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Directions For Use for the following:

QC1™ QUALITY CONTROL SLIDES

PVA (Zn) Slides

INTENDED USE
QC1™ PVA (Zn) Quality Control Slides are designed for the quality control of parasitology stain techniques. The slides utilize a PVA (Zn) fixed parasite as a parasitology stain control, yielding a positive staining reaction. QC1 PVA (Zn) Slides are intended to be used to validate each batch of sample slides to verify both the quality of the staining reagents and the technique of the procedure.

SUMMARY
The identification of the intestinal protozoa is based upon unstained and stained morphology, as observed in several types of staining preparations. A number of simple staining techniques have been developed over the years which are satisfactory for diagnostic work. The most commonly used staining technique is the modified Wheatley's Trichrome Stain procedure.

QC1 PVA (Zn) Slides contain parasite substrates necessary for a positive staining reaction by the Wheatley's Trichrome Stain procedure. The QC1 PVA (Zn) contain a fixed concentration of *Giardia lamblia* trophozoites.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS
Handle the substrate slides by the edges. Do not touch the surface of the slide, as this may damage the substrate. The stain control slides contain PVA (Zn) fixed parasite concentrations. Routine laboratory controls should be used when handling the slides.

STABILITY AND STORAGE
The substrate slides are stable to the stated expiration date when stored at the required temperature. Store at room temperature: 15-30ºC.

USER QUALITY CONTROL
QC1 PVA (Zn) Slides contain substrates at the optimal concentration necessary for a positive staining reaction of *Giardia lamblia* trophozoites.

PROCEDURE
Materials Provided: QC1 PVA (Zn) Slides.

Materials Not Provided: Staining reagents, microscope w/oil immersion lens, coverslips and mounting medium.

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.
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. When stain begins to run from the smear, transfer immediately to the next step.
100% Ethanol**(0003303)	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.
PRO-CLEAR or Xylene or	10 minutes. Remove and drain off excess liquid by touching edge of slide to absorbent material.
Coverslip with a mounting medium and examine with an oil immersion lens	

NOTE: The Xylene substitute AmeriClear® does not yield appropriate stain results and should not be used.
*** NOTE:** Staining time varies depending on the intensity desired for the final result.
****NOTE:** 100% ethanol or ethanol based reagent alcohol (or equivalent).

EXPECTED RESULTS
Wheatley's Trichrome Stain:
The cytoplasm of cysts and trophozoites is blue-green tinged with purple. The nuclear chromatin, chromatoid bodies, erythrocytes and bacteria stain red or red purple.

LIMITATIONS OF PROCEDURES
The Wheatley's Trichrome Stain method is usually a trouble-free procedure when followed as directed. Any problems that may occur will usually be one of the following:

Problem: Poor contrast of chromatin material.
Cause: Over-decolorizing.
Solution: Decolorizing only requires very brief contact with the 90% Acid-Ethanol, followed by an immediate dip in 100% ethanol.

Problem: Stained preparation is "cloudy" with poor contrast of cellular material.
Cause: Carryover of solutions from one step to another. Excessive staining (more than 30-40 slides) will weaken or dilute the stain.
Solution: Chance all solutions regularly to avoid staining clarity problems.

Problem: Persistent staining failure after considering all of the above.
Cause: Faulty technique and/or contaminated reagents.
Solution: Discard the entire stain series. Try again with new staining solutions.

BIBLIOGRAPHY
1. Lennette, EH, et al. Manual of Clinical Microbiology. Third Edition. American Society for Microbiology. 1980. pp. 684-685.
2. 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.
3. Wheatley, WB. A Rapid Staining Procedure for Intestinal Amoeba and Flagellates. American Journal of Clinical Pathology. 1951. Vol. 21:990-991.

CONTACT
CalibreScientific US, 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 Technical@AlphaTecSystems.com, and for Customer Service, email Sales@AlphaTecSystems.com, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY
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PRODUCT CODES
0003251 QC1 PVA (Zn) Slides, 40/Box
0003254 QC1 PVA (Zn) Slides, 10/Box

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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
IVD	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 / Iaktag 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
Σ	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
	Do not reuse / Ne pas réutiliser / No reutilizar / Non riutilizzare / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize