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INTENDED USE

QC1[™] Mycology Slides are designed for the quality control of fungi and yeast staining procedures. They utilize a positive staining yeast and a negative staining bacteria as stain controls. QC1 Mycology Slides are intended to validate the staining reagents and procedure technique.

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SUMMARY

Various laboratory regulatory organizations and Good Laboratory Practices require quality control programs. The performance of equipment, reagents, methods, and techniques must be monitored and documented. The QC1 Mycology Slide is a control slide for use with various mycology stains, eliminating the need to maintain in-house stock cultures for preparing slides.

QC1 Mycology Slides contain substrates (cell suspensions) at optimal concentrations necessary for a positive and negative staining reaction. Mycology Quality Control Slides consist of two "wells". The positive control, Candida albicans, displays a positive staining reaction, and the negative control, *Escherichia coli*, displays a negative staining reaction.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

Handle the slides by the edges and do not touch the surface of the slide as this may damage the substrates. The control slides contain yeast and bacteria that are air dried and heated to adhere to the slide surface. Routine bacteriological safety controls should be used when handling the bacterial slides.

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 Mycology Slides.

Materials Not Provided: Staining reagents, coverslips, fluorescent microscope.

Method of Staining: QC1 Mycology Slides are pre-fixed and should not be fixed by heat or alcohols prior to staining. Stain the QC1 Mycology Slide according to the procedure described by the manufacturer of the stain, or consult appropriate references.

RESULTS

The positive control, C. albicans, appears as ovoid yeast cells or as filamentous hyphae. The negative control, E. coli, appear as bacilli. Refer to the instruction sheet provided with the stain of choice or consult appropriate references for staining results.

LIMITATIONS OF PROCEDURES

Refer to the instruction sheet provided with the stain of choice or consult appropriate references for staining limitations.

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

This product is warranted by CalibreScientific US, Inc. to perform as described in the labeling and literature supplied. CalibreScientific US, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall CalibreScientific US, Inc. be liable for any consequential damages arising out of aforesaid express warranty. QC1[™] is a trademark of CalibreScientific AMER IP LLC., 6201 Trust Dr, Holland, OH 43528.

PRODUCT CODES

0003265 QC1 Mycology Slides, 20/Box







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GLOSSARY OF SYMBOLS

- Batch code / Numéro de lot / Número de Lote / Numero di LOT lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote
- Catalog number / Référence du catalogue / Número de REF 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 IVD 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
- Authorized representative in the European Community / EC REP 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 / Ω 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> Σ 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 / i 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 \otimes / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize