INSTRUCTIONS FOR USE

ESCULIN REAGENT – 1% FERRIC AMMONIUM CITRATE

PRODUCTS

AS-713 Esculin Reagent – 1% Ferric Ammonium Citrate 1 bottle / pkg

INTENDED PURPOSE

Spot biochemical reagents are intended for in vitro diagnostic use by trained laboratory personnel for the identification and differentiation of microorganisms based on specific biochemical characteristic, such as enzymatic activity or metabolic reactions.

INTENDED USERS

Scientists, laboratory, and healthcare professionals trained in anaerobic microbiology techniques working in areas such as clinical, research, industrial, pharmaceutical and veterinary applications.

FORMULATION*

Esculin reagent is used in the Esculin Hydrolysis Test to detect the ability of anaerobic bacteria to hydrolyze esculin. The test determines whether an organism can break down esculin into glucose and esculetin. Esculetin then reacts with ferric ammonium citrate to form a black or dark brown complex, indicating a positive result.

Ferric ammonium citrate	10.00	g
DI Water	1.00	L

*Approximate formula. Adjusted and/or supplemented as required to meet performance criteria.

Final volume: 30.0 mL ± 3.0 mL

PRECAUTIONS

For *IN VITRO DIAGNOSTIC USE* only. Utilize approved biohazard precautions and aseptic technique when using this product. This product is for use by properly trained and qualified personnel only. Sterilize all biohazard waste prior to disposal.

Report serious incidents that occur in direct relation to this product to tech@biolog.com. As necessary, report serious incidents to the regulatory authority in which the user is established.

When working with anaerobic culture media, the potential for ergonomic hazards may exist due to repetitive motions, awkward postures, improper bench/chair heights or poor lighting. Although it is beyond the scope and provision of products by Anaerobe Systems, it should be recognized and mitigated by the end user in the laboratory environment.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store refrigerated at 2 – 8°C until used. Avoid overheating or freezing. Avoid any unnecessary exposure to light. The expiration date applies to the product in its original packaging and stored as directed. Do not use product past the expiration date shown on the label.

Shelf Life: 1 year from the date of manufacture.

PROCEDURE

Specimen Collection: Protect specimens for anaerobic culture from oxygen during collection, transportation, and processing. Consult appropriate references for detailed instructions concerning collection and transportation of anaerobes. The selection of specimens for culture is made by physicians or scientists collecting the sample.

Esculin Test: Inoculate a tube of Peptone Yeast Extract Broth with Esculin (PY ESCULIN, catalog # AS-833) and incubate at 37°C for 48 hours. After incubation, add five drops of Esculin Reagent to the tube and observe for a color change. The development of a black or dark brown complex indicates a possible positive reaction, which should then be confirmed by checking fluorescence under UV light (366 nm). Intact esculin fluoresces blue-white under UV light, whereas hydrolyzed esculin does not fluoresce.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, saline blanks, slides, staining supplies, microscope, incinerator / autoclave, incubators, anaerobic chamber / anaerobic jars, disinfectant, other culture media, and serological / biochemical reagents.

INTERPRETATION OF RESULTS

Positive reaction: Black or dark brown color development and no fluorescence under UV light (366 nm).

Negative reaction: No color development or positive fluorescence under UV light.

LIMITATIONS

Hydrogen sulfide (H_2S), produced by several organisms during metabolism, can react with iron to form a black complex that may interfere with test interpretation. Therefore, all tubes exhibiting a dark color change must be examined under UV light to confirm a positive reaction.

QUALITY CONTROL

The following organisms are routinely used for quality control testing at Anaerobe Systems.

Organism Tested	ATCC® #	Expected Results
Bacteroides fragilis	25285	Positive
Peptostreptococcus anaerobius	27337	Negative
Fusobacterium necrophorum	25286	Negative

User Quality Control: The final determination to the extent and quantity of user laboratory quality control must be determined by the end user.

To evaluate the reactivity and performance of this reagent, it is recommended to test the following ATCC® strains grown in Peptone Yeast Extract Broth with Esculin (PY ESCULIN; catalog # AS-833).

Organism	ATCC® #	Expected Results
Bacteroides fragilis	25285	Positive
Fusobacterium necrophorum	25286	Negative

Physical Appearance: Esculin Reagent should appear as a transparent amber liquid within an opaque plastic bottle.

ATCC® is a registered trademark of American Type Culture Collection.

REFERENCES

1. MacFaddin JF. *Biochemical Tests for Identification of Medical Bacteria*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2000.

2. Leber AL, Burnham CA, eds. *Clinical Microbiology Procedures Handbook*. 5th ed. 4 vols. Washington, DC: ASM Press; 2023.

3. Carroll KC, Pfaller MA, eds. *Manual of Clinical Microbiology*. 13th ed. 4 vols. Hoboken, NJ: Wiley-Blackwell; 2023.

4. Jousimies-Somer HR, Sutter VL, eds. *Wadsworth-KTL Anaerobic Bacteriology Manual*. 6th ed. Belmont, CA: Star Publishing Company; 2002.

GLOSSARY OF SYMBOLS

SYMBOL	TITLE	DESCRIPTION	STANDARD	REF#
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1
LOT	Lot number/ Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.4
XX REP	Authorized Representative	Indicates the Authorized Representative in the identified country or jurisdiction.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.2
	Do not re-use/ Single use only	Indicates a medical device that is intended for one single use only.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.2
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.3
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7
IVD	In vitro diagnostic medical device	Indicates that a medical device is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.5.1
CE	CE Mark European Conformity	Designates that the product labeled Is authorized for sale in European countries.	EU IVDR (EU) 2017/746	

AUTHORIZED REPRESENTATIVE INFORMATION

EC REP
Casus Europe B.V.
Lange Viestraat 2b
3511 BK Utrecht
The Netherlands

CH REP
Casus Switzerland GmbH
Hinterbergstrasse 49
6312 Steinhausen
Switzerland

REVISION 1
Additions: Intended Use, Intended Users, Ergonomics Precautions, Serious Incident Report Contact Information, Glossary of Symbols
Changes: Title change from Product Insert to Instructions for Use. References updated. Contact information.
Deletions: None