

### CERTIFICATE OF ANALYSIS AND QUALITY

|                 |                                     |                       |         |
|-----------------|-------------------------------------|-----------------------|---------|
| <b>Product:</b> | ChromoStreak: UriSelect3/ MacConkey | <b>Catalogue No.:</b> | BD- 915 |
|-----------------|-------------------------------------|-----------------------|---------|

|                            |             |                              |         |              |         |
|----------------------------|-------------|------------------------------|---------|--------------|---------|
| <b>Batch No.:</b>          | 1947        | <b>UriSelect3 Batch No.:</b> | 5J0135  | <b>Exp.:</b> | 10.2018 |
| <b>Manufacturing Date:</b> | 10.MAR.2016 |                              |         |              |         |
| <b>Expiry Date:</b>        | 10.SEP.2016 | <b>MacConkey Batch No.:</b>  | 5084716 | <b>Exp.:</b> | 01.2020 |

#### 1. APPEARANCE:

|                                 |    |                    |      |
|---------------------------------|----|--------------------|------|
| <b>Number of units examined</b> | 50 | <b>Batch size:</b> | 4980 |
|---------------------------------|----|--------------------|------|

|  |                               |
|--|-------------------------------|
| <b>Physical damage</b> (bubbles, particles, leakage, discolor, dried agar) | <b>No. of defective units</b> |
|  | -                             |

#### 2. pH MEASUREMENT:

| Agar       | Measured | Specification |
|------------|----------|---------------|
| UriSelect3 | 7.21     | 7.3±0.2       |
| MacConkey  | 7.14     | 7.1±0.2       |

#### 3. KIT PERFORMANCE\*:

| Inoculum (CFU/ml) | No. of colonies |           |
|-------------------|-----------------|-----------|
|                   | UriSELECT 3     | MacConkey |
| 10 <sup>3</sup>   | 3               | 3         |
| 10 <sup>4</sup>   | 15              | 14        |
| 10 <sup>5</sup>   | >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      | <i>luxuriant</i> | <i>purple</i>             | <i>Growth</i>                         |
| <i>P.mirabilis</i> ATCC 12453 | <i>luxuriant</i> | <i>brown</i>              | <i>Growth</i>                         |
| <i>E.faecalis</i> ATCC 29212  | <i>luxuriant</i> | <i>bright, frank blue</i> | <i>Partial or complete inhibition</i> |
| <i>S.aureus</i> ATCC 25923    | <i>luxuriant</i> | <i>white</i>              | <i>Inhibition</i>                     |

\*\* 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: | 30.03.16 | Signed: |  |
| Approved by:  | L. Chernovsky | Date: | 30.03.16 | Signed: |  |