

**INTENDED USE**

For use in staining smears prepared from clinical specimens suspected of containing Mycobacteria.

**SUMMARY AND EXPLANATION**

The Kinyoun carbol fuchsin stain is a variation of the acid-fast method developed by Robert Koch in 1882. Mycobacteria possess unique acid fast characteristics that make the acid-fast staining techniques invaluable in detecting Mycobacteria species.

**PRINCIPLE OF THE TEST**

The lipid content of the cell wall of acid-fast bacilli makes staining of the organisms difficult. If an organism is to be termed 'acid-fast' it must resist decolourisation by acid-alcohol. A counterstain is then used to emphasise the stained organism.

**MATERIALS PROVIDED**
**Ready to use Stains and Differentiators:**

PL.7021/25	Kinyoun Carbol Fuchsin	250 ml
PL.7021	Kinyoun Carbol Fuchsin	500 ml
PL.7022	Kinyoun Carbol Fuchsin	1000 ml
PL.7024/100	Diff for ZN & Kinyoun CF	100 ml
PL.7024/25	Diff for ZN & Kinyoun CF	250 ml
PL.7024	Diff for ZN & Kinyoun CF	500 ml
PL.7025	Diff for ZN & Kinyoun CF	1000 ml
PL.7026	Diff for ZN & Kinyoun CF	2000 ml
PL.7027/100	Methylene Blue	100 ml
PL.7027/25	Methylene Blue	250 ml
PL.7027	Methylene Blue	500 ml
PL.7028	Methylene Blue	1000 ml
PL.7029	Methylene Blue	2000 ml
PL.7030/100	Malachite Green	100 ml
PL.7030/25	Malachite Green	250 ml
PL.7030	Malachite Green	500 ml
PL.7031	Malachite Green	1000 ml
PL.7032	Malachite Green	2000 ml

**Concentrated Stains (dilute 1 part in 10 with deionized or reverse osmosed water before use):**

PL.8006	Methylene Blue	100 ml
PL.8006/4.0	Methylene Blue	400 ml
PL.8006/5.0	Methylene Blue	500 ml
PL.8007	Malachite Green	100 ml
PL.8007/4.0	Malachite Green	400 ml
PL.8007/5.0	Malachite Green	500 ml

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Glass slides
- Inoculating loops
- Microscope
- Immersion oil PL.396
- AFB QC Slides PL. 4960

**STABILITY AND STORAGE**

Acid-fast stains for Mycobacteria should be stored at 15-25°C 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.

**PROCEDURE**

1. Prepare a smear on a clean glass slide and allow to air dry.
2. Heat fix and allow to cool.
3. Flood the slide with Kinyoun carbol fuchsin, stand for 10 minutes.
4. Rinse with water.
5. Flood the slide with differentiator for ZN & Kinyoun CF for 10 minutes, applying a change of differentiator at 5 minutes.
6. Rinse with water.
7. Flood the slide with counterstain (methylene blue or malachite green), stand for 1 minute.
8. Rinse well with water, gently blot dry or dry using gentle heat.
9. Examine using a microscope.

**QUALITY CONTROL**

Internal quality control of the Kinyoun carbol fuchsin stains must be performed regularly on known reference material.

Recommended quality control:

Positive control – A proven positive

Negative control - A proven negative

CE marked QC slides – PL.4960

**INTERPRETATION OF RESULTS**










Acid-fast bacilli are stained red. Other organisms are stained blue or green dependent on the counterstain used.

**LIMITATIONS**

- 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.
- False staining results can be seen due to cellular debris being stained by the technique.
- Positive staining reactions provide presumptive evidence of the presence of *M. tuberculosis* in the specimen only.
- Negative staining results do not necessarily indicate the specimen will be negative on culture.
- Organisms other than mycobacteria may display varying degrees of acid fastness e.g. *Rhodococcus* spp., *Cryptosporidium* spp., and *Isopora* spp

**REFERENCES**

- Ziehl, F. 1882. Zur Färbung des Tuberkelbacillus. Dtsch. Med. Wochenschr. 8:451.
- Neelson, F. 1883. Ein Casuistischer Beitrag zur Lehre von der Tuberkulose. Centralbl. Med. Wiss. 21:497-501.
- Kinyoun, J. J. 1915. A note on Uhlenhuth's method for sputum examination for tubercle bacilli. Am. J. Clin. Pathol. 46:472-4.
- Manual of Clinical Microbiology. Lennette.
- The Practice of Medical Microbiology. 12th Edition. V2. R. Cruickshank, J. P. Duguid, B. P. Marmion, R.H.A. Swain.

	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use








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**HAZARDS IDENTIFICATION**

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

 <p>DANGER</p>	<p>PL.7021/25 PL.7021 PL.7022</p>	<p>H226, H302+H332, H314, H341, H351, H373, H412</p> <p>P210, P270, P273, P280, P301+P330+P331, P303+P361+353, P310, P305+P351+P338, P501</p>
 <p>DANGER</p>	<p>PL.7024/100 PL.7024/25 PL.7024 PL.7025 PL.7026</p> <p>PL.7027/100 PL.7027/25 PL.7027 PL.7028 PL.7029</p>	<p>H255, H332, H319, H371</p> <p>P210, P270, P280, P303+P361+P353, P304+P340, P305+P351+P338, P312, P501</p> <p>H226, H332, H370</p> <p>P210, P270, P280, P303+P361+P353, P304+P340, P312, P501</p>
 <p>WARNING</p>	<p>PL.7030/100 PL.7030/25 PL.7030 PL.7031 PL.7032</p>	<p>H226, H319, H412</p> <p>P210, P280, P305+P351+P338, P337+P313, P370+P378, P501</p>
 <p>DANGER</p>	<p>PL.8007 PL.8007/4.0 PL.8007/5.0</p>	<p>H226, H318, H361, H411</p> <p>P210, P273, P280, P303+P361+P353, P305+P351+P338, P310, P501</p>
 <p>DANGER</p>	<p>PL.8006 PL.8006/4.0 PL.8006/5.0</p>	<p>H226, H302, H311+H331, H370</p> <p>P210, P270, P280, P301+P310, P330, P304+P340, P311, P501</p>