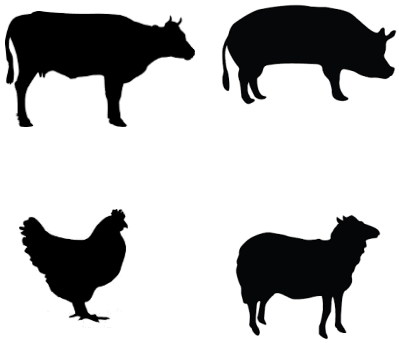
Raw Meat FlowThrough™ Swab Tests

SPECIATION

Validation Report



COW

REF **R6112** (5 Tests), **R6113** (100 tests)

PIG

REF **R6082** (5 Tests), **R6086** (100 tests)

POULTRY

REF **R6114** (5 Tests), **R6115** (100 tests)

SHEEP

REF **R6116** (5 Tests), **R6117** (100 tests)

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Bio-Check's Quality Management System is ISO 9001:2015 approved for the development and manufacture of test kits for the detection of contaminants and adulterants in food products.

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Guidance on the use of this document:

This Validation Report contains the findings of an in-house, single laboratory study of the described test kit method. The aim of the study was to establish certain characteristics of the method in order that objective evidence can be provided to users that performance requirements for the specified uses are being fulfilled. Within this defined scope and period of document validity (see the report's issue and expiry dates on the front cover), we consider that the method is validated and capable of generating meaningful results. It is important to remember that only valid test results can be used as a basis for interpretation, such that reliable information is available to facilitate effective decision making.

This report helps the user decide whether the methods are suitable for their intended use, or that specified by their customer, in accordance with best practice requirements. Please note that, for the most up to date information on performance, you should contact Bio-Check (UK) or its distributor.

For the purposes of this report, clauses from ISO 17025:2017 are used as an example of a laboratory standard widely used both for method accreditation and to describe best practice:

7.2.1.1 *The laboratory shall use appropriate methods and procedures for all laboratory activities …*

If this method is chosen users are required to demonstrate that the method can be competently and impartially performed; if used as such and as indicated in this validation study, it is fit for purpose within that scope

7.2.1.5 *The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance.*

It is usually accepted by an accreditation body that no further validation work is required if the laboratory uses this method exactly as described in its 'Instructions For Use' and within its intended scope (i.e. for analysing defined types of samples and/or categories of food). In such circumstances, only additional method verification is required for the laboratory's own examples of those sample types and food categories.

Conversely, if this method is to be used outside of its intended scope, then the laboratory must validate the method in a manner that is acceptable to the accreditation body, as well as performing method verification for each new sample type or food category.

7.2.2.1 *The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified.*

For clarity on the exact requirements of the standard chosen by your laboratory, please contact the appropriate accreditation body for method validation and verification guidelines. If your laboratory aspires to gain accreditation, please contact EA, ILAC or IAF to determine the appropriate accreditation body(ies) in your country and for your requirements. For method related enquiries, please contact us: info@biocheck.uk

Suggested References:

BS EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

BS EN 15633-1:2009 Foodstuffs. Detection of food allergens by immunological methods. General considerations. Current, under review (April 2018)

SUMMARY

Raw Meat FlowThrough™ Swab Tests

TEST KIT CHARACTERISTICS

PARAMETER	VALUE / DESCRIPTION
SCOPE	
Sample type	Surface swabs
SPECIFICITY	
Antibody	Polyclonal
Antibody specificity	Species-specific serum albumin protein.
REPORTING UNITS	Presence / Absence
LIMIT OF DETECTION (LOD)	0.1 µg albumin (swab) ≅ 0.5µg/100cm^2 (≅ 0.5 mg of meat)
SPECIFICITY	No reaction with defined unrelated species. Reactions with related species.
CROSS REACTION	No reaction with defined commodities.
REPEATABILITY	Compliant results.
ROBUSTNESS	Compliant results.
STABILITY	Up to 12 months at 2°C to 8°C (See test kit expiry date)

CONTENTS

1. Scope

Raw Meat FlowThrough™ Swab (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 status of finished products and in testing laboratories to assist in maintaining good laboratory practice.

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 Raw Meat-FT Swab tests have been validated by the user to ensure that they are fit for purpose.

2. Sensitivity

Tested	Serum Albumin SA (on swab)	Equivalent on 10 x 10cm surface†	Test Response
SA*	>20µg (HIGH)	100 - 500 µg	Positive
SA	<0.1µg (LOD**)	0.1 – 1.0 µg	Positive
No addition	None	None	Negative

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

* SA = 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:
Raw Meat-FT Swab tests can detect well below 0.1 µg albumin on the swab, which equates to as little as 0.5µg/100cm^2 (0.5 mg of meat) on a surface.

3. Selectivity

The purified antibodies used in this kit are highly specific for the specific species albumin protein; other species (see the meats, animal sera and related foods in the table below), if they react at all, do so at levels well below the lowest detectable response level:

Goat	Horse	Horse (serum)	Kangaroo
Donkey (serum)	Mouse (serum)	Rabbit (serum)	Rat (serum)

For each test there are also reactions, to a greater or lesser degree, with closely-related species as follows:

COW	PIG	POULTRY		SHEEP
Bison	Boar	Chicken	Chicken egg white	Deer (slight)
Buffalo		Chicken egg yolk	Duck	
		Goose	Ostrich	
		Partridge	Pheasant	
		Quail	Turkey	

4. Specificity

During the Validation of Bio-Check's High Sensitivity Raw Meat Species ELISAs, which use the same antibodies as the Raw Meat-FT Swab tests, 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:

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	

IMPORTANT NOTE: Only the above food commodities have been tested for potential cross reactivity; it should be assumed that commodities not on this list **may react** in the assay and they should be appropriately validated. Please bear in mind the need for testing only **100% authentic** commodities to determine possible cross reactivity.

5. Repeatability

Conditions	Number of Tests	Sample	Pig FT™ Results Correct
Different operators, different days	48 (over 12 months)	No Addition	100%
		Limit Of Detection	100%
		HIGH	100%

6. Robustness

The following changes to testing conditions were made and the effects on Negative, LOD and SA 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 Swab 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 average around 5 minutes and range from about 4 minutes 30 seconds to 6 minutes.

7. 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

Bio-Check (UK) Ltd ('Bio-Check') supplies products under its Terms and Conditions, as published on its website, which will have been brought to the attention of all customers prior to ordering and further notified in writing with the invoice for the goods. Bio-Check warrants products supplied ('Product' or 'Products') against defects in materials, workmanship or performance, when stored and used exactly in accordance with the applicable Instructions For Use, up to a Product's expiration date. If a customer establishes that Product does not conform to this limited warranty, Bio-Check shall, at its option, replace such of the Products with similar Products or allow the customer credit for the Product's invoice value but Bio-Check will have no further liability to the Customer. Bio-Check makes no other warranties expressed or implied including, but not limited to, any implied warranties or merchantability or fitness for any particular purpose. Bio-Check does not warrant against damages or defects arising in shipping or handling, or against accident in use of, or improper or abnormal use of, Product. Bio-Check shall not be liable for damages of any kind, including special or consequential damages, or expenses arising directly or indirectly from the use of Products or the interpretation by users of results obtained when using Products.

Document changes

LA058: REV 04 (Jan-2019):	Correction of Sheep and Poultry Test Kit REF Numbers
LA058: REV 03 (June 2018):	Additional species
LA058: REV02 (Apr-2017):	Correction to error in Section 2.
LA058: REV01 (Mar-2017):	New product.

Contact us

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