INSTRUCTIONS FOR USE (IFU)

Alveo Sense Poultry Avian Influenza Test Type A H5 H7 or Type A H5 H9

REF ***A-FIN-000037 Alveo Sense Avian Influenza Test Type A H5 H7***

REF ***A-FIN-000031 Alveo Sense Avian Influenza Test Type A H5 H9***

These Instructions for Use (IFU) apply to the following products: A-FIN-000037 (Type A H5 H7) and A-FIN-000031 (Type A H5 H9). Both products share the same intended use and procedural steps.

For use with the Alveo Analyzer and the Alveo Sense Mobile App.

For veterinary use only.

For use with oropharyngeal and cloacal swab samples only.

Developed in partnership with Royal GD Animal Health

AHEAD IN ANIMAL HEALTH

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1 Intended Use

The Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) is a rapid molecular amplification test for the qualitative detection of Avian Influenza Type A viruses and differentiation of H5, H7, and H9 RNA subtypes from oropharyngeal and cloacal samples from symptomatic and asymptomatic chickens. Positive or presumptive positive test results with the Alveo Sense Poultry Avian Influenza Test should be submitted to an authorized reference laboratory for confirmatory testing.

All results are delivered directly to the user via the Alveo Mobile application, Alveo Sense, and saved to Alveo's secure, cloud-based system.

2 Summary and Explanation of the Test

Avian influenza, commonly referred to as bird flu, is a highly contagious viral infection that spreads among migratory and domesticated birds and can significantly impact domestic poultry and other animal species. Because viruses can mutate and reassort potentially giving rise to new strains, avian influenza outbreaks must be closely monitored to evaluate the risk to animal and human health. Rapid detection, surveillance, and control measures are crucial to managing and preventing the spread of avian influenza.

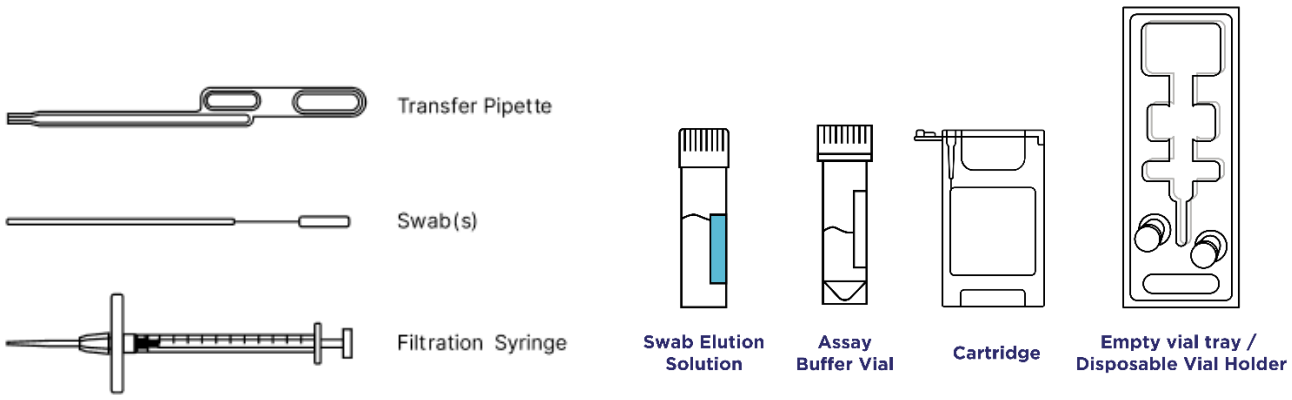
The Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) is a rapid molecular amplification test that detects and differentiates respective avian influenza strains commonly found in domesticated bird populations. The system uses loop meditated isothermal amplification method (LAMP) for rapid and specific detection of viral RNA targets.

3 Principles of the Test

The Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) is a multiplexed rapid molecular test which utilizes loop mediated isothermal nucleic acid amplification technology and electrical impedance sensors to qualitatively detect and differentiate respective avian influenza viral RNA strains in a single-use microfluidic Cartridge in approximately 45 minutes or less. The microfluidic Cartridge is equipped with 6 assays designed for broad detection of Avian Influenza Type A virus (Type A), and precise detection of H5, H7, and H9 RNA subtypes.

4 Materials Required

To complete an Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9), gather the following materials provided in the kit:



4.1 Alveo Sense Poultry Avian Influenza Test Kit Contents

(100) Swabs	(10) Filtration Syringes (Pre-assembled)	(10) Alveo Sense Poultry Avian Influenza Test Type A H5 H7 or Type A H5 H9 Cartridges
(10) Swab Elution Solution Vials (Blue Labels)	(10) Assay Buffer Vials	Quick Reference Instructions (QRI)
(10) Vial Tray Holders	(10) Transfer Pipettes	Electronic Instructions for Use (eIFU)

4.2 Additional Materials Required (Not Provided)

To complete an Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9), the following additional materials are required:

- Alveo Analyzer
- Smartphone with Alveo Sense App installed
    - **Note: The Alveo Sense Mobile App is supported on iPhone iOS 15 and above and Android OS 13 and above.** Certain features may be limited or unavailable on devices running on iOS 14 and below and Android OS 12 and below. Compatibility with other devices or OS versions is not guaranteed.

5 Storage & Handling of Alveo Sense Poultry Avian Influenza Test Kit Components

- Use all Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Kit components between 15-30°C and in uncontrolled relative humidity, non-condensing.
- Change gloves between handling samples and setting up a new test.
- Store all Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Kit components between 2-30°C.
- Do not reuse Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Kit components.
- Use Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Kit components before their individual expiration dates.
- Open packaging of Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Kit components only when ready to begin a test.
    - Open Swab immediately before sample collection.
    - Open Cartridge from foil pouch immediately before use.

6 Warnings and Precautions

- For Veterinary Use Only.
- For use with oropharyngeal and cloacal swab samples only.
- Place the Analyzer on a flat, level surface to insert the Cartridge and run the test through to completion of the test.
- For single use only. Do not reuse test materials.
- Do not use test materials after their expiration date.
- Do not use damaged components.
- Avoid touching the electrical contacts on the Cartridge.
- Failure to follow the test instructions may alter test performance.
- WARNING: Improper sample handling, including incomplete filling or the introduction of air bubbles into the cartridge during sample loading, may interfere with fluid flow and may lead to false negative, false positive, or invalid results. Inspect the cartridge for the presence of air bubbles prior to initiating the test.

7 Limitations

- Results should be interpreted in conjunction with other signs and observations.
- Negative results do not rule out infections or co-infections and should not be used as the sole basis for flock management decisions.

- Performance at the time of testing may vary depending on the sample collection techniques and circulating variants. This product is intended for poultry samples only.

8 Quality Control(s)

All Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) lots undergo Quality Control (QC) testing at Alveo Technologies, Inc. on every lot released. Each individual Alveo Sense Poultry Avian Influenza Test (Type A H5 H7 or Type A H5 H9) Cartridge contains an internal process control. Assuming the test is run properly, amplification in this well is expected and confirms a valid result.

Users should establish their own quality control frequency. All quality control requirements should be performed in conformance with local, state, country and/or federal regulations or accreditation requirements.

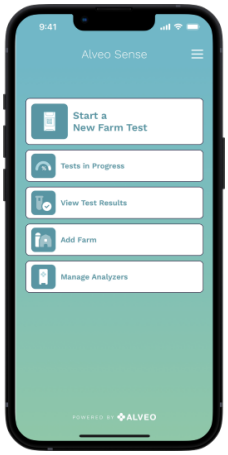
9 How to Run a Test

FOR FIRST TIME USE

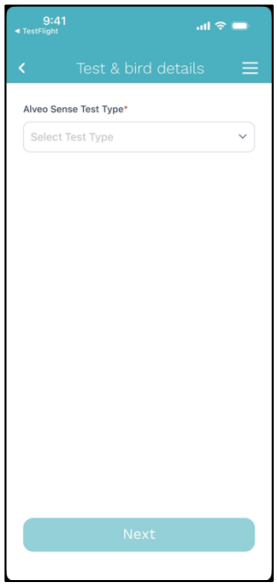
Navigate to the Apple App Store or Google Play Store and download the **Alveo Sense Mobile App** on a **Smartphone** to register a New Account and agree to the Terms of Use. Ensure the Alveo Analyzer is powered on with 4 blue LED lights flashing, charged, nearby, and therefore ready for Bluetooth connection. *Note: The Alveo Sense Mobile App is supported on iPhone iOS 15 and above and Android OS 13 and above. It is not validated on Tablets or iPad.*

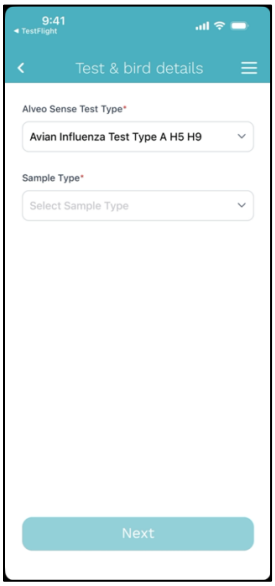
9.1 Log into Alveo Sense Mobile App.

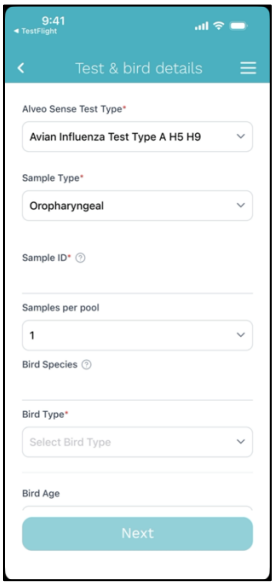
a. Tap **“Start a New Test”**

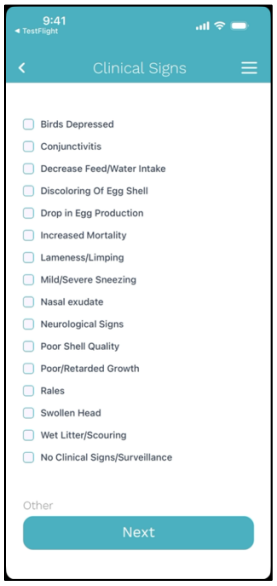


b. Tap **“+Add New Farm”** and add relevant farm location details.
    i. Note: Once a Farm location has been added, recently updated farms will appear under the Search Farms navigation bar.
c. Confirm Farm details, tap **“Next”**
d. Select Alveo Sense Test Type and Sample Type. Add Sample and **Bird Details**, including any notes for bird/flock if applicable, **tap “Next”**
    i. Add **Clinical Signs** of bird/flock, if applicable, **tap “Next”**
    ii. Add **Postmortem Findings**, if applicable, **tap “Next”**

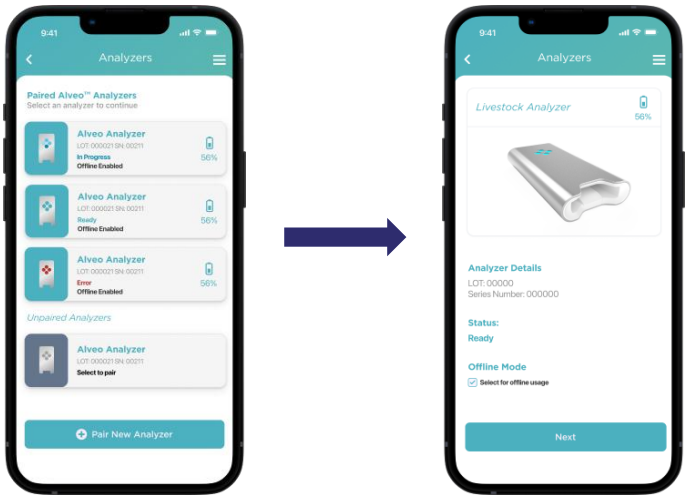








e. Select / Pair Alveo Analyzer
    i. Tap **"+Pair New Analyzer"** if pairing Alveo Analyzer for first time.
    ii. Tap Analyzer selected for testing once it has paired successfully. **Tap "Next"** to confirm. *(Note: Analyzer may need to update which may take ~2 minutes).*



f. Analyzer is now paired. Proceed to sample collection and testing procedure.

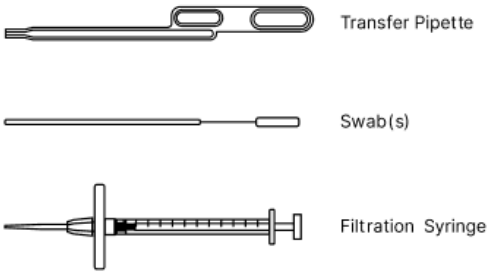
9.2 Gather Materials & Collect Sample

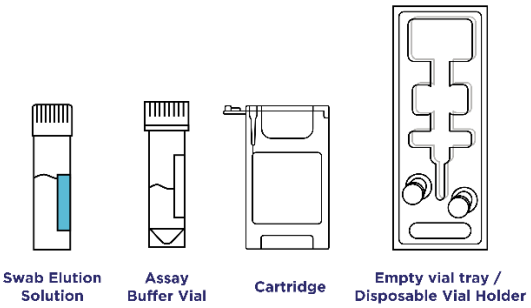
Note: *Read all instructions prior to sample collection and testing.*

Using Swab included in the Test Kit, collect oropharyngeal or cloacal sample from chicken. If pooling samples, collect sample and elute swabs one at a time into Swab Elution Solution. Pooled sample types may not be mixed between oropharyngeal and cloacal samples (all pools must be either oropharyngeal or cloacal samples).

a. Follow in-App prompts: Gather all materials and place on a flat surface. **Tap "Next"**

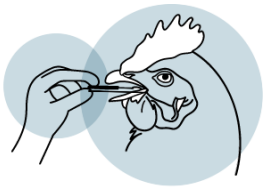
Note: Do NOT open Cartridge pouch or swab until you are ready to collect and prepare sample, then perform test.



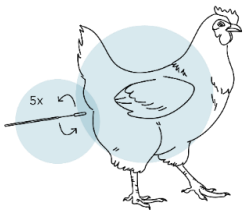


b. Open Cartridge from pouch and locate the Cartridge QR Code on the Cartridge label. **Tap "Scan Cartridge QR Code"**
c. Confirm Cartridge details and UDI. Select **"Yes"** to continue.
d. Collect sample(s).

For oropharyngeal collection: Insert swab into mouth. Press swab tip against the roof of the oropharynx and rotate 5 times. On withdrawing the swab from mouth ensure mucosal material is visible on the swab.



For cloacal collection: Insert swab into the cloaca. Collect sample by rotating swab tip 5 times while pressed against the mucosa. Ensure mucosal material is visible on the swab.



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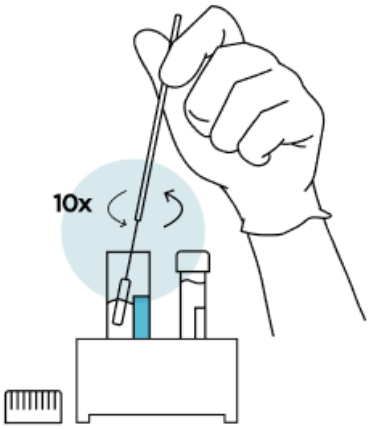
e. **Mix Sample:** Gather Swab Elution Solution (blue labeled vial) and Assay Buffer Vial (white labeled vial) and place inside vial tray / disposable Vial Holder. Remove cap of Swab Elution Solution (blue label).

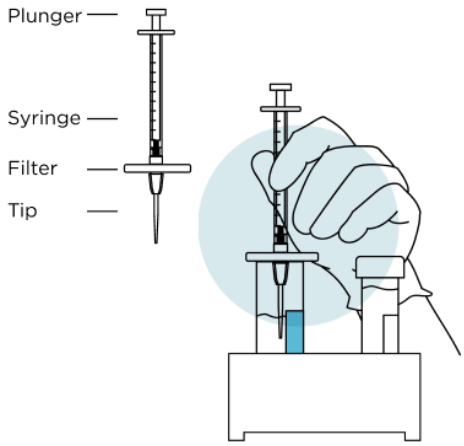
f. Insert the swab (with sample) into Swab Elution Solution Vial (blue label) and stir swab (10) times against the wall of the vial. Close cap.



g. Discard used swab(s) in appropriate biohazardous waste container. **Tap "Next"**

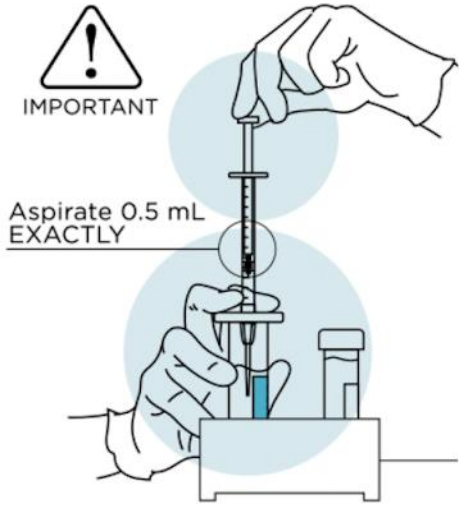
Note for Pooled Samples: *If pooling, stir each swab one at a time into Swab Elution Solution vial. Repeat process of sample collection and Swab Elution Solution Mixing in the same vial (blue label) for subsequent swabs when preparing pools of 2-10 swabs for oropharyngeal samples, or 2-5 swabs for cloacal samples (as decided by the examining veterinarian).*

h. **Gather Filtration Syringe:** Obtain pre-assembled Filtration Syringe from the test kit. Remove cap from Tip.

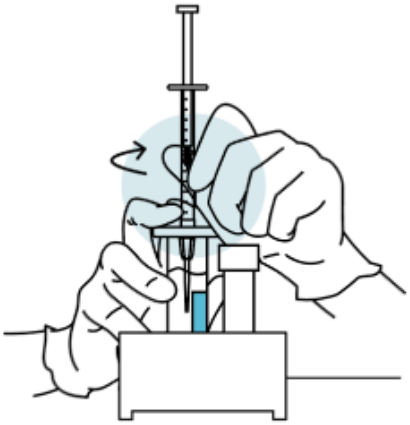


i. **Insert the Tip** of the filtration syringe into the **Swab Elution Solution** (blue label) until the filter contacts the vial opening. **Tap "Next"**
j. **Aspirate Sample** following in-App instruction and animation.

IMPORTANT! Perform reverse filtration step by gently pulling syringe plunger **to collect 0.5mL of fluid** in syringe. **Tap "Next"**



k. **Unscrew Syringe:** Watch in-App animation; **Hold filter in place and unscrew syringe counterclockwise** to detach syringe from filter and tip. Immediately discard the filter & tip in an appropriate biohazard waste container.



l. Re-cap the Swab Elution Solution Vial (blue label) until test is completed successfully. **Tap "Next"**

m. **Dispense Sample into Assay Buffer Vial (white label):**

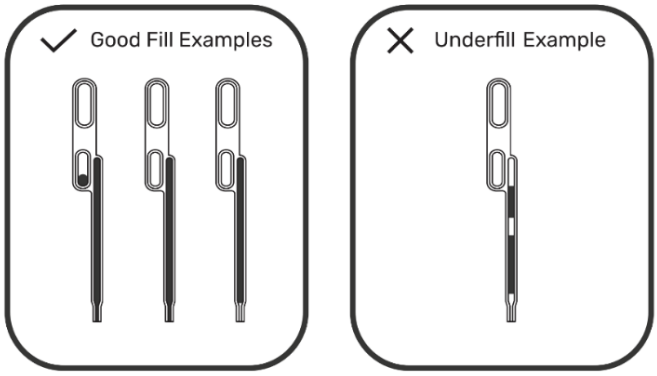


n. Unscrew cap from Assay Buffer Vial (white label). Depress syringe plunger to release sample into the Assay Buffer Vial (white label). Re-cap vial.
o. Discard syringe in appropriate biohazard waste container.
p. Remove Assay Buffer Vial (white label) from holder.
q. Invert Assay Buffer Vial (5) times to mix sample. **Tap "Next"**

9.3. Prepare Sample for Transfer into Cartridge & Running the Test

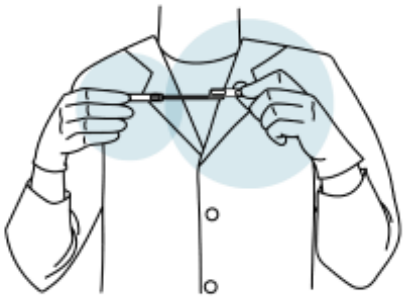
a. **Prepare Sample:** Obtain Transfer Pipette. Remove the cap of the Assay Buffer Vial (white label).
b. Squeeze the **top bulb** of the Transfer Pipette and insert the tip into the Assay Buffer vial (white label), **until it reaches the bottom.**
c. Slowly release the top bulb to fill the Transfer Pipette with the mixed Assay Buffer. Be sure to fill the Transfer Pipette stem completely.

Note: *If the stem is incompletely filled or air gaps or bubbles are present in the long stem of the Transfer Pipette, slowly empty the Transfer Pipette contents back into the Assay Buffer vial and refill slowly.* ***See examples on right of properly filled and underfilled Transfer Pipettes.***

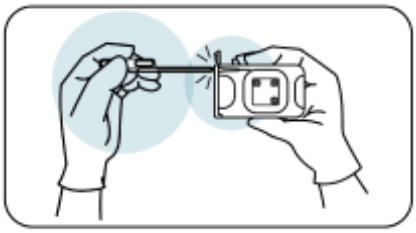


d. **Transfer Sample into Cartridge – Review In-App Animation**

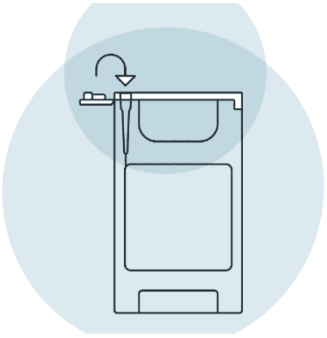
Eye Level View



Top Down View



e. **Hold Cartridge horizontally** (flat) along its sides with the **QR code facing up toward the ceiling.** Avoid touching the area with the gold electrical contacts.
f. Insert the Transfer Pipette firmly into the sample port to form a strong seal between the Cartridge and the pipette.
g. Keep firm inward pressure on the Transfer Pipette and **firmly squeeze the top bulb** to dispense all liquid from stem into the Cartridge.
IMPORTANT! ROTATE CARTRIDGE.
h. Once filled, keep firm pressure on the top bulb and carefully **turn the Cartridge vertically** to the upright position.
i. Fully remove the Transfer Pipette from the Cartridge **before releasing the top bulb** of the Transfer Pipette to avoid filling issues. Discard pipette in an appropriate biohazardous waste container. **Tap "Next"**
j. **Close cap** by securely pressing the cap back into the Cartridge.

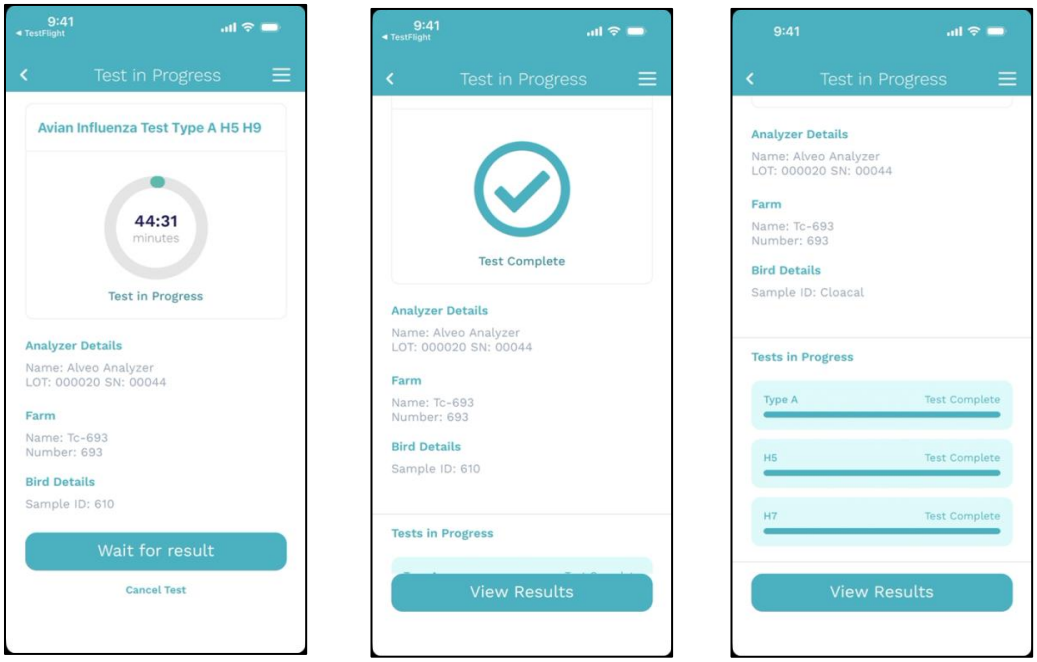


Important: Visually inspect the Cartridge for bubbles. Please note the first well on the Left is empty by design. In Wells 2-8, **if you notice any significant bubbles** (occupying >20% of the well volume), you are at a risk of an invalid or inaccurate test result. **Dispose of the Cartridge**, re-collect sample from the same Assay Buffer Vial (white label), and repeat testing procedure with a fresh Cartridge.

9.4 Inserting Test Cartridge into Analyzer

a. **Insert Cartridge** into Analyzer.
   - Ensure the Analyzer is on a clean, flat surface with the 4 blue LED indicator lights visible on top.
   - Fully insert the Cartridge with QR code facing upwards toward the ceiling into the glowing Alveo Analyzer port.
   - ***Note:*** *The blue dots will change from solid to a circular light pattern when the Cartridge is fully inserted, and the Test will begin.*

b. Test is in progress as soon as Cartridge is inserted into Analyzer.



Note: If needed, a test can be canceled while in progress. Tap the **'Cancel Test'** button and confirm you want to cancel the test. App will report result(s) as "CAN" for target(s) that were canceled before the test completed.

c. App screen will notify when the test is complete:
   - Tap **'View Results'** to access recent and past test results. Results may be shared by tapping 'Share Result' button.
   - Tap **'View Results Key'** for details on how to interpret test results.
   - Once test results are complete, discard remaining Swab Elution Solution Vial (blue label) in an appropriate biohazardous waste container.
   - **Note:** If you are unsure how to interpret a result or require support, please contact Alveo support, support@alveotechnologies.com.

10 Interpretation of Results

- Results will be reported through the Alveo Sense Mobile App as **Positive, Negative, or Invalid**.
- **Positive or Presumptive Positive** test results with the Alveo Sense Poultry Avian Influenza Test should be submitted to an authorized reference laboratory for confirmatory testing.
- **Invalid** test results with the Alveo Sense Poultry Avian Influenza Test indicate that the result cannot be interpreted. A repeat test with a new sample should be performed, if needed. Invalid results for one or more target combinations are possible and are reported specifically for each target.
- In cases where a test was Canceled or an Error occurred, results will display as Canceled or Error.

Interpretation of Results Tables

For REF# A-FIN-000037 Alveo Sense Poultry Test Type A H5 H7:

Type A	H5	H7	Interpretation
NEG	NEG	NEG	Negative; Target RNA is not detected.
POS	NEG	NEG	Type A Positive; Type A RNA target is detected.
POS	POS	NEG	H5 Positive; Type A RNA and subtype H5 target RNA are detected.
POS	NEG	POS	H7 Positive; Type A RNA and subtype H7 target RNA are detected.
POS	POS	POS	Type A, H5, H7 Positive; Type A target RNA, subtype H5 target RNA, and subtype H7 target RNA are detected.
NEG	POS	NEG	H5 Presumptive Positive; Type A is not detected but subtype H5 target RNA is detected and is a presumptive positive.
NEG	NEG	POS	H7 Presumptive Positive; Type A is not detected but subtype H7 target RNA is detected and is a presumptive positive.
NEG	POS	POS	Presumptive H5 H7 Positive; Type A is not detected but subtypes H5 target RNA and H7 target RNA are detected and are a presumptive positive.
INV	INV	INV	Invalid; cannot be interpreted. Repeat test.

For REF# A-FIN-000031 Alveo Sense Poultry Test Type A H5 H9:

Type A	H5	H9	Interpretation
NEG	NEG	NEG	Negative; Target RNA is not detected.
POS	NEG	NEG	Type A Positive; Type A RNA target is detected.
POS	POS	NEG	H5 Positive; Type A RNA and subtype H5 target RNA are detected.
POS	NEG	POS	H9 Positive; Type A RNA and subtype H9 target RNA are detected.
POS	POS	POS	Type A, H5, H9 Positive; Type A target RNA, subtype H5 target RNA, and subtype H9 target RNA are detected.
NEG	POS	NEG	H5 Presumptive Positive; Type A is not detected but subtype H5 target RNA is detected and is a presumptive positive.
NEG	NEG	POS	H9 Presumptive Positive; Type A is not detected but subtype H9 target RNA is detected and is a presumptive positive.
NEG	POS	POS	Presumptive H5 H9 Positive; Type A is not detected but subtypes H5 target RNA and H9 target RNA are detected and are a presumptive positive.
INV	INV	INV	Invalid; cannot be interpreted. Repeat test.

11 Performance Characteristics

11.1 Limit of Blank (LoB):

Limit of Blank testing was conducted with four unique negative cloacal pools (equivalent 5 swabs per pool) and four unique negative oropharyngeal pools (equivalent 10 swabs per pool). Each pool was tested in replicates of five, yielding 20 valid cartridge results per matrix type. Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges.

As shown in Table 1, a 100% negativity rate was observed across both matrices and cartridge types (A/H5/H7 and A/H5/H9). Note that the individual Type A and H5 results are summative, as the assays are shared across cartridge configurations.

Table 1

Matrix Type	Matrix Pool	Qualitative Results by Target *(# Positive | # Tested)*				Qualitative Results by Cartridge *(# Positive | # Tested)*	
		Type A	H5	H7	H9	A/H5/H7	A/H5/H9
Oropharyngeal *(Pool of 10)*	1	0 | 10	0 | 10	0 | 5	0 | 5	0 | 20 (0%)	0 | 20 (0%)
	2	0 | 10	0 | 10	0 | 5	0 | 5		
	3	0 | 10	0 | 10	0 | 5	0 | 5		
	4	0 | 10	0 | 10	0 | 5	0 | 5		
Cloacal *(Pool of 5)*	1	0 | 10	0 | 10	0 | 5	0 | 5	0 | 20 (0%)	0 | 20 (0%)
	2	0 | 10	0 | 10	0 | 5	0 | 5		
	3	0 | 10	0 | 10	0 | 5	0 | 5		
	4	0 | 10	0 | 10	0 | 5	0 | 5		
Qualitative Results by Target *(# Positive | # Tested)*		0 | 80	0 | 80	0 | 40	0 | 40		

11.2 Analytical Sensitivity (Limit of Detection)

Limit of Detection was defined as the lowest concentration where ≥ 95% of the replicates tested positive for the hemagglutinin-specific test (H5, H7, H9). Testing was conducted using four viral samples: an H5N2 strain of the American non-GsGD clade, an H5N8 strain of the 2.3.4.4b clade, an H7Nx strain of the Eurasian lineage, and an H9N2 strain of the G lineage. Testing of H5N2, H5N8, and H7Nx was conducted using two lots of A/H5/H7 cartridges, while testing of H9N2 was conducted using one lot of A/H5/H9 cartridges.

Testing was executed by spiking the inactivated Influenza A viruses into assay buffer containing filtered cloacal (equivalent 5 swabs per pool) or oropharyngeal (equivalent 10 swabs per pool) matrix, and was confirmed if the H5, H7, or H9 indicator achieved ≥ 95% positivity rate across 20 valid cartridge replicates (≥ 19/20). The obtained Limit of Detection dilutions were correlated with Royal GD's Influenza A TaqMan PCR assay to obtain equivalent Ct values.

As shown in Table 2, the LoD for H5N2 corresponds to Ct 33.5 in cloacal matrix and Ct 33.0 in oropharyngeal matrix. The LoD for H5N8 corresponds to Ct 30.6 in cloacal matrix and Ct 31.9 in oropharyngeal matrix. The LoD for H7Nx corresponds to Ct 28.5 in cloacal matrix and Ct 29.0 in oropharyngeal matrix. The LoD for H9N2 corresponds to Ct 31.6 in both cloacal and oropharyngeal matrices.

Table 2:

Sample	**Matrix Type**	**Equivalent *PCR Ct*** *GD TaqMan PCR*	**Qualitative Results by Target** *(# Positive | # Tested)*			
			Type A	**H5**	**H7**	**H9**
H5N2 (Am_nonGsGd)	Cloacal *(Pool of 5)*	33.5	20 | 20	20 | 20	0 | 20	*N/A*
	Oropharyngeal *(Pool of 10)*	33.0	20 | 20	20 | 20	0 | 20	*N/A*
H5N8 (2.3.4.4b)	Cloacal *(Pool of 5)*	30.6	20 | 20	20 | 20	0 | 20	*N/A*
	Oropharyngeal *(Pool of 10)*	31.9	19 | 20	20 | 20	0 | 20	*N/A*
H7Nx (Eurasian)	Cloacal *(Pool of 5)*	28.5	20 | 20	0 | 20	20 | 20	*N/A*
	Oropharyngeal *(Pool of 10)*	29.0	20 | 20	0 | 20	20 | 20	*N/A*

H9N2 (G lineage)	Cloacal *(Pool of 5)*	31.6	19 | 20	0 | 20	*N/A*	20 | 20
	Oropharyngeal *(Pool of 10)*	31.6	17 | 20	0 | 20	*N/A*	20 | 20

11.3 Avian Influenza Virus Inclusivity and Exclusivity

Inclusivity and specificity (exclusivity) testing was conducted with the following 12 Influenza A strains: H3N1, H5N1 (European non-GsGD), two H5N2 strains (one EU-non-GsGD, one AM-non-GsGD), two H5N3 strains (both EU-non-GsGD), H5N8 (2.3.4.4b), H6N1, H7N1 (Eurasian lineage), H7Nx (Eurasian lineage), and two H9N2 strains (G lineage). Testing was performed by spiking the inactivated Influenza A viruses into assay buffer containing filtered cloacal (CL, equivalent 5 swabs per pool) or oropharyngeal (OP, equivalent 10 swabs per pool) matrices, with a minimum of three cartridge replicates per matrix and cartridge type. The Influenza A Ct-value in the final assay buffer suspension was determined with the GD TaqMan Influenza A PCR assay. Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges.

As shown in Table 3, all avian influenza virus strains were correctly detected across Type A, H5, H7, and H9 results. Note that the individual Type A and H5 results are summative, as the assays are shared across cartridge configurations.

Table 3:

Strain *(subtype/lineage/clade)*	**Matrix Type**	**GD TaqMan PCR (Ct)** *A/H5/H7 | A/H5/H9*	**Qualitative Results by Target** *(# Positive | # Tested)*			
			Type A	**H5**	**H7**	**H9**
H3N1	OP	28 | 32	8 | 8	0 | 8	0 | 4	0 | 4
	CL	25 | 25	6 | 6	0 | 6	0 | 3	0 | 3
H5N1 (EU_nonGsGd)	OP	30 | 28	6 | 6	6 | 6	0 | 3	0 | 3
	CL	27 | 27	6 | 6	6 | 6	0 | 3	0 | 3
H5N2 (AM_nonGsGd)	OP	29 | 31	6 | 6	6 | 6	0 | 3	0 | 3
	CL	28 | 28	7 | 7	7 | 7	0 | 4	0 | 3
H5N2 (EU_nonGsGd)	OP	28 | 29	6 | 6	6 | 6	0 | 3	0 | 3
	CL	25 | 25	6 | 6	6 | 6	0 | 3	0 | 3
H5N3	OP	28 | 29	7 | 7	7 | 7	0 | 4	0 | 3

(EU_nonGsGd)	CL	26 | 25	6 | 6	6 | 6	0 | 3	0 | 3
H5N3 (EU_nonGsGd)	OP	29 | 28	6 | 6	6 | 6	0 | 3	0 | 3
	CL	26 | 26	6 | 6	6 | 6	0 | 3	0 | 3
H5N8 (2.3.4.4b)	OP	31 | 25	6 | 6	6 | 6	0 | 3	0 | 3
	CL	27 | 24	6 | 6	6 | 6	0 | 3	0 | 3
H6N1	OP	28 | 30	8 | 8	0 | 8	0 | 4	0 | 4
	CL	26 | 26	6 | 6	0 | 6	0 | 3	0 | 3
H7N1 (Euasian)	OP	29 | 31	6 | 6	0 | 6	3 | 3	0 | 3
	CL	26 | 26	6 | 6	0 | 6	3 | 3	0 | 3
H7Nx (Eurasian)	OP	29 | 31	6 | 6	0 | 6	3 | 3	0 | 3
	CL	27 | 24	6 | 6	0 | 6	3 | 3	0 | 3
H9N2 (G-lineage)	OP	28 | 29	6 | 6	0 | 6	0 | 3	3 | 3
	CL	25 | 25	6 | 6	0 | 6	0 | 3	3 | 3
H9N2 (G-lineage)	OP	26 | 28	7 | 7	0 | 7	0 | 4	3 | 3
	CL	26 | 26	6 | 6	0 | 6	0 | 3	3 | 3

11.4 Non-Avian Influenza Virus Cross-Reactivity

DNA and RNA from the following nineteen non-influenza viruses and bacteria were evaluated: four strains of Infectious bronchitis virus (D388_GI-19, D274_GI-12, M41_GI-1, and 4/91_GI-13), Infectious laryngotracheitis virus, avian met-apneumovirus subtypes A, B and C (AMPV-A, AMPV-B, AMPV-C), Avian paramyxovirus type 1 (Newcastle Disease virus (NCD)), two *Mycoplasma synoviae* strains, two *Mycoplasma gallisepticum* strains, three *Avibacterium paragallinarum* serovars (A1, B1, C4), *Pasteurella multocida*, *Gallibacterium anatis, Ornithobacterium rhinotracheale*, and *Riemerella anatipestifer*. Testing was performed in duplicate per cartridge type by spiking the nucleic acid extracts into assay buffer containing filtered oropharyngeal matrix (equivalent 10 swabs per pool). Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges. Ct-values were determined with the pathogen specific TaqMan GD PCR assay, targeting < Ct 25 in the final reaction. For two bacterial samples (*Ornithobacterium rhinotracheale* and *Riemerella anatipestifer*), a >4.0 McFarland suspension was used without determination of the Ct-value.

As shown in Table 4, none of the organisms tested interfered with the A/H5/H7 test or A/H5/H9 test by generating false positive results. Note that the individual Type A and H5 results are summative, as the assays are shared across cartridge configurations.

Table 4:

Non-Avian Influenza Pathogen ***(serotype or subtype)***	***GD TaqMan PCR (Ct)*** *A/H5/H7 | A/H5/H9*	**Qualitative Results by Target** *(# Positive | # Tested)*				**Qualitative Results by Cartridge** *(# Positive | # Tested)*	
		Type A	**H5**	**H7**	**H9**	**A/H5/H7**	**A/H5/H9**
Infectious bronchitis virus, D388	22 | 22	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Infectious bronchitis virus, D274	21 | 21	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Infectious bronchitis virus, M41	23 | 23	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Infectious bronchitis virus, 4/91	27 | 27	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Infectious laryngotracheitis virus (vaccine like)	24 | 24	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avian metapneumovirus A (AMPV-A) (TRT)	25 | 26	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avian metapneumovirus B (AMPV-B) (TRT)	21 | 23	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avian metapneumovirus C (AMPV-C) (TRT)	27 | 27	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avian paramyxovirus type 1 (NCD)	22 | 22	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Mycoplasma synoviae	21 | 21	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Mycoplasma synoviae	26 | 26	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Mycoplasma gallisepticum	22 | 22	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avibacterium paragallinarum A1	23 | 23	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avibacterium paragallinarum B1	23 | 23	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Avibacterium paragallinarum C4	24 | 24	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Pasteurella multocida	24 | 24	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Gallibacterium anatis	22 | 22	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Ornithobacterium rhinotracheale (ORT)	*N/A*	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
Riemerella anatipestifer	*N/A*	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2

11.5 Reproducibility and Precision

Reproducibility and precision (repeatability) was conducted across two laboratories divided among four operators over three days. Each operator tested three replicates per condition, per day, including a no template control (NTC) and a combined positive control (PC). For the A/H5/H7 test, the PC included H5N2, H5N8, and H7Nx strains, while the PC for the A/H5/H9 test included H5N2, H5N8, and H9N2 strains, each at a concentration of 3x LoD. Testing was conducted by spiking TE Buffer (negative sample) or the combined Influenza A viruses (positive sample) into assay buffer containing filtered cloacal matrix (equivalent 5 swabs per pool). Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges.

As shown in Table 5, Reproducibility and Precision was executed with 100% agreement with the expected result for both A/H5/H7 and A/H5/H9 cartridges.

Table 5:

Laboratory	Test Day	Operator	Qualitative Results by Cartridge Type *(# Positive | # Tested)*			
			A/H5/H7		A/H5/H9	
			Negative	Positive *(H5N2/H5N8/H7Nx)*	Negative	Positive *(H5N2/H5N8/H9N2)*
Laboratory 1	Day 1	Operator 1	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 2	0 | 3	3 | 3	0 | 3	3 | 3
	Day 2	Operator 1	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 2	0 | 3	3 | 3	0 | 3	3 | 3
	Day 3	Operator 1	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 2	0 | 3	3 | 3	0 | 3	3 | 3
Laboratory 2	Day 1	Operator 3	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 4	0 | 3	3 | 3	0 | 3	3 | 3
	Day 2	Operator 3	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 4	0 | 3	3 | 3	0 | 3	3 | 3
	Day 3	Operator 3	0 | 3	3 | 3	0 | 3	3 | 3
		Operator 4	0 | 3	3 | 3	0 | 3	3 | 3
Overall Qualitative Results by Cartridge *(# Positive | # Tested)*			0 | 36	36 | 36	0 | 36	36 | 36

11.6 Validation with Clinical Negative Field Samples

Oropharyngeal swabs from eight postmortem influenza-negative flocks were pooled at a ratio of five (5) swabs per vial per flock and tested with a minimum of two cartridge replicates following the end-to-end workflow. All field samples were confirmed Influenza A negative by the Wageningen BioVeterinary Research reference institute laboratory prior to testing. Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges.

As shown in Table 6, a 100% negativity rate was observed for all negative clinical field samples for both A/H5/H7 and A/H5/H9 cartridges.

Table 6:

Sample	Matrix Type	Qualitative Results by Target *(# Positive | # Tested)*				Qualitative Results by Cartridge *(# Positive | # Tested)*	
		Type A	H5	H7	H9	A/H5/H7	A/H5/H9
01	Oropharyngeal	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
02	Oropharyngeal	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
03	Oropharyngeal	0 | 5	0 | 5	0 | 3	0 | 2	0 | 3	0 | 2
04	Oropharyngeal	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
05	Oropharyngeal	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2
06	Oropharyngeal	0 | 7	0 | 7	0 | 3	0 | 4	0 | 3	0 | 4
07	Oropharyngeal	0 | 5	0 | 5	0 | 3	0 | 2	0 | 3	0 | 2
08	Oropharyngeal	0 | 4	0 | 4	0 | 2	0 | 2	0 | 2	0 | 2

The evaluation of the Alveo Sense Poultry Avian Influenza H5, H7, and H9 subtype tests showed an NPA of ≥99% in combination for both OP and CL samples.

11.7 Validation with Contrived Positive Samples

Validation using clinical positive samples was not feasible in the laboratory setting due to avian influenza testing restrictions. Positive sample validation was thus performed by spiking the viruses used in the LoD experiment (H5N2, H5N8, H7Nx, H9N2) into the sample

matrix prior to testing. The A/H5/H7 test was evaluated with H5N2, H5N8, and H7Nx, while the A/H5/H9 test was validated with H5N2, H5N8, and H9N2. Positive sample testing was concurrently evaluated with pool size validation: oropharyngeal samples were tested in pools of 1, 3, 5, and 10, while cloacal samples were tested in pools of 1, 3, and 5. The virus samples were spiked into the matrix pools and tested following the end-to-end workflow, with a minimum of two cartridge replicates per condition. Testing was performed using one lot of A/H5/H7 cartridges and one lot of A/H5/H9 cartridges. The influenza A Ct-value in the diluted matrix/virus suspension was determined with the GD TaqMan Influenza A PCR assay.

As shown in Table 7, the contrived positive samples yielded a 95.7% (44 | 46) agreement for the A/H5/H7 cartridge type, with 100% (46 | 46) of cartridges showing Influenza A detection. One H5 false negative was observed in an H5N2 sample from an oropharyngeal pool of 10 with an Influenza A Ct 36 (Type A was successfully detected). One Type A false negative was observed in an H5N8 sample from a cloacal pool of 5 with an Influenza A Ct 30 (H5 was successfully detected). The Ct values ranged from Ct 24 to 36.

Table 7:

Strain	Matrix Type	Pool Size	GD TaqMan PCR (Ct)	Qualitative Result by Target *(# Positive | # Tested)*		
				Type A	H5	H7
H5N2 (Am_nonGsGd)	Cloacal	1	29	2 | 2	2 | 2	0 | 2
		3	29	2 | 2	2 | 2	0 | 2
		5	35	2 | 2	2 | 2	0 | 2
	Oropharyngeal	1	33	2 | 2	2 | 2	0 | 2
		3	34	2 | 2	2 | 2	0 | 2
		5	34	2 | 2	2 | 2	0 | 2
		10	36	2 | 2	1 | 2	0 | 2
H5N8 (2.3.4.4b)	Cloacal	1	30	2 | 2	2 | 2	0 | 2
		3	29	2 | 2	2 | 2	0 | 2
		5	30	2 | 3	3 | 3	0 | 3
	Oropharyngeal	1	28	2 | 2	2 | 2	0 | 2
		3	28	2 | 2	2 | 2	0 | 2
		5	30	2 | 2	2 | 2	0 | 2
		10	31	3 | 3	3 | 3	0 | 3
H7Nx (Eurasian)	Cloacal	1	28	2 | 2	0 | 2	2 | 2
		3	30	2 | 2	0 | 2	2 | 2
		5	27	3 | 3	0 | 3	3 | 3
	Oropharyngeal	1	24	2 | 2	0 | 2	2 | 2
		3	25	2 | 2	0 | 2	2 | 2

		5	25	2 | 2	0 | 2	2 | 2
		10	28	3 | 3	0 | 3	3 | 3

As shown in Table 8, the contrived positive samples yielded a 100% (45 | 45) agreement for the A/H5/H9 cartridge type across Type A, H5, and H9 targets. The Ct values ranged from Ct 26 to 33.

Table 8:

Strain	Matrix Type	Pool Size	GD TaqMan PCR (Ct)	Qualitative Result by Target *(# Positive | # Tested)*		
				Type A	H5	H9
H5N2 (Am_nonGsGd)	Cloacal	1	30	2 | 2	2 | 2	0 | 2
		3	30	2 | 2	2 | 2	0 | 2
		5	31	2 | 2	2 | 2	0 | 2
	Oropharyngeal	1	31	2 | 2	2 | 2	0 | 2
		3	33	2 | 2	2 | 2	0 | 2
		5	31	2 | 2	2 | 2	0 | 2
		10	30	3 | 3	3 | 3	0 | 3
H5N8 (2.3.4.4b)	Cloacal	1	29	2 | 2	2 | 2	0 | 2
		3	29	2 | 2	2 | 2	0 | 2
		5	28	2 | 2	2 | 2	0 | 2
	Oropharyngeal	1	29	2 | 2	2 | 2	0 | 2
		3	30	2 | 2	2 | 2	0 | 2
		5	30	2 | 2	2 | 2	0 | 2
		10	28	3 | 3	3 | 3	0 | 3
H9N2 (G lineage)	Cloacal	1	28	2 | 2	0 | 2	2 | 2
		3	29	2 | 2	0 | 2	2 | 2
		5	29	2 | 2	0 | 2	2 | 2
	Oropharyngeal	1	26	2 | 2	0 | 2	2 | 2
		3	27	2 | 2	0 | 2	2 | 2
		5	28	2 | 2	0 | 2	2 | 2
		10	28	3 | 3	0 | 3	3 | 3

The evaluation of the Alveo Sense Poultry Avian Influenza H5, H7, and H9 subtype tests showed a PPA of ≥99% in combination for both OP and CL samples with a Ct range of approximately 30-32.

12 Frequently Asked Questions (FAQs) & Troubleshooting

How to manually reset the Analyzer:

To manually reset the Analyzer, hold the power button until the lights turn off. The Analyzer will turn back on momentarily after.

Responding to Errors During Testing:

If the Analyzer LEDs turn red or other error notices are displayed on the Mobile App **immediately upon insertion of the Cartridge into the Analyzer or mid-test,** remove the Cartridge, restart the Analyzer following restart testing procedure. To clear the redlights on the analyzer, press and hold the power button on the side of the Analyzer near the USB port for 10 seconds and then release it.

Running Multiple Tests at Once:

The system allows for up to six (6) Alveo Analyzers to be connected to a single Smartphone. If running multiple tests at once, the Analyzers should be uniquely named. Follow instructions in the Mobile App on renaming the Alveo Analyzer. Please contact Alveo Technologies Customer Support for assistance.

What happens if cellular or Wifi disconnect during testing?

The system supports “offline mode.” If cellular or WiFi are lost during the testing process, the system saves up to 10 results that will display in the Mobile App as soon as cellular or WiFi are restored.

Notifications/Errors in Alveo Sense App

Analyzer not detected

Please ensure that your Analyzer is turned on and not connected to another phone.

User cannot connect with Analyzer: Make sure Analyzer lights are on and check that the Mobile App is connected to the right Analyzer by going to “Manage Analyzers” in the app.

Phone storage full

The Phone storage full pop-up window indicates that there is not enough storage to use the App and to free up space.

Tap “Ok”.

Application update needed

The Alveo Sense app must be updated before you can continue. A newer version of the Mobile App has been released. Click "Ok" to clear the notification, then go to the App Store to update the “Alveo Sense” Mobile App.

Note: Tapping **Later** defers the update and the application will not be usable until update has been completed.

Invalid credentials

Please, check your e-mail address and password and try again. You may use the “Forgot password” option to request a new password.

Login credentials are invalid. For an existing Alveo Sense account, enter a valid e-mail address and password, or request a new password. If you do not have an account, create and register an account.

Maintenance mode

System is under maintenance for next {number} minutes, please try login again.

Maintenance is being performed on the System. Please wait until the time has passed, then try to log in again.

Update failed

The software on the Analyzer failed to update. Please reset your Analyzer and try again.

The update failed to download or install. Reset the Analyzer then follow the prompts to update the analyzer when they appear in the Alveo Sense Mobile App.

Pairing failed

Please check that the blue lights on the Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth settings and forget the device(s).

Unsuccessful pairing. Check that the blue lights on the Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth settings and "Forget" the device(s) and pair again.

Network error

Please check your internet connection and try again.

No internet service. Check WiFi or cellular service connection, turn off and turn on to reconnect and try again.

Location services

This app requires location services to be enabled in order to scan for Bluetooth devices and connect to the Alveo Analyzer.

Turn on Location services to continue.

Location permission not authorized by user.

Go to settings on mobile device and enable location services.

Location permission

This app requires location permission to be provided in order to scan for Bluetooth devices and connect to the Alveo Analyzer.

Location permission not authorized by user.

Go to settings on mobile device and enable location services.

Bluetooth permission

This app requires Bluetooth permission to be provided in order to communicate with the Alveo Analyzer.

Bluetooth permission has not been authorized.

Go to settings on mobile device and enable Bluetooth services.

Bluetooth services

This app requires Bluetooth to be enabled in order to communicate with the Analyzer. Turn on Bluetooth to continue.

Bluetooth permission has not been authorized.

Go to settings on mobile device and enable Bluetooth services.

This field is required* is shown below a field.

A required field is not entered.

Enter required field.

Please, enter a valid email address" is shown below the Email ID field.

Invalid email ID entered.

Enter correct email ID.

Please check e-mail

Please check your e-mail for the validation message and click the link before logging in.

User tries to login before authenticating via email.

Refer to the email received and click on the confirmation link to login.

Passwords must match *

Password entered does not match password entered in the “confirm password” field.

Check the password entered in both fields to confirm that they match.

Password must satisfy the conditions below.

Conditions for the password are not met.

Enter a password that meets the conditions.

Scan failed: Expired cartridge

Your cartridge is expired. Please get a new cartridge and start over.

Expired Cartridge scanned.

Use a new Cartridge that is not expired and restart the test.

Scan failed: Invalid QR/Barcode

Wrong bar code. Please scan the bar code on the cartridge label or the cartridge packaging.

User scans an invalid QR code or barcode.

Scan the correct QR code on the Cartridge

Scan failed: Cartridge use prohibited

This cartridge use is prohibited. Please use another cartridge.

The scanned cartridge is not permitted to use. Get the right cartridge and scan again.

Test failed: Cartridge removed

Your test could not finish. The cartridge was removed before the test was finished.

User removes Cartridge before the test is completed.

Collect sample and run another test according to the instructions.

Test failed: Unscanned cartridge

Your test cannot be run. The cartridge was loaded without scanning a barcode first. Get a new Cartridge and follow the steps in the app for scanning the Cartridge.

Cartridge not scanned before loading into the Analyzer.

Follow the instructions and scan the Cartridge before starting the test. If Cartridge was inserted, get a new Cartridge and follow the instructions for running a test.

Test failed: System error

Your test could not finish. There was a system error and your test results were lost. Please get a new cartridge and start your test again.

Test fails while running.

Remove the Cartridge from the Analyzer, get a new Cartridge, collect sample and restart the test.

Test failed: Test Data Lost

Your test could not finish. It's possible that the data was deleted from the analyzer before synchronization and your test results were lost. Please get a new cartridge and start your test again.

Test fails while running.

Remove the Cartridge from the Analyzer, get a new Cartridge, collect sample and restart the test.

Test failed: Charging Fault

Try a different cable or charger for the Analyzer

If trying a different cable or charger does not work, please contact Customer Support.

Test failed: Battery Needs Replacing

Contact support@alveotechnologies.com **to arrange a replacement for Analyzer**

Test failed as the battery is depleted. Contact customer service to arrange a replacement.

Temperature Sensor Fault

Restart Analyzer. If it repeats, contact support@alveotechnologies.com

Test Failed because of temperature sensors fault on the analyzer. Restart Analyzer and try to repeat the test.

Couldn't Reach Test Temperature

Try again with Analyzer in a stable, room-temperature spot.

Analyzer did not reach the required temperature to start the test. Run the test with analyzer at room temperature.

Heater Overheated

Let Analyzer cool down before next test.

Analyzer is too hot to run a test. Let the analyzer cool down before starting the test.

Self-Check Failed

Restart Analyzer. If it repeats, contact support@alveotechnologies.com

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Hardware Fault

Restart Analyzer. If it repeats, contact support@alveotechnologies.com

If you cannot start test with analyzer, restart analyzer and try again. If issue persists, reach out to support.

Test Quality Not Met

Run a new test with a fresh cartridge.

If the test results don't match the expected results, repeat the test with a new cartridge. If the issue occurs again, contact Alveo Technical Support for assistance.

Data Transfer Error

Reconnect Analyzer and try again.

If the test data is not transferred and results are not shown, repair the analyzer and try again.

Internal Memory Error

Restart Analyzer. If it repeats, contact support@alveotechnologies.com

The analyzer's internal memory reported an error; restart the analyzer and repeat the test.

Phone storage full

You do not have enough storage to use the Alveo Sense app.

Mobile device storage space is full.

Check to make sure there is enough storage on the mobile device for the test to run. If necessary, free up space by deleting content you no longer use.

Remove cartridge

Please remove the cartridge from the Analyzer before you start a new test.

User attempts to start a new test with a Cartridge already inserted.

Remove the Cartridge from the Analyzer port, then scan the new Cartridge and start the test.

Invalid Assay Configuration

The cartridge's assay configuration is invalid.

Contact Customer Support as there is a configuration issue.

Select Test Type Doesn't Match Scanned Cartridge

Please confirm you selected the correct test type and scan again.

There's a mismatch between the test type selected and cartridge type that was scanned. Correct the test type or select the appropriate cartridge if the test type is correct.

Selected Test Type Not Available Offline

Please confirm test type and if correct, connect to the internet and scan again.

Assay data is missing from your local device. Connect to the internet, re-login to the app to download that data and then start a new test to try again.

Test in Progress

A test is in progress on this Analyzer. Please wait for test to complete.

User tries to start another test while a test is in progress.

Wait for the current test to complete before starting a new test.

Communication failure

There has been an error in configuring your Analyzer. Please ensure you are within 3 feet of the Analyzer and try again.

User sees an error in the app while configuring the Analyzer

Make sure that the Analyzer is close to the mobile device and try again to start the test. Also check that the mobile device is paired with the correct Analyzer. If this doesn't resolve the issue, restart the Analyzer by pressing the button on top of the Analyzer for 5 seconds and then attempt to start the test again.

Operation Timeout

Cartridge insertion has timed out. Please restart the test.

User is informed the time to insert the cartridge to start the test has expired

Make sure to initiate test on the Mobile App at the time of sampling and sample preparation, not in advance.

Battery Low!

Your paired Analyzer has low battery. Please charge Analyzer to at least 34% or connect a new Analyzer.

The analyzer requires at least 34% battery charge to run a single assay. Please charge the analyzer to at least that level before trying again.

Too hot to run test

Your room is too hot to run a test. Please move the Analyzer to a cooler place so the test can run.

Room temperature is too hot to run a test.

Move the Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended temperature range, wait for the Analyzer to cool down and then start the test.

Too cold to run test

Your room is too cold to run a test. Please move the Analyzer to a warmer place so the test can run.

Room temperature is too cold to run a test.

Move the Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended temperature range, wait for the Analyzer to achieve normal temperature and then start the test.

Upload Offline Data

The data is uploaded automatically to the cloud when the mobile device goes online. (A blue banner is shown on the Home screen with the upload progress).

Once all tests are uploaded, a green banner appears with the message “All Offline tests synced.”

If user action is required before uploading the data, the **Home** screen shows a yellow banner with the text “0 of 1 synced, 1 test need attention.” Tap on the yellow banner and all tests that require actions are displayed with the required action in red text. After the issues are resolved, the tests may be uploaded by tapping the **Upload Test Results** button.

After tapping **Upload Test Results**, the screen shows the tests being uploaded and their status.

If there is an issue with upload, Upload Failed will be displayed next to the test.

In this case, the following options are provided:

- Verify
- Continue

Verify will check the offline tests and attempt to resolve any issues.

If there is no internet during the upload, the upload will fail and a message is displayed indicating internet connectivity should be enabled and upload retried.

Turn on internet connectivity and upload offline data or tap Continue.

When the tests are uploading, an Uploading message is displayed next to the test. This message changes to Upload Completed once the upload is successful.

Tap the “Continue” button once the upload is completed. It is disabled while the tests are being uploaded.

Delete Offline Test

The Delete Offline Test popup allows the user to permanently delete a test. NOTE: once deleted, the test data cannot be accessed or restored.

Firmware Update: Unfinished Update

Analyzer did not finish updating. Go to Analyzers to finish it.

Go to the Manage Analyzers page to finish the update. If that does not work, start a new test, select this analyzer and a dialog will appear to start the firmware upgrade.

Firmware Update: Bluetooth is off

Turn on Bluetooth to continue updating your analyzer.

Make sure Bluetooth is enabled on the mobile device.

Firmware Update: Update Failed

The software on your Analyzer failed to update. Please reset your Analyzer and try again.

Press and hold the button on the Alveo Analyzer for 5s to restart it and then repeat the firmware upgrade process.

13 Symbols

	Manufacturer		Caution
	Batch code		Consult Instructions For Use
	Part number		Use-by YYYY-MM-DD
	Serial number		Do not use if packaging is damaged
	Keep dry		Single use, do not re-use
	Temperature limit		Sterilized using ethylene oxide
	Dispose of material		One (1) box contains materials for ten (10) tests
	Input rating		Electrical and Electronic Equipment Waste: Discard product at separate collection facility for recovery and recycling.
			Compliance to FCC Part 15 Subpart B

14 Customer Support

For assistance for ordering products, please contact your local Distributor or contact Alveo Technologies at sales@alveotechnologies.com

For technical support, please contact your local Distributor or contact Alveo Technologies Support for assistance.

For product quality issues, please contact Alveo Technologies Support directly.

Email: support@alveotechnologies.com

Web site: Connect with Alveo Technologies | Contact Us

Telephone: +1 (855) 817-3055

15 Product Descriptions

REF A-FIN-000037 Alveo Sense Poultry Avian Influenza Test Type A H5 H7

REF A-FIN-000031 Alveo Sense Poultry Avian Influenza Test Type A H5 H9

REF A-FIN-000039 Alveo Analyzer

REF Alveo Sense Mobile App

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