

## **FREQUENTLY REQUESTED TESTING INFORMATION**

### **9CFR TESTING**

**9C-AOP-BOV** – 9/CFR Animal Origin Products Bovine Virus Assay. The objective of this assay is to evaluate the TA for extraneous bovine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: BTV, BAV1, BAV5, BPV, and BRSV, REO, Rabies, and BVDV. Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request. Common requests are VSV and BLV.

**9C-AOP-POR** – 9/CFR Animal Origin Products Porcine Virus Assay. The objective of this assay is to evaluate the TA for extraneous porcine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: PAV, TGE, HEV, PPV, REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request. Common requests are PCV1, PCV2, and PCMV.

**9C-AOP-EQU** – 9/CFR Animal Origin Products Equine Virus Assay. The objective of this assay is to evaluate the TA for extraneous equine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: EHV/ERV, EVA, REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

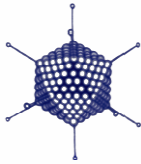
FA for other viruses can be added per request. EIA is commonly requested.

**9C-AOP-LAP** – 9/CFR Animal Origin Products Lapine Virus Assay. The objective of this assay is to evaluate the TA for extraneous lapine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request.



**9C-AOP-CAN** – 9/CFR Animal Origin Products Canine Virus Assay. The objective of this assay is to evaluate the TA for extraneous canine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: CCV, CDV, CPV, REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request.

**9C-AOP-FEL** – 9/CFR Animal Origin Products Feline Virus Assay. The objective of this assay is to evaluate the TA for extraneous feline viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: FCV, FPL, REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request.

**9C-AOP-MUR** – 9/CFR Animal Origin Products Murine Virus Assay. The objective of this assay is to evaluate the TA for extraneous murine viruses as specified in USDA-APHIS 9/CFR 113.53c which includes 113.46 and 113.47.

Specific viruses tested: REO, Rabies, and BVDV.

Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

FA for other viruses can be added per request.

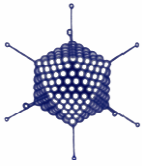
## **EMEA TESTING**

EMEA/9CFR – Animal Origin Products Bovine Virus Assay. This test is in compliance with:

- EMEA/CVMP/743/00-Rev.2 (2005) 4.3.3.1, 4.3.3.2
- EMEA/CPMP/BWP/1793/02 (2003) 5.3.1, 5.3.2, 5.3.3
- European Pharmacopoeia 5.2.5 (01/2005:50205)
- General Requirements for Inactivated (7Blm2a) and Live (7Blm1a) Vaccines for Veterinary use
- USDA-APHIS 9/CFR 113.53c (which includes 113.46 and 113.47)

For full compliance the following 5 tests must be performed:

Assay 1: **(EM-AOP-BOV)** EMEA/9CFR Animal Origin Products Bovine Virus Assay. The objective of this assay is to evaluate the TA for extraneous bovine viruses using the EMEA and 9/CFR requirements defined in the documents listed above. Specific viruses tested: BTV, BAV1, BAV5, BPV, VSV, BLV, BRSV, REO, Rabies, and BVDV.



Hemadsorption is performed to test for extraneous hemadsorbing viruses (testing for PI-3 is covered in this test also), and GIEMSA staining for CPE virus groups (testing for IBR is covered in this test also).

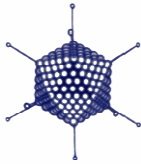
Assay 2: (**EMCT-AOP-BOV**) EMEA (CT) Comparative Titration (Serum Inhibitory Test). This assay is a compliance method for the requirement in EMEA/CPMP/BWP/1793/02 (2003), section 5.3.4. The assay is intended to detect BVD virus in a TA serum by growing cells permissive to BVD virus with at least 3 subcultures in the presence of the TA serum. Then, the cells are used to titrate a reference strain of BVD virus. The reference strain titer from TA serum-treated cells is compared to the titer of the reference strain determined in control cells grown in the presence of a BVD virus-free control serum.

Assay 3: (**QUANT-AOP-BOV**) EMEA Ultracentrifugation and Quantitation of BVD Virus in Serum. The objective of this assay is to quantitate BVD virus in serum after concentration by ultracentrifugation as a compliance method for EMEA/CVMP/743/00 (4.3.3.2) and EMEA/CPMP/BWP/1793/02 (5.3.3).

Assay 4: (**SN-AOP-BOV-4**) Serum Neutralization (SN) with Diluted Serum and Constant Virus. The objective of this assay is to measure serum neutralization to various bovine viruses as required by EMEA/CVMP/743/00 (4.3.3.3) and EMEA/CPMP/BWP/1793/02 (5.3.3).

Assay 5: (**VR-AOP-BOV**) EMEA Virus Reduction SN Assay. The objective of this assay is to detect serum neutralizing antibodies to a non-cytopathic BVD virus. This assay is intended as a compliance method for the requirement in EMEA/CVMP/743/00-Rev. 2 (2005), section 4.3.3.3 and more generally in EMEA/CPMP/BWP/1793/02 (2003), section 5.3.3. The assay provides a risk assessment of the potential impact of the presence of these antibodies in a serum on the partial or complete neutralization of possible virus present and on the validation process.

Assay 6 (optional): (**ALPHA-AOP-BOV**) EMEA Alpha Serum Neutralization Assay tests a constant amount of serum against differing dilutions of virus. The objective of this assay is to detect serum neutralizing antibodies to a cytopathic BVD virus. It is intended as a compliance method for the requirement in EMEA/CVMP/743/00-Rev. 2 (2005), section 4.3.3.3 and more generally in EMEA/CPMP/BWP/1793/02 (2003), section 5.3.3. The assay result provides a risk assessment of the potential impact of the presence of these antibodies in a serum on partial or complete neutralization of possible BVD virus present and on the validation process. Results are reported as TCID<sub>50</sub> of BVD virus neutralized by 1ml of the serum and can be used for additional support for or replacement of the BVD virus antibody testing component of the SN-AOP-BOV assay, and/or the VR-AOP-BOV assay depending on individual release requirements.



## OTHER TESTING

**MEM-AOP-BOV-BLV** – Stand-alone EMEA BLV Assay. The objective of this assay is to evaluate a TA for BLV alone using EMEA procedures.

**MEM-AOP-BOV-BVD** – Stand-alone EMEA BVDV Assay. The objective of this assay is to evaluate a TA for BVDV alone using EMEA procedures.

**M9C-AOP-BOV-BTV** – Modified 9/CFR Animal Origin Products Assay on Bovine Cells for BTV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for BTV using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

**M9C-AOP-BOV-BVD** – Modified 9/CFR Animal Origin Products Assay on Bovine Cells for BVD by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for BTV using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

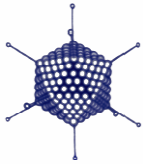
**M9C-AOP-BOV-BLVVSV** – Modified 9/CFR Animal Origin Products Assay on Bovine Cells for BLV and VSV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for BLV and VSV using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

**M9C-AOP-BOV-BTVVSV** – Modified 9/CFR Animal Origin Products Assay on Bovine Cells for BTV and VSV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for BTV and VSV using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

**M9C-AOP-POR-PCV1&2** – Modified 9/CFR Animal Origin Products Assay on PT cells for PCV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for PCVI and PCVII using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

**M9C-AOP-POR-PPV** – Modified 9/CFR Animal Origin Products Assay on Porcine Cells for PPV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for PPV using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).

**M9C-AOP-POR-PCMVPCV1&2** – Modified 9/CFR Animal Origin Products Assay on PT cells for PCMV and PCV by FA. The objective of this not less than 21 day assay is to evaluate Animal Origin Products for PCMV, PCVI, and PCVII using procedures detailed in USDA-APHIS 9/CFR 113.53c (which includes 113.47).



**9C-PT-POR** – 9/CFR Assay of Porcine Trypsin for Porcine Parvovirus. The objective is a not less than 28 day assay for porcine parvovirus in porcine trypsin in strict compliance with USDA-APHIS 9/CFR 113.53d (which includes 113.47)

**QT-AOP-BOV** – Rapid assay for BVD virus in TA. The objective is to screen TA for BVD virus in a relatively short time.

**LT-AOP-BOV** – 21 day assay for IBR, PI-3, and BVD viruses. Modified from 9 CFR 113.53c (which includes 113.46 GIEMSA and Hemadsorption that will detect IBR, PI-3, and 113.47 specific FA analysis for BVDV).

**CT-AOP-BOV** – Stand alone Comparative Titration (Serum Inhibitory Test). This assay is a compliance method for the requirement in EMEA/CPMP/BWP/1793/02 (2003), section 5.3.4. The assay is intended to detect BVD virus in a TA serum by growing cells permissive to BVD virus with at least 3 subcultures in the presence of the TA serum. Then, the cells are used to titrate a reference strain of BVD virus. The reference strain titer from TA serum-treated cells is compared to the titer of the reference strain determined in control cells grown in the presence of a BVD virus-free control serum.

WE ALSO HAVE TESTING FOR MASTER VIRUSES. THESE ARE CALLED **9C-MSV-** AND WE CAN TEST FOR ALL VIRUSES LISTED ABOVE. THE **9C-CL-** TESTS ARE FOR TESTING MASTER CELL STOCKS AND AGAIN WE TEST FOR THE SPECIES SPECIFIC VIRUSES ABOVE. THERE ARE OTHER SCREENING TESTS LIKE **FA-CL-BOV-BVD** IN WHICH WE TEST CELL LINE ISOLATES OR ESTABLISHED LINES IN A RAPID TEST BY GROWING THE CELLS AND RUNNING A FA FOR BVDV.

IF YOU HAVE SPECIALTY TESTING AND DO NOT SEE A TEST THAT FITS YOUR NEEDS, WE CAN USUALLY DESIGN TESTING TO COVER THE VIRUSES AND 9/CFR OR EMEA REQUIREMENTS AS LONG AS WE CAN ACQUIRE CONTROL VIRUSES AND CELL STOCKS NEEDED FOR THE TESTS. WE HAVE A LARGE COLLECTION BUT OCCASIONALLY WE MAY BE UNABLE TO FIND A COMPONENT.