

CERTIFICATE OF ANALYSIS AND QUALITY

Product:	ChromoStreak: UriSelect3/ MacConkey	Catalogue No.:	BD- 915
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Batch No.:	2058	UriSelect3 Batch No.:	6A0136	Exp.:	01.2019
Manufacturing Date:	28.JUL.2016				
Expiry Date:	28.JAN.2016	MacConkey Batch No.:	5307523	Exp.:	06.2020

1. APPEARANCE:

Number of units examined	50	Batch size:	4947
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Physical damage (bubbles, particles, leakage, discolor, dried agar)	No. of defective units
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2. pH MEASUREMENT:

Agar	Measured	Specification
UriSelect3	7.21	7.3±0.2
MacConkey	7.18	7.1±0.2

3. KIT PERFORMANCE*:

Inoculum (CFU/ml)	No. of colonies	
	UriSELECT 3	MacConkey
10 ³	3	2
10 ⁴	14	12
10 ⁵	>50	>50

* Number of *E.coli* colonies at different concentrations.


4. CULTURAL RESPONSE:**

Organism	UriSELECT 3		MacConkey
	Growth	Colour	
<i>E.coli</i> ATCC 25922	luxuriant	purple	Growth
<i>P.mirabilis</i> ATCC 12453	luxuriant	brown	Growth
<i>E.faecalis</i> ATCC 29212	luxuriant	bright, frank blue	Partial or complete inhibition
<i>S.aureus</i> ATCC 25923	luxuriant	white	Inhibition

** Cultural characteristics observed after an incubation of 24 h at 35 ± 2°C.

5. STERILITY TESTING:

A statistical sample of product was monitored for sterility at 35 ± 2°C for at least 5 days and was found to be compliant with the sterility specification for the product.

Performed by:	M.Botvinnik	Date:	22.08.16	Signed:	
Approved by:	L. Chernovsky	Date:	22.08.16	Signed:	