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# CERTIFICATE OF ANALYSIS AND QUALITY

Product:	Chr	omoStreak: UriSe	Catalogue No.:		BD-915	
Batch No.:		2134	UriSelect3 Batch No.:	5G0135	Exp.:	10.2018
Manufacturi	ng Date:	07.NOV.2016				
Expiry Date:	:	07.MAY.2017	MacConkey Batch No.:	6147880	Exp.:	04.2021
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### 1. APPEARANCE:

Number of units examined	50	Batch size	e: 5400
Dhuging Ldomes of (high high martialise 1	No. of defective units		

Physical damage (bubbles, particles, leakage, discolor, dried agar)

#### 2. pH MEASUREMENT:

Agar	Measured	Specification
UriSelect3	7.22	7.3±0.2
MacConkey	7.1	7.1±0.2

#### **3. KIT PERFORMANCE \*:**

	No. of colonies			
Inoculum (CFU/ml)	UriSELECT 3	MacConkey		
10 <sup>3</sup>	4	3		
104	16	12		
105	>50	>50		

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

#### 4. CULTURAL RESPONSE \*\*:

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

\*\* Cultural characteristics observed after an incubation of 24 h at  $35 \pm 2^{\circ}$ C.

## 5. STERILITY TESTING:

# A statistical sample of product was monitored for sterility at $35 \pm 2^{\circ}$ C for at least 5 days and was found to be compliant with the sterility specification for the product.

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Performed by:	M.Botvinnik	Date:	27.11.16	Signed:	That
Approved by:	L. Chernovsky	Date:	27.11.16	Signed:	lefus.