

Product Specifications

| January 2020



The Detectapen Range

The Detectapens are industry renowned as the highest quality choice of stationery for use in hygiene critical food processing environments. Every feature of the pen is designed with the food industry in mind, resulting in a truly unique set of properties designed to minimise contamination risks and improve food safety.

The Detectapen range is manufactured using our flagship XDETECT plastic compound - optimised for metal and x-ray detection in the food and pharmaceutical industries. Our Detectapen range also incorporates silver ion antibacterial technology, which is effective against E-Coli, MRSA & Salmonella. All materials used in the construction of our pens feature extensive food contact approvals including EU & FDA compliance.

Our iconic retractable Detectapen design features a spring free mechanism with no detachable parts, whilst our ECO style Detectapen has a hexagonal profile to stop the pen rolling from surfaces. All Detectapen designs feature minimal germs traps and are ergonomically designed, easy to hold and difficult to drop.

All Detectapens are available with or without a dual detectable clip. The clip is moulded in to the pen making it near impossible to snap off without the use of tools. All Detectapens feature high quality metal ink cartridges, further adding to detectability of the pen.

Detectapen Range Advantages

- ✓ Detectable by in-line metal detection systems & x-ray inspection systems
- ✓ Incorporates antibacterial technology to protect against pathogenic germs and moulds
- ✓ Available in up to 8 bold colours for easy visual identification (*Varies per model*)
- ✓ Strong, durable, shatter resistant & chemically resistant material
- ✓ Compliant with EU & FDA food contact legislation, including mandatory EU migration test standards
- ✓ Available in a variety of body styles and ink types to suit specific requirements
- ✓ Can be used as part of HACCP and BRC procedures
- ✓ Displays due diligence in the prevention of foreign body contamination

PRODUKTINFORMATIONEN

Product Description: The L550 is designed to offer the most luxurious writing experience a detectable pen can offer. The spring loaded 1mm fine-liner nib offers smooth and clear writing on non- glossy surfaces, best suited to production environments with an ambient temperature.

The ink cartridge is made from nickel-plated brass and is fully and permanently enclosed within the dual detectable XDETECT pen body. The L550 is also supplied with an XDETECT 2.0 dual detectable cap to prevent the ink from drying out. This cap attaches firmly to the top of the pen when not in use.

Housing Material:	XDETECT [Polypropylene Co-Polymer]		
Cartridge Material:	Nickel Plated Brass		
Order Code:	8900182-B, 8900186-B, 8900082-B, 8900086-B		
Pack Size:	10 Pack		
Pack Weight:	0.20 Kg		
Body Colours:	Blue		
Ink Colours:	Blue, Black		
Write Out Length:	The total write out length of the cartridge as per ISZ testing is 500m +/- 30%		
Ink Specifications:	✓ MITI Listed (Japan)	✓ ISO 12575 - 1 A M	✓ TSCA Listed (USA)
	✓ ISO 12575 - 2 DOC G2	✓ ISO 12575 - 2 DOC H	✓ ISO 12575 - 2 G2 M
	✓ ISO 12575 - 2 DOC A2		



Above: L550 Fineline Ink Cartridge

Food Contact Status (EU)

Hereby we declare that the material XDETECT in various colours is manufactured in line with the relevant requirements of 2023/2006/EC on good manufacturing practice (GMP) for materials and articles intended to come into contact with food.

The raw materials used in the manufacturing process of the above mentioned materials (XDETECT in various colours) can be considered suitable for food contact applications in terms of compliance with European regulations. The raw materials used meet the relevant requirements of EU Framework Regulation 1935/2004 on materials and articles intended to come into contact with food.

All monomers, starting substances and additives used to manufacture these grades are listed in Commission Regulation (EU) No. 10 (2011) on plastic materials and articles intended to come into contact with food. Applicable restrictions on monomers, additives etc. (SML, QM) are available on request. The finished articles are required to meet the Overall Migration Limit (OML) of 10 mg/dm(sq) or 60 mg/kg food.

Colourants used are compliant with European Council Resolution AP(89) 1 on the use of colourants in plastic materials coming into contact with food.

PRODUKTINFORMATIONEN

XDETECT (various colours) is compliant with Directive 1895/2005/EC on the restriction of use of certain epoxy derivatives (BADGE, BFDGE, NOGE), since the latter substances are not intentionally used in the manufacturing process of XDETECT.

The Detectable Products hereby declare that articles manufactured from XDETECT are, according to EU regulations, authorised to come into direct contact with all types of foodstuffs at a maximum temperature of 40°C for a maximum time period of one hour.

Migration Testing

The following overall migration results for XDETECT were obtained using a UKAS accredited laboratory, with overall migration simulants and conditions as detailed in EU Regulation No 10/2011 as amended, on plastic materials and articles intended to come into contact with food.

Sample: *PP-C-2013/393*

Test conditions: Simulants A, B and 95%v/v ethanol: 10 days at 40°C. Iso-octane: 2 days at 20°C

Method	EN-1186-3 Migration into 10% v/v Ethanol (Simulant A)	EN-1186-3 Migration into 3% w/v Acetic Acid (Simulant B)	EN-1186-14§ Migration into Iso- octane (Substitute test)	EN-1186-14§ Migration into 95% Ethanol (Substitute test)
Replicate #1	0.2 mg/dm ²	0.5 mg/dm ²	19.4 mg/dm ²	0.8 mg/dm ²
Replicate #2	0.3 mg/dm ²	0.5 mg/dm ²	21.0 mg/dm ²	0.9 mg/dm ²
Replicate #3	0.0 mg/dm ²	0.3 mg/dm ²	20.8 mg/dm ²	0.6 mg/dm ²
Mean Result	0.2 mg/dm²	0.4 mg/dm²	20.4 mg/dm²	0.8 mg/dm²
EU Limit	10.0 mg/dm²	10.0 mg/dm²	#20.0 mg/dm²	10.0 mg/dm²
Tolerance			#6.0 mg/dm²	

#Limit and tolerance are quoted after the application of a fatty food reduction factor of 2 as quoted in EU Regulation 10/2011

To summarise the overall migration test results, the PP-C-2013/393 complies with the overall migration requirements given in EU Regulation 10/2011, as amended, with regards to use with all non-fatty foods, aqueous foods and fatty foods that require a reduction factor of 2 (or greater), as given in EU regulation 10/2011, as amended.

Food Contact Status (FDA)

The polypropylene base resin used in XDETECT meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations – latest revision (1/4-2011) - in 21 CFR 177.1520 (a) (3) (i) , (b) and (c) (3.1a).

At the same time this base resin grade meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C through H in 21 CFR 176.170 (c), Table 2., and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1. Also the mineral additives and the pigments used are GRAS (Generally Recognized As Safe) or are FDA cleared under specific FDA citations.

PRODUKTINFORMATIONEN

Detectapen Antibacterial Technology

Detectapen products are manufactured from XDETECT with built in silver ion antimicrobial technology, supplied by our partners SteriTouch. This technology offers continuous protection against cross infection, reducing the risk of spreading pathogenic germs such as MRSA, E.Coli and Salmonella. The antibacterial surface protection harnesses the natural sterilising properties of silver; this protection is permanently embedded into the XDETECT compound and will not wear off over time.

These antibacterial properties have been laboratory tested and proven to be effective against harmful bacteria and mould including but not limited to:

Bacterium

Bacillus Cereus
Bacillus Subtilis
Campylobacter
Klebsiella Pneumonia
Pseudomonas Aeruginosa
Streptococcus Mutavs
Vibri Parahaemolyticus MRSA
E.Coli
 Salmonella

Fungus

Aspergillus Niger
Aureobasidium Pullulans
Candida Albicans
Cladosporium Cladosporioides
Fusarium Solani
Penicillium Funiculosum Streptococcus Pyogenes

The antibacterial additive used in XDETECT 2.0 complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes) and also with the relevant requirements of Regulation 10/2011/EC (PIM), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce the antibacterial additive are listed in the Union List of Authorized Substances of Regulation 10/2011/EC. Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture of or formulation of this product.

Antibacterial Laboratory Testing Method:

All testing is conducted by an independent laboratory using the JIS Z 2801:2000 test method. Where possible, all test materials are taken from samples of the actual product. Samples typically measure 50mm x 50mm as specified by the JIS Z 2801:2000 method, although where this is impractical it is permissible to use smaller samples with the method being modified accordingly.

Each test sample is inoculated with a suspension of the test organism (for example MRSA). The inoculum is held in contact with the test sample using a sterile polyethylene film. All test samples are inoculated in triplicate, with an additional three replicates of the control.

The bacterial population on three control replicates is evaluated immediately following inoculation. This is assumed to be the initial population on all test samples. The remaining samples are incubated for the test period (typically 24 hours) at 35°C, at which time the bacterial population is evaluated.

Antibacterial Laboratory Testing Results:

Salmonella Results Table

Sample Material	Bacterium	CFU at 0 Hours	CFU at 24 Hours	Comparison
Control	Salmonella. enteritidis	150000	140000	N/A
XDETECT	Salmonella. enteritidis	150000	<10	99.999% reduction

PRODUKTINFORMATIONEN

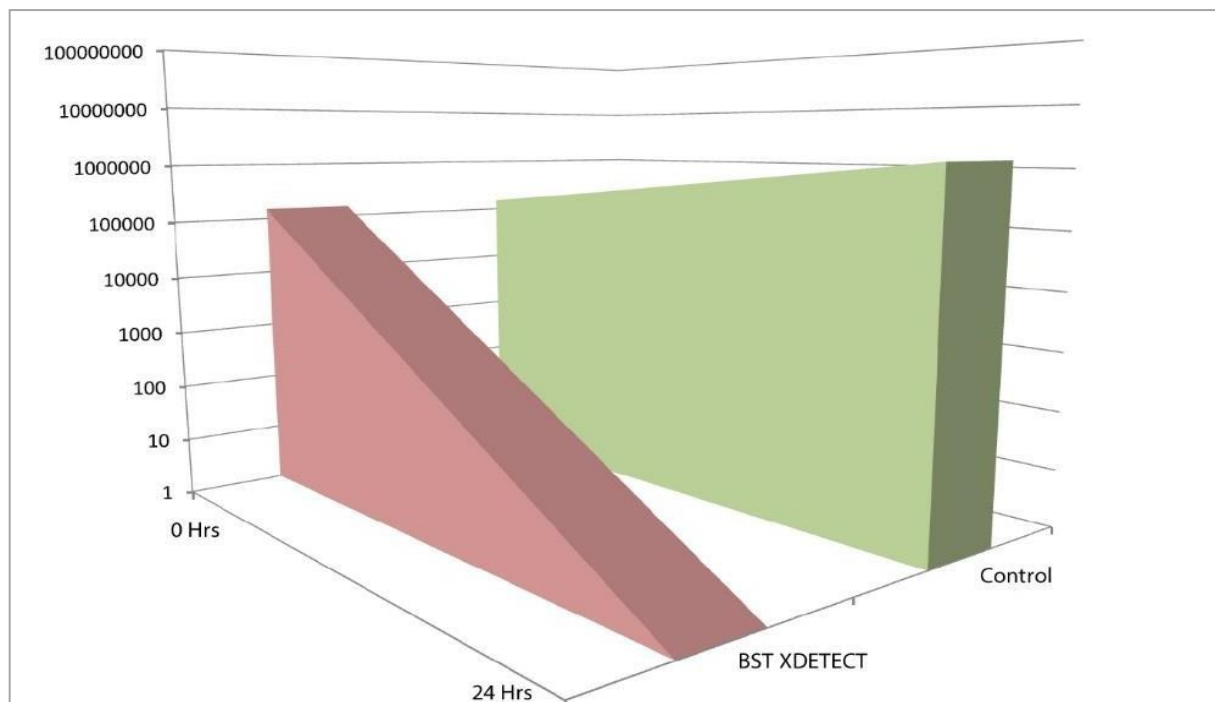
MRSA Results Table

Sample Material	Bacterium	CFU at 0 Hours	CFU at 24 Hours	Comparison
Control	MRSA	100000	470000	N/A
XDETECT A	MRSA	100000	<10	99.998% reduction
XDETECT B	MRSA	110000	<10	99.998% reduction
XDETECT C	MRSA	110000	<10	99.998% reduction

E. Coli Results Table

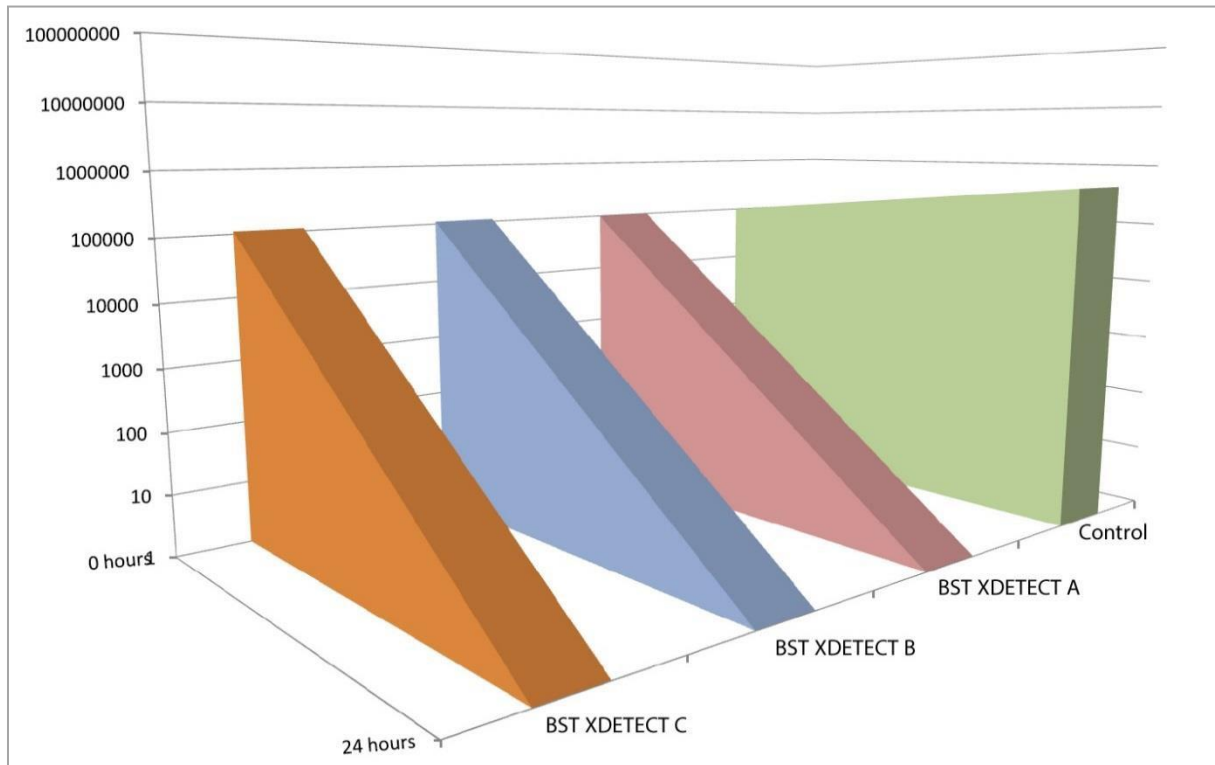
Sample Material	Bacterium	CFU at 0 Hours	CFU at 24 Hours	Comparison
Control	E. Coli	140000	11000000	N/A
XDETECT A	E. Coli	140000	<10	99.999% reduction
XDETECT B	E. Coli	140000	<10	99.999% reduction
XDETECT C	E. Coli	140000	<10	99.999% reduction

Salmonella Results Graph

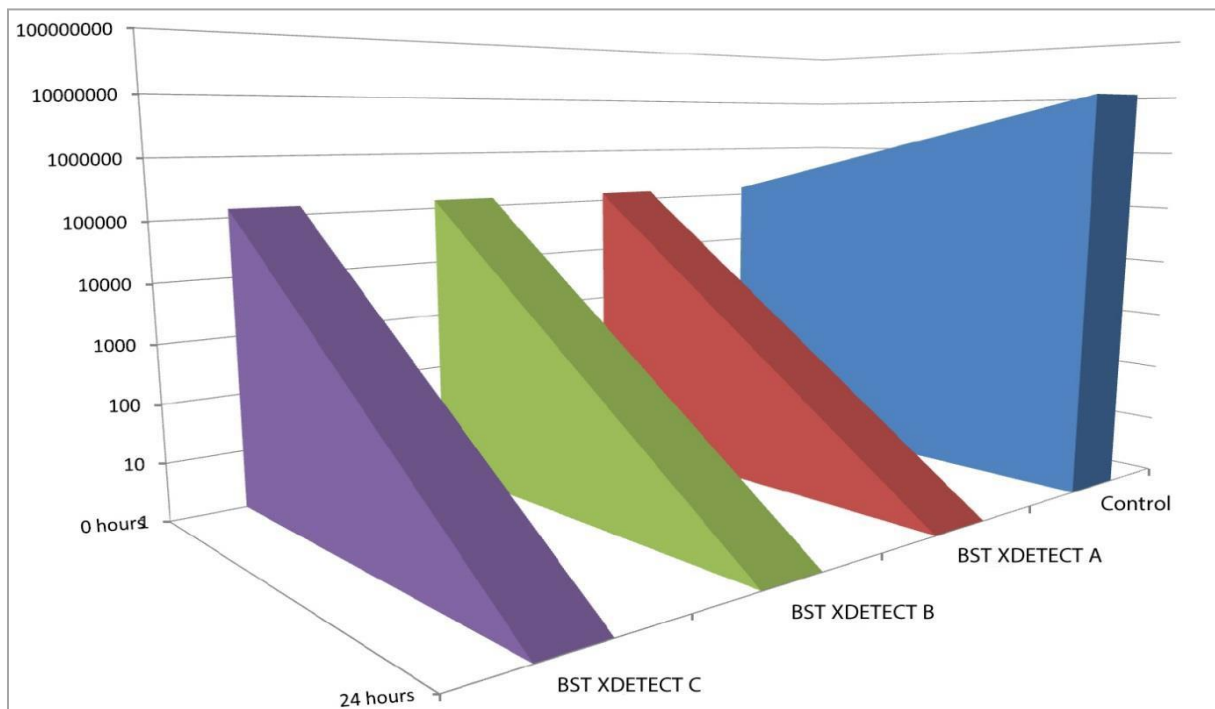


PRODUKTINFORMATIONEN

MRSA Results Graph



E. Coli Results Graph



PRODUKTINFORMATIONEN

Detectapen Metal Detectability

The Detectapens are made using XDETECT, an electromagnetically detectable and x-ray visible plastic compound. Within the pen housing is a stainless steel ink cartridge. The metal detectability of this product will vary based on, but not limited to:

- Calibration Levels
- Product Type (E.g. Wet, Dry, Frozen, Liquid)
- Aperture Dimensions
- Orientation

Orientation is a highly influential factor for the metal detectability of a contaminant that is non spherical, i.e. it will be easier to detect the contaminant when passing in one orientation compared to another - this is known as the orientation effect.

During testing of the Detectapen we used a worst case scenario which is through the geometric centre of the aperture and in the worst case orientation.

For ease of calibration, we have equated the full pen and pen parts to their ferrous ball test piece equivalents, which are widely used for metal detector testing and calibration. UKAS accredited test pieces are available to purchase from Niebling.

Component	Dimensions	Worst Case Orientation	Test Piece Recommended	Engineer Notes
Full Pen	146 (L) x 12 (Ø) mm	Short Edge Leading	5.00 mm	If the on-site detector is detecting 5.0mm ferrous or smaller, then it will detect the pen regardless of orientation.
Pen Housing	146 (L) x 12 (Ø) mm	Short Edge Leading	2.0 mm	If the on-site detector is detecting 2.0mm ferrous or smaller, then it will detect the pen housing regardless of orientation.
Pen Clip	17 x 6 x 2 mm	Short Edge Leading	1.0 mm	If the on-site detector is detecting 1.0mm ferrous or smaller, then it will detect the pen clip regardless of orientation.

Please note that the pen clip cannot be detached from the pen without extreme force or the use of tools. Generally speaking, the only circumstances where by such a small pen component could be introduced to food product would be through deliberate action or the pen going through an extreme process such as crushing, blending, mincing etc.

The above table is based on our own testing using one type of metal detector, and is supplied purely for customer convenience. Different metal detectors will feature different sensitivity settings, as well as settings for different product types (E.g. Wet, Dry, Frozen, Liquid).

For this reason Niebling recommend that all our products be thoroughly tested on your metal detection systems by a trained and certified professional. It may be the case that your equipment needs to be recalibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your metal detection system.

PRODUKTINFORMATIONEN

Detectapen X-Ray Visibility

In contrast to metal detection, x-ray visibility is determined by material density. For this reason, XDETECT contains an additional, evenly dispersed, food safe, high density additive.

Based on our experience and testing, positive readings should be consistent both for whole pens and XDETECT fragments as small as 5mm. X-ray detection performance will be reduced when small fragments are buried in deeper, denser products - detection will depend on product type and density.

Figure 1 shows an empty Detectapen body (top) and an empty ECO Detectapen body (bottom) through a popular x-ray inspection system, inside a packaged garlic bread product. Figure B shows a 5mm XDETECT fragment inside the same product and through the same system.

We highly recommend that all our products be thoroughly tested on your x-ray inspection systems by a trained and certified professional. It may be the case that your equipment needs to be recalibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your x-ray inspection system.

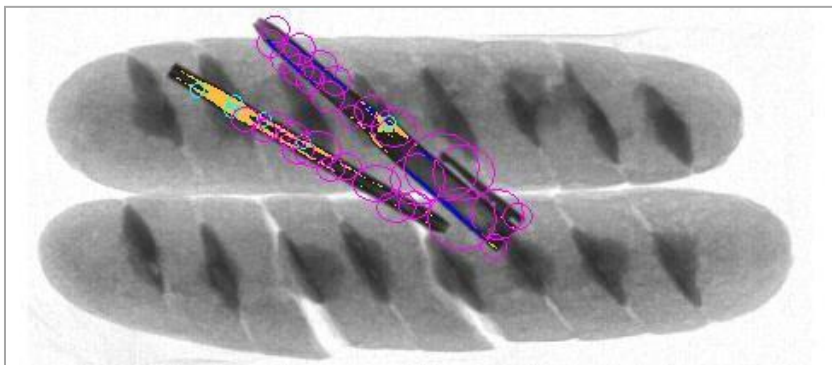


Figure 1

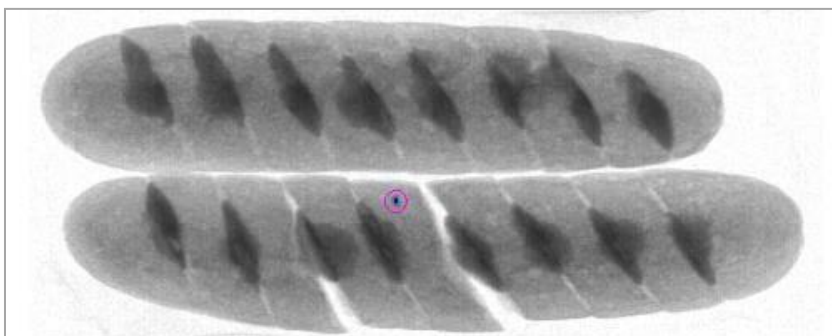


Figure 2

DISCLAIMER

The information provided in this product specification sheet is based on our experience and knowledge to date and we believe it to be true and reliable. This information is intended as a guide for your use of our products, the use of which is entirely at your own discretion and risk. We, Niebling Technische Bürsten GmbH, cannot guarantee favourable results and assume no liability in connection with the use of our products.