

Appendix A: Defining samples/materials and test results

Samples and Materials

The presence of Alphainfluenzavirus influenzae H5N1 (avian influenza A[H5N1]) in samples or other materials contributes to the determination of applicable regulatory, reporting, and containment requirements.

Table A defines the terms used throughout the Biosafety Advisory that describe whether samples and other materials may contain avian influenza A(H5N1), along with examples. This information helps to clarify and determine what samples and materials are subject to the outlined recommendations and requirements.

Table A: Description of terms used to define whether samples and other materials contain avian influenza A(H5N1)

Description	Samples/materials	Examples
<p>Does not contain (Synonym: Highly unlikely to contain)</p> <p>Known to be free of viable avian influenza A(H5N1) or very high likelihood that the material does not contain viable avian influenza A(H5N1).</p>	<ul style="list-style-type: none">• Originating from, or associated with, an animal, human or environment that has no symptoms or potential exposure to avian influenza A(H5N1).• Rendered non-infectious by a validated inactivation method.	<ul style="list-style-type: none">• Pasteurized store-bought milk.• Samples from small animal veterinary clinics (e.g., from companion animals with no contact with farm or wild animals, or from companion animals who don't eat raw food).• Blood work for pre-surgery workup (i.e., not associated with human diagnostic disease testing).• Samples that are not submitted for, or associated with, avian influenza A(H5N1) testing.• Irradiated or chemically inactivated virus stocks or viral antigens that have been safety tested.• Heat inactivated serum samples.

Description	Samples/materials	Examples
<p>May contain (but unlikely to contain) (Synonym: Not suspected to contain) Reasonable belief that the material does not contain viable avian influenza A(H5N1) but, due to specific circumstances, its presence cannot be ruled out.</p>	<ul style="list-style-type: none"> • Not originating from, or associated with, an animal, human or environment that has had contact with an infected animal or person, or contaminated place, but where avian influenza A(H5N1) may be present in the broader region. 	<ul style="list-style-type: none"> • Raw milk samples collected from a dairy farm in a region where no avian influenza A(H5N1) has been detected in cattle, but where it has been detected locally in poultry and/or wild animals. • Waste water samples taken from a region with an infected dairy or poultry farm, but not in direct proximity to the farm or associated agricultural water runoff. • Swabs from a commercial poultry. • Farm flock without symptoms, but located within a surveillance zone.
<p>Contains (Synonyms: Known to contain, highly likely to contain) Known to contain viable avian influenza A(H5N1) or a high likelihood that the material will contain viable avian influenza A(H5N1).</p>	<ul style="list-style-type: none"> • Avian influenza A(H5N1) or part thereof that retains its pathogenicity. • Any sample or material, including primary specimens, that has been confirmed to contain avian influenza A(H5N1) or part thereof that retains its pathogenicity. • Any product created with, or derived from, avian influenza A(H5N1) or part thereof that retains its pathogenicity. 	<ul style="list-style-type: none"> • Positive test controls that are known to contain viable avian influenza A(H5N1). • Allantoic fluid from fertilized eggs infected with influenza A (i.e., cultured avian influenza A(H5N1)). • Human or animal primary specimens confirmed positive for avian influenza A(H5N1) (e.g., blood, tissues, swabs, feathers, feces, secretions). • Primary specimens from an animal experimentally infected with avian influenza A(H5N1).

Description	Samples/materials	Examples
<p>Contains also includes materials that are likely or suspected to contain, which is the reasonable belief that the material can or will contain viable avian influenza A(H5N1) due to specific circumstances.</p>	<ul style="list-style-type: none"> • An animal, human or environmental sample or material with a non-negative test result for avian influenza A(H5N1). • Originating from a symptomatic animal that is known to have been in close contact with an infected animal or person, or an environment known to be contaminated with avian influenza A(H5N1). • Originating from an animal that has been in an environment known to be contaminated with avian influenza A(H5N1). • Originating from an environment known to be contaminated with avian influenza A (H5N1) such as a CFIA declared infected or high-risk premises. 	<ul style="list-style-type: none"> • Raw milk from a farm with symptomatic cows. • Samples collected from deceased chickens (e.g., tracheal cloacal swabs, blood samples, tissues) or areas/farms (e.g., bedding, feed, water from the premises) with high mortality rates. • Environmental samples from animal pens, rooms or enclosures where recent outbreaks have been confirmed. • Primary specimens collected from symptomatic humans to diagnose or monitor infection. • Air samples from a school with cases of avian influenza A(H5N1).

Test Results

Once samples and other materials have been tested for avian influenza A(H5N1), the results will fall within one of the following categories. This information helps to clarify and determine what samples and materials are subject to the outlined recommendations and requirements.

Table B: Definition for negative, non-negative, and positive avian influenza A(H5N1) test results

Test Result	Explanation and interpretation
Negative	<p>A diagnostic test result indicating the complete absence of avian influenza A(H5N1), with no suspicious or inconclusive findings.</p> <p>A negative result signifies that the sample has undergone appropriate testing and can be officially confirmed as free from detectable avian influenza A(H5N1) (e.g., no detectable genetic material, no immunological or serological reaction).</p>
Non-Negative (Synonyms: probable, presumptive, suspected, suspicious, inconclusive, and detected)	<p>A diagnostic test result that cannot be officially reported as either “negative” or “positive.”</p> <p>This may include preliminary screening that suggests the presence of avian influenza A(H5N1) genetic material, samples that react to avian influenza A antigen or antibodies in serological or immunological tests, evidence of gross pathology where the specific strain has not yet been confirmed, or other results that are suspicious or inconclusive (e.g., failed tests, invalid results pending retest, necropsy findings). Further analysis, testing or retesting may be needed to confirm the presence of avian influenza A(H5N1) and to rule out contamination.</p>
Positive (Synonyms: confirmed, diagnosed)	<p>A diagnostic test result that confirms the presence of avian influenza A(H5N1). A positive result indicates that the sample has undergone appropriate testing and can be officially reported as containing detectable avian influenza A(H5N1) (e.g., detectable genetic material, immunological or serological reaction).</p>