

Certificate of Conformity

VWR Catalogue Number	See List
Description	Transport Swab with medium
Country of Origin	Manufactured in Italy
Date of Issue (yyyy-mm-dd)	2022-04-19

Catalogue Number	Type	Cap Colour	Shaft/head	Transport medium
710-0441	Swabs for throat, vaginal, wound and skin use	White	Plastic/viscose	Stuart liquid
710-0438	Swabs for throat, vaginal, wound and skin use	White	Plastic/viscose	Amies liquid
710-0432	Swabs for throat, vaginal, wound and skin use	Blue	Plastic/viscose	Amies gel
710-0434	Swabs for throat, wound and urogenital use	Black	Plastic/viscose	Amies gel with charcoal
710-0439	Swabs with mini tip for male urethral use	Orange	Aluminium/viscose	Amies liquid
710-0440	Swabs for nasopharyngeal use	Blue	Twisted aluminium/viscose	Amies liquid
710-0433	Swabs with mini tip for male urethral use	Orange	Aluminium/viscose	Amies gel
710-0436	Swabs with mini tip for nasopharyngeal use	Blue	Twisted aluminium/viscose	Amies gel
710-0435	Swabs for male urethral use	Orange	Aluminium/viscose	Amies gel with charcoal
710-0437	Swabs for nasopharyngeal use	Blue	Twisted aluminium/viscose	Amies gel with charcoal

Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & ISO 13485:2016** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirement

Product Specifications

Medium Visual Appearance and Mechanical Controls: **passed according to internal SOP.**

pH of the medium at 25 °C acceptability limits 7.2 ± 0.3 : **passed**

Microscopic Bioburden Specifications, maximum 2 micro-organisms per 20 microscopic fields at 10X100 magnification: **passed.**

Cultural Response: swabs were inoculated with the tester organisms (see the table) and placed in the medium. Recovery obtained after 24 hours at 20-25°C: **passed.**

TRANSYSTEM AMIES AND STUART CLEAR GEL AND WITH CHARCOAL	TRANSYSTEM AMIES AND STUART LIQUID	TRANSYSTEM CARY BLAIR
Neisseria gonorrhoeae ATCC 43069	Neisseria gonorrhoeae ATCC 43069	Campylobacter jejuni ATCC 33291
Bacteroides fragilis ATCC 25285	Streptococcus pyogenes ATCC 19615	Escherichia coli ATCC 25922
Haemophilus influenzae ATCC 10211	Haemophilus influenzae ATCC 10211	Shigella flexneri ATCC 12022
/	/	Yersinia enterocolitica ATCC 9610

Material

Caps: High Density Polyethylene (HDPE).
Tube: Polypropylene (PP).
Sponge: Polyurethane foam (PU).
Plastic applicator: Polystyrene (PS).
Swab tip: Rayon.

Sterilization

Products are gamma irradiated. Sterilisation procedure is validated in conformity with BS EN ISO 11137-1:2015 and BS EN ISO 11137-2:2015 to guarantee SAL 10^{-6} .

ATP Assay

Not applicable.

DNase & RNase Free

Not applicable.

BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).
Cytotoxicity	The product is free of Cytotoxicity effects.
Non-Pyrogenic Statement	Not applicable.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Not applicable.
RoHS	Not applicable.
REACH Statement	No substances as listed on >Substance of Very High Concern< candidate list published 2022-01-17 are used in manufacturing of the raw materials used to produce this product. No routinely analysis is performed.
Storage Conditions	5 – 25 °C.
Shelf Life	20 Months, whereas 15 Months for 710-0441.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
This document has been produced electronically and is valid without a signature