /mL	2 vials	22 days

Option virus tests: CHV \*\*, \*\*\*, \*See page 5

# GTH

## FELINE RAW MATERIAL TESTING

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENGTH
TEST ARTICLE TYPE: ANIMAL	ORIGIN PRODUCT		
9C-AOP-FEL/VERO*	Feline Virus Assay   9 CFR 113.53(c)	50 mL or 2 grams	22 days
M9C-AOP-FEL	Modified Feline Virus Assay (virus specific)	50 mL or 2 grams	22 days
M9C (or MEM)-AOP-MON-ROTA	Rotavirus Assay using MA-104 cells	50 mL or 2 grams	22 days
EM-AOP-FEL	Felne Virus Assay   EP 5.2.5	50 mL or 2 grams	22 days
MEM-AOP-FEL	Modified Feline Virus Assay (virus specific)	50 mL or 2 grams	22 days
SN-AOP-FEL	Serum Neutralization Assay, Feline Viruses	5 mL	7 days
LT-AOP-FEL (BVD, HAD/Giemsa)	CPE, HAD Virus Assay and BVD by FA	30 mL or 2 grams	22 days
TEST ARTICLE TYPE: CELL LI	NE**		
9C-CL-FEL-PT1 and/or PT2	Feline Virus Assay of Feline Cell Line I 9 CFR 113.52(e)&(f)	Call or Email	22 days
M9C-CL-FEL	Modified Feline Virus Assay of Feline Cell Line	Call or Email	22 days
EM-CL-FEL-PT1 and/or PT2*	Virus Assay of Feline Cell Line I EP 5.2.4 — Viruses to be specified by customer	Call or Email	22 days
M9C (or MEM)-CL-MON-ROTA	Rotavirus Assay of Cell Line using MA-104 cells	Call or Email	22 days
TEST ARTICLE TYPE: MASTER	R SEED VIRUS***		
9C-MSV-FEL	Feline Virus Assay of Master Seed Virus I 9 CFR 113.55	2 x 1 mL	22 days
M9C-MSV-FEL	Modified Feline Virus Assay of Master Seed Virus	2 x 1 mL	22 days
VT-MSV-FEL	Virus Titration of Virus Stock to Determine TCID <sub>50</sub> /mL	2 vial	7 days

\*Viruses tested by FA include: BVD, REO, RAB, FIP, FPL. Non-specific viral testing includes: Cypathic Effect (Giemsa), and Hemadsorption Option virus tests: FCV, FHV, FVR, FeLV \*\*, \*\*\*, \*See page 5

## MULTIPLE SPECIES RAW MATERIAL TESTING

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	CATALOG #	ASSAY DESCRIP
	TEST ARTICLE TYPE: ANIMAL ORIGIN	PRODUCT
	9C-AOP-CAP/VERO	Caprine Virus As
	9C-AOP-OVI/VERO	Ovine Virus Assa
	9C-AOP-LAP/VERO	Lapine Virus Ass
	9C-AOP-HAM/VERO	Hamster Virus As
	9C-AOP-MUR/VERO	Murine Virus Ass
	9C-AOP-MUS/VERO	Mustelid Virus As
	TEST ARTICLE TYPE: CELL LINE**	
	9C (or M9C)-CL-CAP-PT1 and/or PT2‡	Caprine Virus As
	9C (or M9C)-CL-LAP-PT1 and/or PT2*	Lapine Virus Ass
	9C (or M9C)-CL-HAM-PT1 and/or PT2*	Hamster Virus As
	9C (or M9C)-CL-OVI-PT1 and/or PT2 <sup>‡</sup>	Ovine Virus Assa
	9C (or M9C)-CL-MUR-PT1 and/or PT2*	Murine Virus Ass
	9C (or M9C)-CL-MUS-PT1 and/or PT2*	Mustelid Virus As
	TEST ARTICLE TYPE: MASTER SEED	/IRUS***
	9C (or M9C)-MSV-CAP	Caprine Virus As
	VT-MSV-CAP	Virus Titration of
	9C (or M9C)-MSV-LAP	Lapine Virus Ass
	VT-MSV-LAP	Virus Titration of
	9C (or M9C)-MSV-HAM	Hamster Virus As

VT-MSV-MUS \*\*, \*\*\*See page 5

VT-MSV-HAM

VT-MSV-MUR

9C (or M9C)-MSV-MUR

9C (or M9C)-MSV-MUS

### PTION I REGULATION SATISFIED

ssay | 9 CFR 113.53(c) say | 9 CFR 113.53(c) say | 9 CFR 113.53(c) Assay | 9 CFR 113.53(c) say | 9 CFR 113.53(c)

Assay | 9 CFR 113.53(c)

ssay of Bovine Cell Line | 9 CFR 113.52(e)&(f) say of Bovine Cell Line | 9 CFR 113.52(e)&(f) Assay of Bovine Cell Line | 9 CFR 113.52(e)&(f) ay of Bovine Cell Line | 9 CFR 113.52(e)&(f) say of Bovine Cell Line | 9 CFR 113.52(e)&(f) Assay of Bovine Cell Line I 9 CFR 113.52(e)&(f)

ssay of Master Seed Virus | 9 CFR 113.55 f Virus Stock to Determine TCID<sub>50</sub>/mL say of Master Seed Virus I 9 CFR 113.55 f Virus Stock to Determine TCID<sub>50</sub>/mL Assay of Master Seed Virus I 9 CFR 113.55 Virus Titration of Virus Stock to Determine TCID<sub>50</sub>/mL Murine Virus Assay of Master Seed Virus I 9 CFR 113.55 Virus Titration of Virus Stock to Determine TCID<sub>E0</sub>/mL Mustelid Virus Assay of Master Seed Virus I 9 CFR 113.55 Virus Titration of Virus Stock to Determine TCID<sub>50</sub>/mL

### VOLUME REQUIRED ASSAY LENGTH

50 mL or 2 grams	22 days
50 mL or 2 grams	22 days
50 mL or 2 grams	22 days
50 mL or 2 grams	22 days
50 mL or 2 grams	22 days
50 mL or 2 grams	22 days

Call or Email	22 days
Call or Email	22 days

2 x 1 mL	22 days
2 vials	7 days
2 x 1 mL	22 days
2 vials	7 days
2 x 1 mL	22 days
2 vials	7 days
2 x 1 mL	22 days
2 vials	7 days
2 x 1 mL	22 days
2 vials	7 days

# **STERILITY TESTING**

VMRD Testing Services sterility assays include assessment of bacteriostasis/fungistasis of each test article in order to validate the sterility result and confirm that there are no antimicrobial properties within the test article. Our testing paradigm therefore encapsulates 9 CFR 113.25(d) in addition to 9 CFR 113.26.

# **STERILITY TESTING**

CATALOG #	ASSAY DESCRIPTION I REGULATION SATISFIED	VOLUME REQUIRED	ASSAY LENGTH
BACTERIA & FUNGI TESTING			
9C-B&F	Sterility Assay of Animal Origin Product   9 CFR 113.26	100 mL or 10 grams	14 days
9C-B&F-MSV	Sterility Assay of Virus Samples   9 CFR 113.27(c)	5 x 1 mL	14 days
9C-B&F-CL	Sterility Assay of Cell Lines I 9 CFR 113.52(d)	25 x 1 mL	14 days
9C-B&F-BAC	Sterility Assay of Master Seed Bacteria   9 CFR 113.27(d)	5 x 1 mL	14 days

# MYCOPLASMATESTING

VMRD Testing Services offers mycoplasma assays to satisfy various regulations, including:

- USDA-APHIS 9 CFR (9 CFR 113.52c,113.53a using methods described in 113.28)
- European Pharmacopeia (EP), European Medicinal Agency (EMA) (EP 2.6.7, EMA)
- United States Pharmacopeia (USP <63>)

Each assay has been validated or verified to provide the best possible sensitivity for the detection of Mollicutes in your test article. The EP mycoplasma testing includes an inhibition assay (substrate qualification) to evaluate the test article for inhibition of mycoplasma growth as per EP 2.6.7 & USP <63> regulations and has been validated with seven different Mollicutes strains.\*

Veterinary product for sale in USA

Veterinary product for sale in Europe

Serum for use in production of human & veterinary medicine for

Trypsin for use in production of human medicine for sale in Euro

Viral veterinary vaccines for sale in Europe

Serum, media, or other byproducts with a non-specified use

Approved by the International Serum Industry Association

VMRD Catalog Number(s)

\*In addition, we offer a fully validated Large Volume method that achieves a level of sensitivity unattainable by the regulated methods. Ask us today which mycoplasma detection method is the best fit for your needs.

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atisfy various regulations, including:
nods described in 113.28)
gency (EMA) (EP 2.6.7, EMA)
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	9 CFR 113.28	EP 2.6.7	USP <63>	LARGE VOLUME BARILE METHOD
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or sale in Europe		>		
rope		>		
		>		
	✓	<b>&gt;</b>	✓	<
	✓	✓	~	
	9C-MY	EPUSP-MY-DIR EPUSP-MY-IND (Substrate Qualification) EPUSP-MY-DIR-17025 EPUSP-MY-IND-17025 (ISO 17025:2017 accredited assays)		LVB-MY-B&A LVB-MY-IND

# **MOLECULAR TESTING**

#### ASFv

We offer a US-based solution for your ASFv testing needs. Following the Ministry of Agriculture and Rural Affairs (MARA) requirements of the People's Republic of China, we have developed an ASFv PCR test that has been verified for veterinary biologics destined for export. This includes live vaccines, aqueous and non-aqueous adjuvant attenuated vaccines. This assay is currently available and adaptable to your product. Contact us today for your sample suitability testing needs for this assay.

VMRD Catalog #: PCR-ASF

**BVDV Genotypes 1, 2, 3** 

VMRD Catalog #: PCR-BVD

#### Karyotyping

When creating a master cell bank, it is important to have complete cell line characterization to 9 CFR 113.52. To provide complete testing for cell line characterization, we have partnered with a specialized lab to provide karyotyping. All samples that need karyology can be sent to VMRD directly and we will handle the rest!

VMRD Catalog #: 9C-CL-KAR

### **Deep Sequencing**

To round out your cell line characterization we offer speciation of cell lines through deep sequencing. Our partnering lab is local to our facility, and we are able to hand deliver your sample for deep sequencing, eliminating the chance for shipping errors. Contact us today for your speciation needs!

VMRD Catalog #: 9C-NGS

We offer a fully validated Reverse Transcriptase PCR assay to CVB and ICH standards, in addition to our classical infectivity assay using cell culture with direct fluorescent antibody detection technique(s).

# SPECIALIZED TESTING



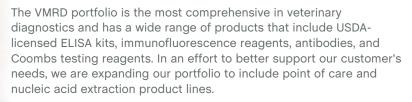
# Are you not finding what you looking for, but still need testing services?

Our laboratory setup and structure allows us to offer custom testing to fit your needs. Some examples include, but are not limited to:

- Master Cell and Master Seed Generation and Associated Regulatory Testing
- Mycoplasma consultation
- Validation Studies
- Non-Clinical Laboratory Study Support
- Viral Inactivation Studies
- And much more!

## Contact us today to find out more!





All of VMRD's ELISA kits are USDA licensed and offer diagnostic tools for a variety of species including bovine, equine, caprine, and ovine.

VMRD immunofluorescence reagents include slides, monoclonal antibodies, conjugates, and more. These products target both large and companion animal diseases.

VMRD brings testing to the animal's side with lateral flow test kits for horses and soon to come feline testing. Its compact reader size travels easily and its quantitative output provides real-time results of current disease status. BUSINESS HOURS Monday - Friday, 7 am - 4 pm (Pacific Time Zone)

#### **ORDERING TESTING SERVICES PROCEDURES**

Contact our Testing Services Sales department at services@vmrd.com to get more information and a quote. After a quote has been generated this can be used as a reference for submitting samples for testing on our customer portal.

### **CUSTOMER PORTAL**

VMRD Testing Services Customer Portal acts as a bridge between the submitting laboratory and our Laboratory Information Management System (LIMS). Our portal lets you submit samples for testing, and have secure 24-hour access to up-to-date testing information. In addition, final reports are available immediately after QA approval, which provides you with faster access to results.

### SAMPLE SUBMISSION & SHIPPING PROCEDURES

Samples that are ready to be tested are submitted through our online portal. Using the provided quote you can select for the specific tests that correlate to each sample. For more information on our sample submission, please visit vmrd.com/biologics-testingsubmission/

After samples have been submitted through our online portal, the samples can be shipped to our Sample Submission Address (see page 20). The address and sample submission form are very important when shipping samples to our facility. For more information regarding sample packaging recommendations, please visit vmrd.com/biologics-testing-submission/



Submit

SAMPLE SUBMISSION

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Caps Lock

# SAMPLE SUBMISSION ADDRESS

VMRD, Inc – Testing Services 425 NW Albion Dr. Suite 2 Pullman, WA 99163

# **INVOICING PROCEDURES**

Billing Invoices for our services are emailed after the test has completed and the final report has been released. Default payment terms are Net 30 days, payable in U.S. Dollars. Please inquire to arrange payment by wire transfer. Payment may also be made by Visa, MasterCard, or American Express credit cards. Please specify payment by credit card when the order is placed. Do not use email to send credit card information. Invoice questions may be directed to our Customer Service Department at +1-509-334-5815 or 1-800-222-8673. Bank Wire Transfer Notification and payment instructions are available upon request.

Email: services@vmrd.com Phone: 509.334.5815 Toll Free: 800.222.8673

VMRD, Inc., P.O.Box 502 Pullman, WA 99163

# www.vmrd.com



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