Ordering Information

QBC *F.A.S.T.* Malaria Stain Kits:

Size	**Catalog No.**
120 mL Kit	427760
250 mL Kit	427761
3.8 L Kit	427762

Drucker Diagnostics
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EC REP
Emergo Europe
Prinsessegracht 20, 2514 AP, The Hague, The Netherlands
Tel: (31) (0) 70-345-8570, Fax: (31) (0) 70-346-7299


Manufacturer

EC REP
Authorized Representative in the European Community


Use By

REF
Catalog Number

IVD
In Vitro Diagnostic Medical Device


Temperature Limitation

LOT
Batch Code (Lot)


Consult Instructions for Use


Flammable


Irritant

Made in the U.S.A.

Drucker Diagnostics
Innovative Solutions for a Healthier World

QBC *F.A.S.T.*™ Malaria Stain Kit

Instruction Manual

CE

4277-400-174 Rev. C
Revised 2017-9-20

Quality Control Procedure

Positive and negative smears with known results should be stained with *F.A.S.T.* Malaria Stain by the technician performing laboratory smear preparations. Correct results from the known samples should be confirmed before testing patient specimens. Quality Control should be performed routinely and in accordance with governing regulations. Results should be recorded.

When staining multiple slides, maintain distance between individual slides, such that stain and any loose sample cannot cross between them. This will minimize the potential for cross contamination.

When properly performed, uninfected RBCs in a smear stained with *F.A.S.T.* Malaria Stain should exhibit a pale green fluorescence and should be easily identified. If individual RBCs cannot be distinguished or seen, the smear should be repeated. If the problem persists, the cause may include failure of reagents, instrument, and operators. If the problem still persists after investigation of all of the above factors, an alternate method for malaria detection should be used. Do not report patient results until system failure is corrected.

Materials Needed But Not Included

QBC *F.A.S.T.* Malaria Stain is designed to work with the QBC ParaLens System and other fluorescence microscope systems equipped with filters and a light source capable of exciting the specimen at 450 nm and transmitting fluorescence from 500 nm to 600 nm. Also needed are clean microscope slides and methanol.

Ordering Information

For more information on ordering *F.A.S.T*. AFB Kits and accessories, consult our website at www.druckerdiagnostics.com. Drucker Diagnostics sales staff is also available at +1-814-692-7661 (U.S.A.) and via email at qbcsales@druckerdiagnostics.com.

English

QBC *F.A.S.T.*™ Malaria Stain Kit

Intended Use

For Investigational Use Only

For use in the aid of the detection of plasmodium species in whole blood specimens

Contents

The *F.A.S.T.* Malaria Stain Kit includes the following items:

- QBC *F.A.S.T.* Fluorescent Stain (120 mL, 250 mL, or 3.8 L)
- 1 Product Insert

Storage Conditions

Store *F.A.S.T.* Malaria Stain at 4° C to 45° C in closed opaque vial

QBC *F.A.S.T.* Malaria Stain has been tested to a minimum shelf life of 6 months from date of manufacture

Warnings and Precautions

For Investigational Use Only

Human clinical specimens can harbor infectious diseases such as malaria, hepatitis, and human immunodeficiency virus (HIV). Universal Precautions and local guidelines should be followed when handling all clinical specimens.

The chemicals in this kit can be hazardous and may be harmful or fatal. Use in a well ventilated area with proper personal protective equipment. Consult the kit MSDS for additional information regarding safety and disposal.

Malaria microscopy preparation and examination procedures should be performed only by those persons having proper training and exhibiting appropriate competence in the techniques involved.

Instructions for Use

F.A.S.T. Malaria stain is designed to work with whole blood film preparations

Thin Blood Film Preparation

Place a 7-10 µl drop of whole blood 2-3 cm from the end of a clean glass microscope slide. Using another clean microscope slide, place end on middle of the slide at a 45 degree angle. Keeping the slide at a 45 degree angle, move the slide backwards until it touches the drop of blood. Allow the drop of blood to spread along the edge of the slide at a 45 degree angle. In a quick, smooth motion, move the angled slide across the flat slide to spread the blood into a thin film. Allow slide to air dry. Once dry, dip entire smear into 100% methanol for 30 seconds to fix and allow to air dry.

Thick Blood Film Preparation

Place three 7-10 µl drops of whole blood on a clean, dust free microscope slide about 1 cm from the edge. Using another clean microscope slide connect the three drops and spread them into a single smear approximately 10mm in diameter. The smear should be round in shape and contain approximately 10 layers of red blood cells. Thickness should be such that newsprint can be read through the smear. Allow Slide to air dry. Do NOT fix in methanol.

Thin blood film staining procedure

1. **Flood fixed smear with *F.A.S.T.* Malaria Stain**
2. **Hold for 45 seconds**
3. **Tap off excess stain**
4. **Gently dip into fresh water 5 times (Do not agitate water with slide)**
5. **Allow slide to air dry standing vertically**

Thick blood film staining procedure

1. **Flood fixed smear with *F.A.S.T.* Malaria Stain**
2. **Hold for 10 minutes**
3. **Tap excess stain off of slide**
4. **Flood with fresh water**
5. **Hold for 5 minutes**
6. **Tap off excess water**
7. **Allow slide to air dry**

Examination and Quantification Procedure

Note: For best results, examination procedure should be performed in a dark room or with a microscope equipped with eye cups. Use the QBC ParaLens Advance™ or equivalent fluorescence microscope at 1000x magnification to examine smear.

Place stained smear on microscope stage and add a drop of immersion oil to edge of smear where monolayer of cells is located. Bring the objective to oil until it just touches the oil. While looking through the microscope oculars, slowly focus the fine focus until the blood cell layer comes into view. The thin film should exhibit a pale green fluorescence.

Examine the monolayer of red blood cells (RBCs) for malaria infections. At least 100 microscopic fields should be examined before reporting the slide as negative.

For thick films, examine thick film in a 2 systematic review pattern for malaria parasites.

To quantify degree of parasitemia, count the number of infected and uninfected RBCs in a microscopic field and record. Repeat with additional fields until at least 100 RBCs have been counted. Report results as % parasitemia using the following equation:

(number of Infected RBCs/(number of infected RBCs + number of uninfected RBCs)) x 100%

Expected Results

Malaria parasites will exhibit a yellow-gold fluorescence and will be inside of RBCs. White blood cells (WBCs) and platelets will also exhibit some fluorescence but are easily distinguished from malaria. Platelets exhibit a pale green fluorescence that is similar to that of uninfected RBCs and are not the gold-color exhibited by malaria. WBCs are significantly larger than RBCs and exhibit green and gold fluorescence.