



ID NOW™ COVID-19 2.0\*, INFLUENZA AND  
RSV

# Sample Safeguards

\*Emergency Use Authorization Granted by FDA



# Important Facts

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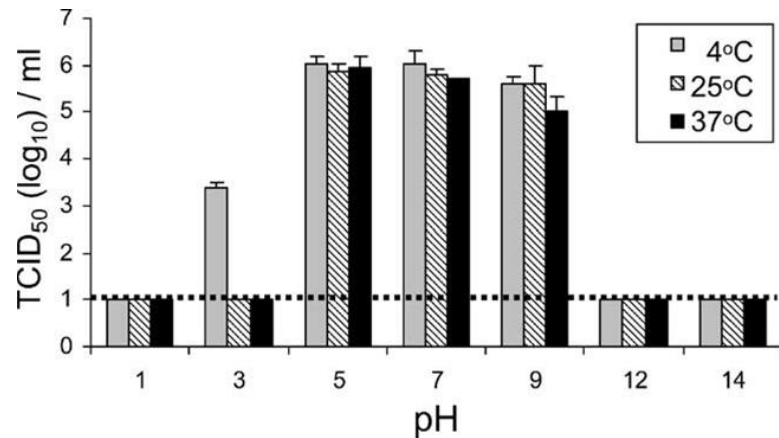
- **Sample processing in the ID NOW™ instrument does not add risk to testing**
  - The viruses are inactivated due to the combination of hydrochloric acid, detergent and heating of the sample receiver. The solution denatures the membrane in the sample receiver due to its acidity at a pH of 2.0<sup>1</sup>, the detergent is an effective surfactant in solubilizing proteins and the sample receiver is heated to 56°C.
  - The sample receiver is only about one-quarter full of liquid reagent with 2.5 ml
  - Based on this low volume in the sample receiver, "splash" is not generated when mixing with the swab in the sample receiver according to the product insert instructions.
  - An operator using ID NOW™ would have to make a deliberate effort to generate a “splash”.
- **Evidence does not exist that the testing process generates aerosols and droplets have not been observed when following the package insert instructions**

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<sup>1</sup> Darnell MER, Subbarao K, Feinstone SM, and Taylor DR.  
Inactivation of the coronavirus that induces severe acute  
respiratory syndrome, SARS-CoV

# Safety of ID NOW™

## Mechanism of Viral Inactivation - pH



- The virus is not stable in alkaline (pH > 12) or acidic conditions (pH < 3)<sup>1</sup>
  - This information is from SARS-CoV which is identical in the lipid membrane to SARS-CoV-2 as membranes are made via budding through the eukaryotic cellular membrane. Flu and RSV viruses are also enveloped with a lipid membrane.
- The elution solution is at a pH of 2
  - Low pH solutions are commonly used to inactivate envelope viruses since this condition leads to a spontaneous denaturation

<sup>1</sup> Darnell MER, Subbarao K, Feinstone SM, and Taylor DR. Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV



## Mechanism of Inactivation - Detergent

- The primary use is isolating membrane proteins by dissolving the lipid membrane layer<sup>1</sup>
  - The hydrophobic portion of the molecule pushes through the lipid membranes of the Flu, RSV and SARS-CoV-2 viruses forming holes. Water rushes in to then lyse the envelope

<sup>1</sup><https://www.labome.com/method/Detergents-Triton-X-100-Tween-20-and-More.html>

# ID NOW internal biohazard study

- There has been some concern raised as to whether the use of the ID NOW™ platform leaves users at risk of infection from spill/splash during swab elution. Recently, Abbott conducted a study using the ID NOW™ Covid-19 test to identify any potential risk. Please note that the study did not evaluate placing the swab back into the wrapper.
- In this study we used Glo-Germ UV gel to visualize the potential risk of spill/splash when using the instrument by simulating 34 consecutive swab elutions on a single instrument, equivalent to an 8 hour shift.
- Experiment Overview
  - Glo-Germ UV gel is used as a surrogate for a patient sample
  - Each swab is eluted according to the instructions in the ID NOW™ COVID-19 Package Insert
  - For each of the 34 swab elutions, 4 UV pictures are taken
    - Swab head prior to elution in the sample receiver
    - Elution buffer after the swab is eluted
    - Operator's hands after the swab is eluted
    - ID NOW™ instrument after sample receiver is removed and discarded
  - The ID NOW™ **was not** cleaned or wiped down between samples
  - The sample receiver and operator's gloves were changed between samples
  - On the following slides, select swabs (1<sup>st</sup>, 10<sup>th</sup>, 20<sup>th</sup>, 30<sup>th</sup>, 34<sup>th</sup>) are documented

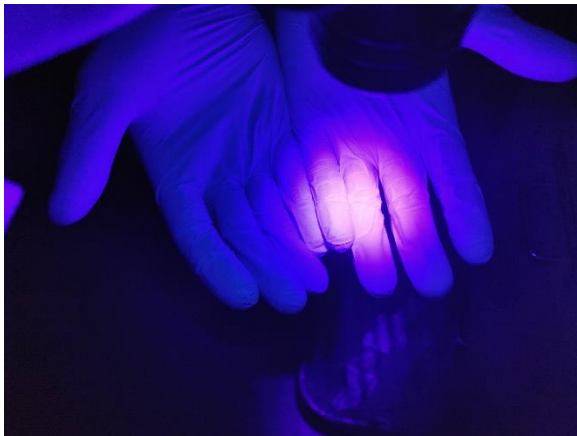
# Swab 1



Swab Coated with Glo-Germ



Glo-Germ Eluted in Sample Receiver



Operator's Hands After Elution



Instrument After Sample Receiver Discarded

## Summary of Findings

- No UV liquid was observed on or in the instrument, outside of the sample receiver, at any time during the experiment
- No UV liquid was observed on the operator's hands at any time during the experiment



The 34<sup>th</sup> and final swab eluate in sample receiver. There are no drops of liquid outside the consumable.



Following the experiment, with the last sample receiver removed. There is no evidence of splashing in the instrument.



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