Polychrome Methylene Blue & Fixative

(for *In Vitro* Diagnostic use only)

PRODUCT CODE: PL.7061, PL.7061/5, PL.7066, PL.7066/5

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INTENDED USE

For use in detecting capsulated *Bacillus anthracis* in clinical specimens.

SUMMARY AND EXPLANATION

The Polychrome Methylene Blue staining procedure for blood or tissue smears taken from dead animals (M'Fadyean's reaction) was established in 1930, and remains accepted as a highly reliable, rapid diagnostic test for anthrax. *Bacillus anthracis* is a Hazard Group 3 organism. If suspected clinically, refer specimens directly to the appropriate Reference Laboratory without doing any further work/manipulations. All laboratory procedures such as staining should be performed by experienced scientists in a Containment Level 3 facility using a Class 1 protective safety cabinet.

PRINCIPLE OF THE TEST

Polychromatic Methylene Blue is a 'ripened' methylene blue solution, which is still recognised as the most simple and reliable method for the identification of capsulated *B. anthracis*. When Methylene Blue solution is left to stand, oxidation takes place which produces homologs such as Azure. These homologs stain the capsule surrounding *B. anthracis*, allowing its visualisation in blood/tissue smears.

MATERIALS PROVIDED

-	PL.7061	Polychrome Methylene Blue	250 ml
-	PL.7061/5	Polychrome Methylene Blue	500ml
-	PL.7066	Polychrome Methylene Blue Fixative	250ml
-	PL.7066/5	Polychrome Methylene Blue Fixative	500ml

Per 100ml solution:

- Polychrome Methylene Blue contains 0.37g of Methylene Blue powder.

MATERIALS REQUIRED BUT NOT PROVIDED

- Glass slides
- Inoculating loop
- Immersion oil PL.396
- Microscope

STABILITY AND STORAGE

Polychrome Methylene Blue and Polychrome Methylene Blue Fixative should be stored at 15-25ºC in their original containers. Product stored under these conditions will be stable until the expiry date shown on the product label.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Do not use beyond the stated expiration dates.
- Microbial contamination may decrease the accuracy of the staining.
- Safety precautions should be taken in handling, processing and discarding all clinical specimens.
- Samples should be processed in the correct containment level conditions.
- Dispose of all material in accordance with local regulations.

TEST PROCEDURE

1. Prepare a smear on a clean glass slide and allow to air dry.
2. Cover smear with Polychrome Methylene Blue Fixative for 3 minutes and allow to air dry.
3. Flood the slide with Polychrome Methylene Blue for 30-45 seconds.
4. Wash the slide gently with water or as a safety precaution, wash the slide using a 10% hypochlorite solution.
5. Examine using a microscope.

QUALITY CONTROL PROCEDURE

Internal quality control of the Polychrome Methylene Blue and Polychrome Methylene Blue Fixative must be performed regularly on known reference material.

Recommended Quality Control:
Positive – a proven positive
Negative – a proven negative

INTERPRETATION OF RESULTS

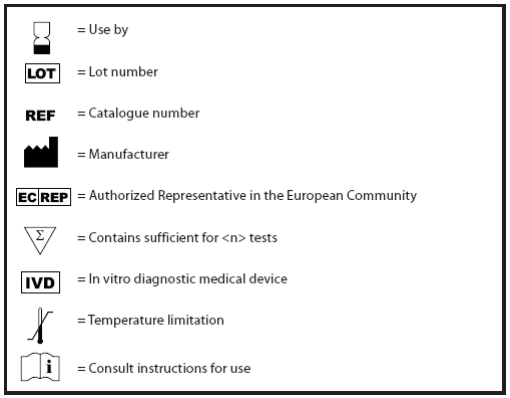
Virulent *B.anthracis* rods will be surrounded by a clearly demarcated zone giving the appearance of a reddish pink capsule.
If *B.anthracis* is suspected, all washings, blotting materials, and slides must be properly autoclaved.

LIMITATIONS OF THE PROCEDURE

- Only experienced personnel should carry out the interpretation of stained slides.
- Read prepared slides as soon as possible after staining. Failure to do so may affect the results.
- Many species of bacilli may also be encapsulated. Any positives must be confirmed at a Reference Laboratory.

REFERENCES

- Balzevic, D.J. and Edrer, G.M. (1975). Principles of Biochemical Tests in Diagnostic Microbiology. *John Wiley & sons*, New York, NY.
- Koch, R. (1876) [Investigations into bacteria: V. The etiology of anthrax, based on the ontogenesis of Bacillus anthracis], *Cohns*.
- Lowrance, B.L., Reich, P. and Traub, W.H. (1969). *Journal of Applied Microbiology* 17:923-924.
- M'Fadyean, J. (1903a). A peculiar staining reaction of the blood of animal's dead of anthrax. *Journal of Comparative Pathology*. 16:35-41.
- Sutter, V.L. and Carter, W.T. (1972). *American Journal of Clinical Pathology* 58:335-338



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HAZARDS IDENTIFICATION

Please refer to Safety Data sheets for full text for all hazard and precautionary statements.

 WARNING	**PL.7061 PL.7061/5**	**H226, H319** **P210, P280, P305+P351+P338, P337+P313, P403+P235, P501**
 DANGER	**PL.7066 PL.7066/5**	**H225, H319, H332, H371** **P210, P280, P303+P361+P353, P304+P340, P305+P351+P338, P312, P501**

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