

## Raw PIG FlowThrough™ Swab

### VALIDATION REPORT



**REF:**

**R6082** (5 Tests)

**R6086** (100 Tests)

#### Intended use

Raw PIG FlowThrough™ Swab (Pig-FT Swab) tests can help validate and verify that cleaning regimes designed to ensure meat product residue reductions are effective. They can be used in the food manufacturing environment and help to ensure the 'pork-free' status of finished products and in testing laboratories to assist in maintaining GLP.

A robust, well designed and appropriately validated sampling & testing regime, which encompasses the use of confirmatory laboratory techniques helps to increase the level of protection.



**It is important that the use of PIG-FT Swab has been validated by the user to ensure that it is 'fit for purpose'.**

#### Performance characteristics

Parameter	Description	Section
<b>Sensitivity</b>	The lowest concentration that can be detected on a surface.	1
<b>Selectivity</b>	The extent to which a method can determine particular analytes.	2
<b>Specificity</b>	The effect of any interfering substances.	3
<b>Repeatability</b>	The agreement between results under repeatability conditions.	4
<b>Robustness</b>	The effect of changes to operational parameters on the results.	5
<b>Stability</b>	Recommended storage conditions and duration.	6

## 1. Sensitivity

Tested	PSA (on swab)	Equivalent on 10 x 10cm surface†	Test Response
PSA*	25 µg (HIGH)	125 - 500 µg	Positive
PSA	0.03 µg (LOD**)	0.15 – 0.6 µg	Positive
No addition	None	None	Negative

† Assumes transfer from the swabbed surface onto the swab of 5%-20%.

\* PSA = Porcine Serum Albumin protein; present in raw meats/fat at a level of ~0.1% by weight.

\*\* LOD = Assigned Limit Of Detection for Final QC purposes.

### Conclusion:

The Pig-FT Swab tests are capable of detecting 0.03 µg albumin on the swab, which equates to as little as 0.15µg/100cm<sup>2</sup> (0.15 mg of pork meat) on a surface.

## 2. Selectivity

The purified antibody used in this kit is highly specific for pork protein; other species (see the meats, animal sera and related foods in the tables below), if they react at all, do so at levels well below the 0.1% pork content response level:

Bison	Deer	Horse (serum)	Quail
Buffalo	Donkey (serum)	Kangaroo	Rabbit (serum)
Chicken	Duck	Mouse (serum)	Rat (serum)
Chicken egg white	Goat	Ostrich	Sheep
Chicken egg yolk	Goose	Partridge	Turkey
Cow	Horse	Pheasant	

### 3. Specificity

The following samples did not react when 1mg of solid material/liquid was applied directly to the fibrous swab bulb prior to testing:

Almond	Chocolate drink	Lupin	Potato	Soya Flour
Beef Gravy	Cod	Mustard	Prawn	Sugar
Beef Protein	Corn Flour	Oats	Quinoa	Sunflower Seed
Black pepper	Egg White	Paprika	Rice	Walnut
Brazil nut	Fish Gelatin	Pea protein	Salmon	Wheat Flour
Buckwheat	GF Cake Mix	Pine nut	Sesame	
Celery	Ginger powder	Pistachio	Skim milk powder	
Chicken Gravy	Gluten	Pork Gelatin	Soy sauce	

These samples returned strong positive test results when 2.5 x the LOD amount of PSA was also added to the fibrous swab bulb, prior to testing as per the Pig-FT Swab IFU.

During the Validation of Bio-Check's High Sensitivity Raw Pig assay, which uses exactly the same antibodies, over 80 different foods and food ingredients were found not to react with the same antibodies as used in this test – contact Bio-Check for details, if required.

### 4. Repeatability

Conditions	Number of Tests	Sample	Pig FT™ Results Correct
Different operators, different days	48 (over 13 months; one month past expiry date)	Zero	100%
		Limit of Detection	100%
		HIGH (830 x LOD)	100%

### 5. Robustness

The following changes to testing conditions were made and the effects on Negative, LOD and HIGH PSA levels were observed:

Procedural change	Results
Test units opened at 2-8°C for 4 hours	All compliant
Test units opened at room temperature for 4 hours	All compliant
Test units opened at 30°C for 4 hours	All compliant
Tests carried out at 2-8°C	All compliant
Tests carried out at 30°C	All compliant
Swabs kept for six days before testing	All compliant
Bulbs pumped three days before testing	All compliant
Test result read up to one hour after testing	All compliant

**Disinfectants:** 50µL of a variety of 0.5% cleaning agent solutions (Klenzan Oxysan S; Klenzan Stericlenz S; Holchem Terminol and Holchem Perbac) were added to the test system, followed by the Zero, LOD or the HIGH amount of PSA.

**Results:** There was little or no effect on the intensity of either the “T” or the “C” spots for all disinfectants.

**Flow times** of the test averaged 5 minutes 12 seconds and ranged from 4 minutes 35 seconds to 6 minutes 5 seconds.

## 6. Stability

Storage conditions	Assessment	Results
Refrigerated at 2-8°C (12 months)	Based on historical studies and stability trial data (tested to expiry date + one month)	Comply

## Warranty

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## Document changes

LA058: REV02 (Apr-2017): Correction to error in Section 2.

LA058: REV01 (Mar-2017): New product.

## Contact us

Please contact us for further assistance.