



INTENDED USE

QC1[™] Parasitology Slides are designed for the quality control of parasitology staining procedures. They are intended to validate both the quality of the staining reagents and the technique of the procedure.

SUMMARY

The microscopic identification of the intestinal protozoa is based upon observing the morphology of stained organisms. Staining facilitates identification by differentiating internal structures and separating organisms from background material and artifacts. A number of simple staining techniques have been developed which are satisfactory for diagnostic work. One of the most commonly used is the Wheatley's Trichrome Stain procedure.

The QC1 Parasitology Slides contain parasite-positive and parasitenegative substrates necessary to produce the correct staining results when performing the Wheatley's Trichrome Stain procedure. The positive area consists of a smear containing fixed *Giardia lamblia* trophozoites; the negative area is a similar smear that does not contain parasites.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

QC1 Parasitology Slides contain substrates that are applied as a smear. Handle the slides by the edges and do not touch the surface of the slide as this may damage the substrates.

STABILITY AND STORAGE

Store slides at room temperature (15-30°C). The slides are stable to the stated expiration date when stored at the required temperature.

PROCEDURE

Materials Provided: QC1 Parasitology Slides.

Materials Not Provided: Staining reagents, coverslips, mounting medium, microscope.

Wheatley's	Trichrome	Stain	Procedure
------------	-----------	-------	-----------

Reagent	Timing
70% Ethanol (0003359)	3-5 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
70% Ethanol	3-5 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
Wheatley's Trichrome Stain (0003351)	10 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
90% Acid-Ethanol (0003350)	1-3 seconds. Remove and drain off excess liquid by touching edge of slide to absorbent material.
	NOTE : When stain begins to run, transfer immediately to the next step.
100% Ethanol (0003356)	5-10 seconds. Remove and drain off excess liquid by touching edge of slide to absorbent material.
100% Ethanol	3 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
100% Ethanol	3 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
PRO-CLEAR™ (0003336) or Xylene (0003342)	10 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material and coverslip with mounting fluid.
PRO-CLEAR or Xylene	10 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material and coverslip with mounting fluid.

NOTE: Staining time can vary depending on the intensity desired for the final stain result.

NOTE: The Xylene substitute AmeriClear[®] does not yield appropriate stain results and should not be used.

EXPECTED RESULTS

Positive Control with Wheatley's Trichrome Stain:

The cytoplasm of the *Giardia lamblia* trophozoites stains blue-green and may be tinted with purple. Nuclei and internal structures will stain red/purple. Background vegetative material, bacteria and artifacts will stain shades of green, blue, purple or red.

Negative Control with Wheatley's Trichrome Stain:

Vegetative material, bacteria and other artifacts will stain shades of green, blue, purple or red.

LIMITATIONS OF PROCEDURES

The Wheatley's Trichrome Stain method is usually a trouble-free procedure when followed as directed. In some instances, due to the nature of the staining reagents and slide fixatives, microorganisms may migrate during the staining procedure onto the negative area of the slide. Any other problems that may occur will usually be one of the following:

Problem: Poor contrast of the chromatin material.

Cause: Over-decolorizing.

Solution: Decolorizing requires only a very brief contact, followed by an immediate dip in ethanol.

Problem: Stained preparation is "cloudy" with poor contrast of cellular detail.

Cause: Carryover of solutions from one step to another. Excessive staining (more than 30-40 slides) will weaken or dilute the stain. **Solution:** Change all solutions regularly to avoid staining clarity problems

BIBLIOGRAPHY

- 1. Lennette, EH, et al. Manual of Clinical Microbiology. Third Edition. American Society for Microbiology. 1980. pp. 684-685.
- Melvin, DM and Brooke, MM. Laboratory Procedures for the Diagnosis of Intestinal Parasites. 3rd Edition. US Department of Health and Human Services Pub. No. (CDC) 1982. 82-8282.
- Wheatley, WB. A Rapid Staining Procedure for Intestinal Amoeba and Flagellates. American Journal of Clinical Pathology. 1951. Vol. 21:990-991.

CONTACT

Alpha-Tec Systems, Inc. offers a complete line of reagents, stains, and QC1[™] Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing, as well as O&P collection systems and concentration devices for Parasitology. For Technical Assistance, email <u>Technical@AlphaTecSystems.com</u>, and for Customer Service, email <u>Sales@AlphaTecSystems.com</u>, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY

This product is warranted by Alpha-Tec Systems, Inc. to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS

PRO-CLEAR[™] and QC1[™], and are trademarks of Alpha-Tec Systems, Inc., 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA.

AmeriClear® is a trademark of Cardinal Health, McGaw Park, IL, USA.

PRODUCT CODES

0003262 QC1 Parasitology Slides, 40/Box







Manufactured by Alpha-Tec Systems, Inc. 1311 SE Cardinal Court, Suite 170 Vancouver, WA 98683 USA



GLOSSARY OF SYMBOLS

- LOT Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote
- REF Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog nummer / Het aantal van de catalogus / Kataloška številka / Número de catálogo
- IN vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro
- **EC**[REP] Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Germachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeu Autorizado
 - Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada
 - Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante
 - Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / laktag försiktighet / Previdno / Atenção
 - Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperature comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas
 - Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenuto sufficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebina zadostuje za <n> testov / Contém quantidade suficiente para <n> testes
 - Consult instructions for use / Consulter la notice d'utilisation / Consulte las instrucciones para el uso / Consultare le istruzioni per l'uso / Bitte beachten Sie die Anwendungsvorschriften / Raadpleeg instructies voor gebruik / Konsultera bruksanvisningen innan användning / Glej navodila za uporabo / Consulte instruções para o uso