FERA Diagnostics and Biologicals

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY DIAGNOSTIC PRODUCT

AccuMast® Diagnostics plates (dairy cows).

United States, Canada, China, Vietnam, Italy, Spain, Germany, Holland, United Kingdom, New Zealand, Australia, Brazil, Mexico.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The **AccuMast®** Diagnostics plate is a three-chambered plate containing three selective chromogenic agars. This unique agar combination provides a comprehensive scheme for identifying the various infectious agents.

Color:
Media 1: Tan to beige
Media 2: White/cream to light grey
Media 3: Tan/beige to gold

Appearance:
Media 1: Clear
Media 2: Opaque
Media 3: Clear to hazy with precipitate

This is to certify that the medium passed the following criteria:
pH:
Media 1: 7.0 ± 0.2 @ 25°C
Media 2: 7.3 ± 0.2 @ 25°C
Media 3: 7.3 ± 0.2 @ 25°C

Fill or Weight: 6-7 mL per section

For a full list of excipients, see section 5.1.

Sterility Check:
Final pH:
Media 1: 7.2
Media 2: 7.5
Media 3: 7.4
Sterility samples demonstrated greater than 95% sterility after 72 hours incubation at 30-35°C & 20-25°C.

Growth Performance:

Media I
ATCC# 25922 *Escherichia coli:* Growth of mauve colonies
ATCC# 25923 *Staphylococcus aureus*: Inhibited growth of white colonies

Media II
ATCC# 12386 *Streptococcus agalactiae*: Growth of blue colonies
ATCC# 29212 *Enterococcus faecalis:* Growth of purple colonies
ATCC# 25922 *Escherichia coli:* Inhibited

Media III
ATCC# 25923 *Staphylococcus aureus*: Growth of mauve colonies
ATCC# 25922 *Escherichia coli:* Inhibited

3. PHARMACEUTICAL FORM

Nutrient plate appearance: media tan to beige, or white, opaque with no precipitate, chips or debris. Consistency is firm, not soft.

4. PHARMACOLOGICAL/CHEMICAL PROPERTIES

Schedule B (or USHTS) Number: 3821.00.0000 – Miscellaneous chemical products

4.1 Chemical properties

The **AccuMast®** Diagnostics plate contains nutrients, such as peptones, amino acids, yeast extract, minerals, vitamins and agar solidifiers. Unlike traditional media, they contain chromogenic substrates or chromogens.

5. CHEMICAL PARTICULARS

5.1 List of excipients

Media 1 selective media for the isolation of Gram-negative pathogens: Composition in g/L - Agar 15.0; Peptone and yeast extract 17.0; color mix; pH 7.0 +/- 0.2.
Color (Media 1): Tan to beige

Media 2 selective media for the isolation of Streptococcus ssp.: Composition in g/L – Agar 15.0; Peptones & growth factors 22.0; Salts 7.5; Color mix; Total 46.9 g/L; pH 7.3 +/- 0.2.
Color (Media 2): White/Cream to light gray

Media 3 selective media for the isolation of Staphylococcus ssp.: Composition in g/L - Agar 15.0; Peptone and yeast extract 40.0; Salts 30.0; color mix; pH: 7.3 +/- 0.2
Color (Media 3): Tan/beige to gold

5.2 Incompatibilities

None known.

5.3 Shelf life

Each **AccuMast®** Diagnostics plate is manufactured under strict GMP conditions and packaged using proprietary technology that allows for the longest shelf life (6 months) for products in its class.

5.4. Special precautions for storage

Short-term storage and transportation: ambient temperature
Long-term storage: Plates should be stored at 2 - 8°C (36 – 46°F), inverted and protected from light.
Freeze protection is a must.

5.5 Nature and composition of immediate packaging

At this time, all **AccuMast®** Diagnostics plates are produced and packed at a commercial bacterial culture media laboratory located in the Northeast United States; inspected by the Food and Drug Administration for compliance with the current Good Manufacturing Practices regulations for Medical Devices and Diagnostic Products, CFR 21, Part 820.

Plates are made to order and packed inside a customized Foil ZipSealed, 4.5mils thick, Mylar® bags, with 100cc oxygen absorbers and sterile desiccant paper.

Marketing presentations: Each bag contains 4 **AccuMast®** Diagnostics plates.

5.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

This product is for in-vitro diagnostic only. Specimens for culture may contain microorganisms that may be infectious to humans. Strict adherence to aseptic techniques and established precautions against biohazards should be followed throughout the procedure. Properly dispose of all inoculated plates and any implements that come into contact with animal specimens.

6. CLINICAL PARTICULARS

6.1 Target species

Cattle (dairy cows).

6.2 Indications for use, specifying the target species

Use for bacteriological culture of milk samples. Identification and isolation of bacterial causes of clinical and subclinical mastitis in dairy cows.

6.3 Contraindications

The **AccuMast®** Diagnostics plates are for veterinary use only.

4.4 Special warnings

None

4.5 Special precautions for use

(i) Special precautions for use in animal
None

(ii) Special precautions to be taken by the person performing and manipulating the diagnostic kit

Wash hands after use. Properly dispose of all inoculated plates and any implements that come into contact with animal specimens.

(iii) Special precautions to be taken by the person performing the plating procedure and interpreting the diagnostic kit

At 16-24 hours post inoculation, inspect each section of the plate for bacterial growth and note the color and morphology of the resulting

colonies in each of the three sections of the plate. For accurate results, plates should be read no later than 24 hours post inoculation. Prolonged incubation can alter the characteristic color reactions and may reduce the inhibitory properties of selective media.

The **AccuMast®** Diagnostics plates have been formulated to produce uniquely pigmented colonies when inoculated with those organisms for which the product has been validated.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The **AccuMast®** Diagnostics plates are recommended for culturing milk samples from clinical and subclinical mastitis cases, before the drying-off process and bulk tank cultures.

4.8 Interaction with other medicinal products and other forms of interaction

Initiation of antimicrobial therapy prior to inoculation may affect organism growth and colony color.

4.9 Amounts to be administered and administration route

Culture milk samples only.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal periods

Not applicable

7. MARKETING AUTHORISATION HOLDER

FERA Diagnostics and Biologicals, Corp.
950 Danby road, suite 206
Ithaca, NY
14850

8. MARKETING AUTHORISATION NUMBER

Centre for Technology Licensing (CTL) contract number: C2016-12-10768

9. DATE OF FIRST AUTHORISATION OF THE AUTHORISATION

16 May 2019

10 DATE OF REVISION OF THE TEXT

May 2019

Approved: 08/07/2019