INSTRUMENT RETURN PROCEDURES

An instrument problem may be reported by calling, faxing or e-mailing BioFire Diagnostics. The contact numbers are located below. You will also need the following documents:

Declaration of Decontamination

Phone

1-800-735-6544 - United States and Canada 801-736-6354 - Utah +1-801-736-6354 - International

Fax

1-801-588-0507 - United States and Canada IDD+1-801-588-0507 - International

E-mail

support@biofiredx.com - Customer Technical Support

Web Site

http://www.biofiredx.com/support/returnforms.html

Address

BioFire Diagnostics Service Center 415 W. Bearcat Drive Salt Lake City, UT 84115-2519 USA



Decontamination Labels (2 labels)





REPORTING AN INSTRUMENT PROBLEM AND RETURNING AN INSTRUMENT

If you need assistance with your BioFire Diagnostics (BFDX) instrument or a problem with the instrument occurs, call or email BFDX Customer Technical Support. All of these contact numbers are found on the Support page at www.biofiredx.com. Customer Technical Support will issue a return material authorization (RMA) number and instructions for returning the instrument. The steps for returning an instrument are listed below.

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Obtain a RMA Number

Note: A RMA number is absolutely necessary for returning an instrument.

You should receive a RMA number when you initially contact Customer Technical Support. If you did not receive a RMA number at that time, contact Customer Technical Support for a number. You will need to supply the instrument serial number so warranty status can be confirmed. If you instrument is out of warranty, please supply a blank purchase order (PO) number for the repair charges.

The RMA number must be recorded on the Decontamination Form and the Decontamination Labels.

2

Decontaminate All Returned Equipment

You must decontaminate all equipment being returned to BFDX to remove amplicon contamination and to ensure that personnel handling the equipment are not harmed by pathogenic organisms.

- 1. Put on a lab coat and gloves.
- 2. Wipe the area to be decontaminated with water.

3. Wet a paper towel with 10% bleach (1-part bleach to 9-parts water) and wipe the exterior of the instrument, the surface of the inner sample chamber and under the lid.

- 4. Change gloves.
- 5. Repeat steps 3 to 5 twice with fresh paper towels for a total of three bleach wipes.6. Wet a paper towel with distilled water and wipe the exterior of the instrument, the surface of the inner sample chamber and under the lid.
- 7. Change gloves.
- 8. Repeat step 6 with a fresh paper towel.

Use the Decontamination Labels and Form

After the above steps have been completed, you must complete and sign two decontamination labels. Attach one label to the instrument and the other to the exterior of the shipping container.

You should also complete and sign the Declaration of Decontamination form. Make a photocopy for your records, and place the original with the instrument. Two copies of removable forms and labels have been provided for your convenience.







Packaging and Shipping

Note: To ensure there is no loss of data, any computers being returned must be backed up before shipping. BioFire Diagnostics is not responsible for any lost data.

- 1. Pack instruments as follows: (see instrument operator manual for box dimensions). Please include the completed Decontamination Form.
 - **BioFire**[®] **FilmArray**[®] **Instrument:** Place the instrument back in the original packaging, if available. If the original packaging material is not available, contact BioFire Diagnostics Customer Technical Support. If you are returning the instrument to BioFire Diagnostics, follow the procedures outlined in Instrument Return Procedures in the *FilmArray Operators Manual*. Repair returns may not require allaccessories to be returned. BioFire Diagnostics Customer Technical Support will advise.
- 2. Seal the box with packing tape.

Note: The RMA number and decontamination label must be visible on the exterior of the shipping container.

WARNING: BioFire Diagnostics reserves the right to return or refuse receipt of any materials at the customer's expense that do not meet the above requirements.

All returns should be sent to the following address:

BioFire Diagnostics Service Center 415 W. Bearcat Drive Salt Lake City, UT 84115-2519 USA

Contact BFDX Customer Technical Support with any packaging or shipping questions (see page 1 for contact information).



RETURN MATERIALS AUTHORIZATION FAX

This form may be faxed to our return center at 1-801-588-0507 (U.S. and Canada) or IDD+1-801-588-0507 (International). It must also be included with the returned instrument.

| From: | F | Pages: |
|---------------|--|---------------------------------|
| Attn.: | | |
| Ship to: | BioFire Diagnostics Service Co 415 W. Bearcat Drive Salt Lake City, UT 84115-2519 USA | enter |
| Date: | | |
| RMA#: | (require | d when returning an instrument) |
| Institution: | | |
| Department: _ | | |
| Phone: | | Fax: |
| Serial No. | | _ |
| Notes: | | |
| | | |
| | | |

The decontamination form and labels must be completed before the instrument is returned to BioFire Diagnostics. If the unit is returned without decontamination documentation, it will be shipped back to you at your expense. If the unit cannot be repaired, it will either be returned to you or disposed of upon your request. Thank you for your business and for supporting the health and well being of our employees.

Signature: _____ Date: _____



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RETURN MATERIALS AUTHORIZATION FAX

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DECONTAMINATION LABELS

Please complete these decontamination labels and affix one to the instrument and the other to the exterior of the shipping carton next to the shipping label. Failure to decontaminate before shipping to BioFire Diagnostics, Inc. will result in the immediate return of the instrument at your expense.

Cut out label and attach it to the product being returned.

| ECONTAMINATION | NOTICE: | |
|--|---------------------------|--|
| This product has been decontaminated per Return Equipment policy: Yes / No | | |
| BioFire Diagnostics Return Materia | als Authorization (RMA#): | |
| Instrument User Name: | | |
| Instrument User's Return Address | (street address): | |
| | | |
| | | |
| Signature: | Date: / _/ | |

Cut out label and attach it to shipping container.

| ECONTAMINATION N | OTICE: |
|--|---|
| This product has been decontaminated | d per Return Equipment policy: Yes / No |
| BioFire Diagnostics Return Materials A | uthorization (RMA#): |
| Instrument User Name: | |
| Instrument User's Return Address (stre | et address): |
| | |
| Circatura | |
| Signature: | Date:/ / |

