

RAZOR® Detection Kit

Not for Diagnostic Use

RAZOR Pouch Instruction Booklet



Manufactured by
BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, Utah 84107 USA
+1-801-262-3592 | www.BioFireDefense.com

Customer and Technical Support

Reach Us on the Web

www.BioFireDefense.com

Reach Us by E-mail

support@biofiredefense.com

Reach Us by Phone

8 a.m. to 5 p.m. - Mt. Standard Time

1-801-262-3592 - US and Canada
IDD Prefix-1-801-262-3592 - Intl

Reach Us by Fax

1-801-447-6907 - US and Canada
IDD Prefix-1-801-447-6907 - Intl

RAZOR® Pouch Instruction Booklet

PATH-PRT-0036-09 February 2020

© Copyright 2007–2020, BioFire Defense, LLC
All rights reserved. Printed in the United States of America

The purchase of this product includes a limited, non-transferable license under specific claims of one or more U.S. patents as listed on BioFire Defense's Web site (<http://www.biofiredefense.com/LegalNotices/>) and owned by the University of Utah Research Foundation and/or BioFire. No right is conveyed, expressly, by implication, or by estoppel, to use any instrument or system under any claim of such U.S. patent(s), other than for the amount of product contained herein.

BioFire Defense, BioFire®, the BioFire logo, and RAZOR® are trademarks of BioFire Diagnostics, LLC and/or BioFire Defense, LLC and are registered trademarks in the United States. All other names of products and brands appearing in this manual are trademarks or registered trademarks of their respective owners.

The information contained in this document is subject to change without notice. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of BioFire Defense, LLC.

BioFire Defense, LLC makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. BioFire Defense, LLC shall not be liable for errors contained herein or for incidental consequential damages in connection with the furnishing, performance or use of this material.

Table of Contents

Background.....	1
Pouch Configurations.....	2
General Precautions	3
Laboratory Precautions	3
Handling of Biohazard and Toxic Wastes	3
Storage Specifications.....	4
Instrument Use Specifications.....	4
Loading the Run Protocol on a RAZOR Instrument.....	5
Scanning the Square Barcode (Run Protocol).....	5
Scanning the Rectangular Barcode (Pouch Information).....	6
Sampling and Preparation Procedures.....	8
Dry Sample (Powders, etc.)	8
Liquid Sample (Automatic air samplers, etc.).....	9
Dilution.....	9
Loading Reagent Pouches	10
Reagent Pouch Preparation	10
How to Load a Syringe	11
Understanding the Slots	12
Loading the Samples.....	12
Pouch Loading Tips.....	13
Remove Old Pouch	14
Load Liquid or Inject All Ports	14
Remove Combs.....	14
Twist Plungers	15
Use Tool to Plunge	15
Insert Pouch	15
Performing a Run	16
Performing a Run	16

Pouch Troubleshooting	17
Packaging Issues	17
Freeze-Dried Reagent Pellets	18
Reagent Issues.....	19
Pouch Loading Problems	20
Decontamination	21
Leaking Pouch.....	21
Instrument Decontamination.....	22
Nearest Neighbors Test - The 10® Test Kit.....	22
Nearest Neighbors Test - Other Test Kits	24
Warranty	26
Symbol's Glossary	27

Background

The RAZOR Instrument is a hand-held field portable real-time polymerase chain reaction (PCR) instrument. It uses PCR to detect the presence of nucleic acid (DNA) in unknown samples. If PCR amplification occurs, the RAZOR instrument will provide a positive (+) PCR result. This means the gene target was present in the unknown sample.

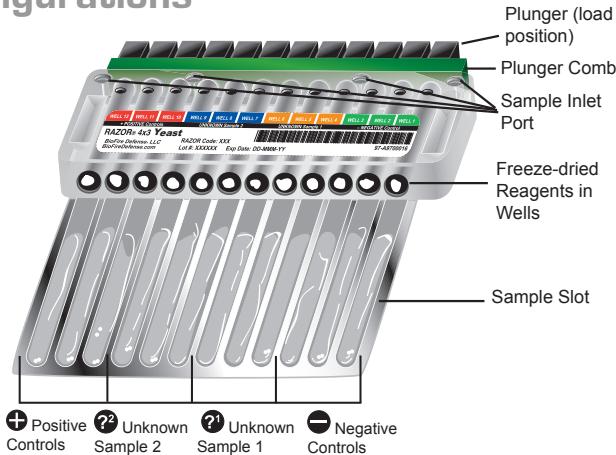
Kit Contents

Pouch containing freeze-dried reagents in a foil bag	Assay card to match the reagents
Sample swabs	1 mL and/or 3 mL syringes with tips
5 mL unknown sample bottles	5 mL control buffer
Instruction booklet	2 mL transfer pipettes

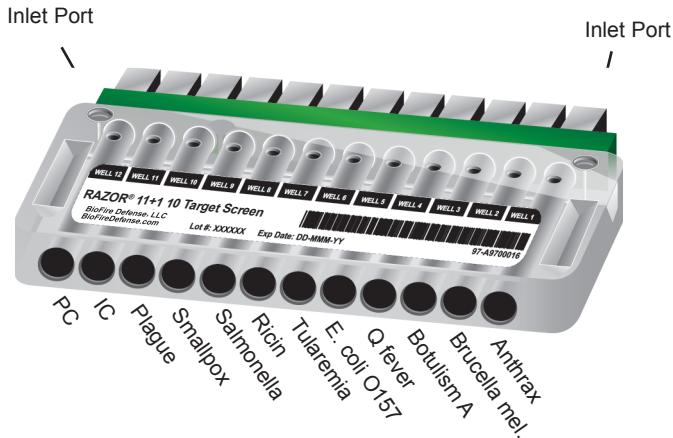
Required Equipment

RAZOR Instrument

Pouch Configurations



A 4x3 configuration pouch. Pouch configurations may vary depending on the product ordered.



Example of The 10[®] configuration pouch. Pouch configurations may vary depending on the product ordered.

General Precautions

One of the most important rules of working with biological pathogens and toxins is to avoid contamination. When samples are prepared, be sure to follow the instructions provided in this document. Safeguards have been put into place to help avoid contamination.

⚠ WARNING: If you suspect that the unknown sample to be tested contains a pathogen or toxin, it must be handled by trained personnel and treated as if it were highly poisonous or infectious throughout the sample purification procedure, the assay procedure, and while disposing of all waste materials that have come in contact with it.

Laboratory Precautions

For general biosafety safety guidelines, refer to *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and Prevention and National Institutes of Health, December 2009. Available from <http://www.cdc.gov/biosafety/publications/bmbl5/>.

Handling of Biohazard and Toxic Wastes

Dispose of used pouches, syringes, and vials according to good laboratory practices. Inactivate waste from potentially positive samples or samples containing amplified DNA molecules by using appropriate procedures before disposing of them.

For more information refer to DHHS (NIOSH) Publication No. 88-119 *Guidelines for Protecting the Safety and Health of Health Care Workers* (section 6, Hazardous Waste Disposal).

This product is for presumptive testing only and is not to be used for diagnosis of disease or to confirm absence of Ricin toxin. Positive tests should be confirmed by a certified public health laboratory. Negative results are possible even when the toxin is present, if the toxin is pure, or due to various factors including PCR inhibitors, improper sample preparation, damage to the test kit or instrument, or human error.

Storage Specifications

Store contents at room temperature (18 - 28°C). **DO NOT FREEZE OR REFRIGERATE.**
When the foil pouch bag is opened, use its contents immediately.

Storage Temperature Range	18 - 28°C
Storage Humidity Range	< 85% non-condensing
Set-up and Analysis Temperature Range	4 - 30°C
Set-up and Analysis Humidity Range	<85% non-condensing
Storage Light Exposure Condition	No light

Instrument Use Specifications

Instrument Platforms	RAZOR EX or RAZOR Mk II Instruments
Sample Type(s)	Swab (environmental or powder), air sample, liquid or diluted culture samples
Nucleic Acid Type	DNA
Chemistry Requirements	Hybridization probes
Detection Control	RAZOR instruments make metacalls that interpret the results of the Unknowns, Negative, Positive and Inhibition Controls.
Time to Setup	<10 min.
Time to Run	~30 min.
Time to Analyze	<1 min.
Ease of Setup	Critical / Basic Users

Loading the Run Protocol on a RAZOR Instrument

Scanning the Square Barcode (Run Protocol)

Run Protocols are the steps that the instrument takes to perform a successful run. All of the protocols for each of the tests that BioFire Defense offers are pre-loaded on to the instrument. However, in case a protocol is removed, it will need to be scanned in again.

Protocols are preprogrammed in the square barcode that is found on the assay card inside each kit. Use the barcode to scan the protocol into the instrument; be sure to scan the protocols into the instrument before it is taken to the field.

1. To load the protocol, select **Main Menu > Utilities** by using the directional arrows and the Select button. Next select **Scan Protocol Code**.
2. Scan protocols using the **square** protocol barcode found on the assay card in each kit. The barcode reader is located on the back of the instrument.



Note: Be sure that all barcodes are as smooth and flat as possible.

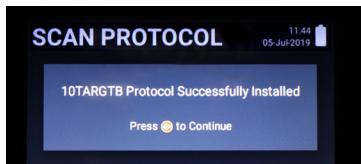


Note: During the scan, the barcode reader emits a bright green aiming beam surrounded by red light. Hold the barcode about 6 - 8 in. from the back of the instrument and allow the field of red light to touch the barcode; center the green aiming beam on the barcode to scan. When the scan is complete, the aiming beam turns off and the instrument displays a confirmation message indicating that the barcode was read correctly. If the scan does not complete immediately, flatten the image and/or move the barcode gradually closer to the instrument while scanning.

3. If the barcode is scanned correctly, the screen displays a successful message.



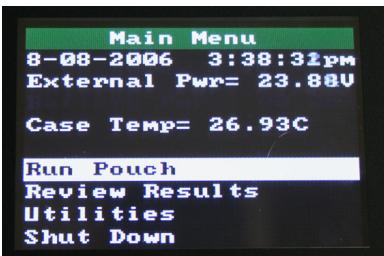
RAZOR EX Screen



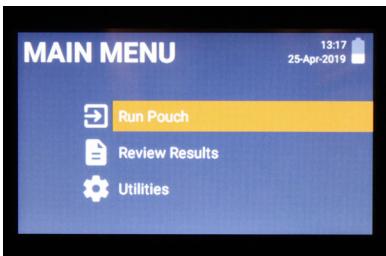
RAZOR Mk II Screen

Scanning the Rectangular Barcode (Pouch Information)

1. Select Main Menu > Run Pouch to start the loading instructions.



RAZOR EX Screen



RAZOR Mk II Screen

- Follow the instrument prompt to scan the **rectangular** pouch barcode from the reagent pouch label. Press **Back** to abort the barcode scan.



Note: If the wrong barcode is scanned, the instrument displays the message **Invalid Barcode Data**. Ensure that the rectangular barcode on the pouch's fitment label is being scanned. If the pouch barcode becomes smeared or unscannable, there are barcodes available on the assay card that comes with each kit or in the *RAZOR Operator's Manual*.



Note: If the barcode is not read in time, the reader will abort the scan. Press **Select** to return to the Main Menu, then **select Run Pouch again**.

If the wrong barcode is scanned, an Error message will appear **Error, Invalid Barcode Data**. Rescan the rectangular barcode on the pouch label. If any barcode becomes smeared or unscannable, barcodes are available on the assay card found in each kit.



Note: If the correct run protocol is not present on the instrument, the machine will prompt to scan the **square** protocol barcode from the assay card found in each kit.

Sampling and Preparation Procedures



Note: Do not tear the pouch when it is being removed; the contents can easily contaminate the instrument and surrounding area.



HAZARDOUS MATERIAL: Use standard laboratory procedures when handling biohazardous material. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container.

Prepare the sample before opening the reagent pouch. Each unknown sample must be in liquid form before running PCR and it must have a minimum volume of 500 μ L (0.5 mL) unless the assay card lists a different volume. Sample preparation is essential to running a successful test, it removes any contaminating salts and other compounds that would disrupt or inhibit the enzymatic reactions and fluorescent dyes that are required to run the test. Label all unknown tubes with unique identifiers (i.e., Sample 1) before collecting the unknown samples.

Dry Sample (Powders, etc.)

1. Touch the dry swab to the unknown powder, or swab a 2-in. by 2-in. area of the surface to be tested.
2. Place the swab into the appropriately labeled vial and break off the swab at its break point.
3. Secure the cap on the vial and shake the vial vigorously for **30 sec.**
4. If dilution is **NOT** necessary, proceed to the *“Loading Reagent Pouches”* section in this booklet.
5. Repeat this procedure for the remaining samples. Use a fresh swab and the correctly labeled vial for each sample.

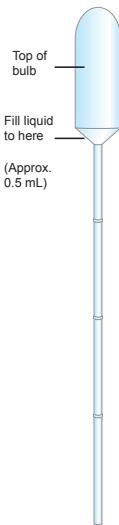


Liquid Sample (Automatic air samplers, etc.)

1. Transfer approximately 0.5 mL of liquid to the appropriately labeled vial.

 **Note:** Some pouch configurations may require more liquid; if so, the correct volume will be listed on the pouch-specific assay card.

To draw a sample with the transfer pipette, first squeeze and hold the top of the bulb. Insert the tip of the pipette into the liquid and release the bulb to draw the sample up to the fill line (see illustration). Transfer the pipette to the vial and squeeze the bulb to empty the sample into the vial.



2. Secure the cap on the water vial and shake the vial vigorously for **30 sec**.
3. Repeat this procedure for the remaining samples. Use a fresh pipette and the appropriately labeled vial.
4. Load the diluted samples into a pouch. Follow the instructions in the *“Loading Reagent Pouches”* section of this booklet.

Dilution

For a sample that might contain a high level of inhibitors, a dilution step may be necessary.

To perform a dilution on a 4 x 3 pouch with dry or liquid samples, follow these steps:

1. Add sample to a vial as described in the previous two sections.
2. Transfer approximately 0.5 mL from the vial to another labeled vial (i.e., Diluted Sample 1) using a transfer pipette.
3. Secure the cap and shake vigorously for ~30 sec.
4. Load both the undiluted and diluted samples into a pouch using the *“Loading Reagent Pouches”* section.

To rerun an 11 x 1 pouch that gives a result of “Inhibition Control Failure”, follow these steps:

1. Transfer approximately 0.5 mL from the previous sample vial to another labeled vial (i.e., Diluted Sample 1) using a transfer pipette.
2. Secure the cap and shake vigorously for ~30 sec.
3. Load the diluted sample into a new pouch using the *“Loading Reagent Pouches”* section.

Loading Reagent Pouches

Prepare the samples before opening the reagent pouch. Refer to the previous section for information about collecting and preparing samples. Each unknown sample must be in liquid form, have a minimum volume of 0.5 mL (or the correct volume for the assay card being used), and be free of any contaminating salts and other compounds that would disrupt or inhibit the enzymatic reactions and fluorescent dyes required to run the reaction.

The format of each of the freeze-dried reagent pouch is target specific and fixed. The reagent pouch is disposable and contains all of the ingredients for real-time PCR identification of target DNA using the RAZOR system. The **Unknown** samples for the RAZOR are loaded in liquid form into the freeze-dried reagent pouch. The pouch contains freeze-dried reagents for **Positive**, **Negative**, and/or **Inhibition** controls as well as for **Unknown** samples.

The RAZOR instrument has built-in instructions to guide you through the steps of preparing a reagent pouch and performing a run. Use the steps provided by the instrument as well as this booklet when preparing the pouch.

After preparing the unknown samples correctly, use the following steps to insert them into the sample pouch and run a test.

Reagent Pouch Preparation

⚠ Do not remove the pouch from its packaging unless that pouch can be tested within 30 min.

1. Remove the freeze-dried reagent pouch from the aluminum can and air-tight foil bag.
2. Place the pouch on a flat, clean surface with the inlet ports and label face up. Make sure the plunger comb is in place.



How to Load a Syringe

⚠ Do not prepare syringes until indicated in the following steps.

1. Uncap the end of a syringe. The end of the syringe is preloaded with a cannula tip necessary for pouch loading (avoid touching cannula tip to other surfaces).
2. To avoid splashing, slowly insert the cannula end of syringe into the control water or sample.

⚠ If there are air bubbles in the syringe, DO NOT remove them by tapping and then pushing bubbles out of the cannula tip into the air (this could contaminate both you and the area). Instead, reinsert the syringe into the sample vial and slowly express the liquid. Slowly redraw the sample into the syringe. Repeat until the liquid in the syringe is free of air bubbles.

3. Draw the appropriate volume for the pouch (see note below) of control water or sample into the syringe by pulling up on the syringe plunger until it reaches the correct volume for the pouch. (The correct volume for each pouch type is listed in the following note. For other pouch types that are not listed, refer to the assay card.) Avoid introducing any air into the system, which can cause bubbles in the syringe.



Volumes per Port According to Pouch Type

4 x 3 pouch— 0.5 mL	12 x 1 pouch— 0.2 mL	6 x 2 pouch— 0.4 mL
10 + 2 pouch— 2.0 mL	11 + 1 pouch— 2.0 mL	1 x 12 pouch— 2.0 mL

Understanding the Slots

The instrument uses four separate types of reagents.

- **Positive (+)** control slots are designed to confirm that the instruments and reagents work. If the test runs correctly, these slots will be positive.
- **Negative (-)** control slots provide a check to verify that the reagent pouch was not contaminated. If the test runs correctly, these slots will be negative.
- **Inhibition (I)** control slots, if present, provide a check that PCR amplification was not prevented by the presence of other substances, such as salts, in the unknown samples. If other substances are present and they prevent PCR amplification, then it is possible to have a false negative in the test result. The possibility of having a false negative is minimized by using Inhibition controls.
- **Unknown (U)** slots contain the unknown samples that are being tested.

Loading the Samples

With the unknown prepared samples, use the following steps to insert them into the sample pouch and run a test.

Follow this Sample Loading Order to Minimize Cross-Contamination and User Error:

Step 1	Step 2	Step 3
Negative Controls (if present) ➔ -	Unknown Samples ➔ ?	Positive/Inhibition Controls (if present) +

The procedure is essentially the same for loading the negative controls, the unknown sample, the positive controls, and (if present) the inhibition controls.

1. Load a syringe with the correct volume of sample.

 **CAUTION:** Do not push the syringe plunger to force liquid into the pouch. This can fill the pouch with air and may damage it or cause contamination.

2. After the syringe is prepared, hold it by the syringe body and gently insert the cannula tip into the **correct** inlet port. Push the syringe down until you feel a faint pop and an ease in resistance. A broken inlet port allows the liquid to be pulled into the pouch by vacuum.
 - For the **Negative** control inlet port, insert **reagent grade water or control buffer**. The appropriate bottle will be provided with your pouch.
 - For the **Unknown Sample** inlet ports, insert the correct **unknown sample**.
 - For the **Inhibition** control inlet port (if present), insert the correct **unknown sample**.
 - For the **Positive** control inlet port, insert **reagent grade water**.

3. Each time a syringe is inserted into an inlet port, push the syringe down until a faint pop is felt and an ease in resistance. This indicates that the seal on the inlet port has been broken, allowing liquid to be pulled into the pouch. The syringe should sit in the inlet port for at least **30 sec.** so the liquid can dispense evenly. Once the syringe plunger has stopped moving, remove the syringe and discard it in a biowaste container.

⚠ If the liquid does not flow into the pouch automatically, refer to the *Pouch Troubleshooting* section or use a new reagent pouch.



Pouch Loading Tips

In the following procedures, press the **next** arrow key on the RAZOR to move on to the next screen.

⚠ CAUTION: Pressing the pouch plungers when the pouch is not in the plunge bracket may damage the pouch, prevent the sample from entering the sample slot, or cause back flow leading to contamination.

1. Be sure that the outside of the pouch looks clean before it is inserted into the instrument. If the pouch looks unclean, gently wipe it with a dry, lint-free cloth.

2. When handling and load samples, avoid contamination problems by using standard laboratory techniques and following the appropriate protocols for loading samples. Change gloves frequently to avoid cross-contamination of samples.
3. DO NOT push pouch plungers down until “**Use Tool to Plunge**” step or until prompted on the RAZOR screen.

Remove Old Pouch

Before starting a new run, remove the old pouch from the instrument and dispose of it. To remove the pouch, pull it out of the pouch slot.

Dispose of used pouches, syringes, and vials according to good laboratory practices. Inactivate waste from potentially positive samples or samples containing amplified DNA molecules by using appropriate procedures before disposing of them.

Load Liquid or Inject All Ports

Load liquid samples into the pouch by injecting them into all of the ports. This can be done by following the instructions in the “*Loading Reagent Pouches*” section in this booklet. The prompt on the RAZOR screen will tell you to load liquid. The prompt on the RAZOR screen will tell you to inject all ports.

The instrument will begin preheating, the next screen message will occur after the instrument has successfully finished preheating.



Remove Combs

Remove all the plunger comb by pulling it away from the pouch.



Twist Plungers

1. Twist plunger by using the Plunger Twist Tool (Part No. TOOL-DRV-0016) or the end of the plunger comb and rotate each of the plungers 90° towards the center of pouch; this prevents leaking and cross-contamination of neighboring wells. Plungers can also be rotated by hand or with a small flat-head screwdriver.
2. With the pouch plungers up, lightly tap the pouch on a flat surface.



Use Tool to Plunge

1. Place the pouch onto the plunge bracket located near the pouch slot on the instrument.
- ⚠ CAUTION: Pressing the plungers when the pouch is NOT in the plunge bracket may damage the pouch, prevent the sample from getting to the sample slot, or cause back flow leading to contamination.**
2. Hold the reagent pouch in the bracket and **slowly** push the plungers down to force the liquid into the individual sample slots. When all of the plungers have forced liquid into the sample pouch, the samples are now ready to run.



Insert Pouch

1. Insert the pouch into the instrument with the label facing up and the plungers toward the front of the instrument. The pouch fitment should sit perfectly in the groove over the insert slot.
2. Press the **Next directional** button to begin the run. The instrument seals the pouch and begins the run.

Performing a Run

This section contains specific instructions for performing a run on either instrument.

Performing a Run

1. Select **Main Menu > Run Pouch** to start the loading instructions on the instrument. To cancel the run steps, press the **Back** button.
2. To continue with the run, the instrument will prompt to scan the **rectangular** pouch barcode from the reagent pouch label.
3. The instrument displays the message **Remove Old Pouch**. Remove the pouch from the previous run and discard it as biohazardous waste.
4. Press the **Select** button to continue.
5. The instrument displays an **Inject All Ports** screen. Load the syringes and inject the ports as described in “**Load Liquid or Inject All Ports**.”
6. When the ports have been injected, press the **Select** button to continue.
7. When the instrument displays a **Preheat Complete** window, press the **Select** button to continue.
8. Follow the remaining pouch prompts to prepare the pouch for testing.
9. Insert the prepared pouch into the instrument when prompted with the label facing up and the plungers toward the front of the instrument. The pouch fitment should sit perfectly in the groove over the insert slot. After the pouch has been inserted, press the **Select** button.
10. The **Run in progress** screen displays.

PCR will begin unless you choose to quit by pushing the back button and selecting **Yes**.



Pouch Troubleshooting

Packaging Issues

Problem	Potential Causes	Resolutions
The foil bag is not tight around the can or pouch.	The packaging has lost vacuum.	Contact BioFire Defense Customer Support.
A hiss was heard when the can is opened.	A hissing sound is normal when opening the foil bag, but not when opening the can. This indicates a packaging defect.	Contact BioFire Defense Customer Support.
The pouch is missing white reagent pellets.	<ol style="list-style-type: none">1. Old pouch pellets can be small, shriveled, or hard to see. Make sure pouch has not expired.2. The pouch is for use with liquid reagents. Check the packaging.	If the pouch has not expired and is not for liquid reagents, contact BioFire Defense Customer Support.

Freeze-Dried Reagent Pellets

Normal Pellets



Bubbles in Pellets - Normal

Bubbles in pellets are normal and do not affect the performance of the reagents.



Powdery Pellets - Normal

These pellets are considered normal and do not affect the performance of the reagents.



Shrunken Pellets - Normal

These pellets are considered normal and do not affect the performance of the reagents.



Crystallized Pellets - Normal

These pellets are considered normal and do not affect the performance of the reagents.



Missing Pellets - Not Normal

Do not fill the pouch. Use another pouch and return the defective pouch to BioFire Defense for replacement.



Note: Always inspect pouches to confirm that all pellets are present and are white in color.



Missing pellet

Reagent Issues

Problem	Potential Causes	Resolutions
Shriveled/spread pellets.	1. Old reagents 2. Failed vacuum 3. Poor reagents	1. Check the expiration date. 2. If these pellets correlate with a channel that pulls no liquid, then vacuum loss is the cause. Contact BioFire Customer Support. 3. If amplification does not work, contact BioFire Customer Support.
Failed amplification (the positive or inhibition controls are called negative).	1. Old reagents 2. Incorrect protocol 3. Inhibitors	1. Check the expiration date. 2. Confirm that the correct protocol is being used. 3. Make sure that the water and the sample used to resuspend reagents are clean and free of amplification inhibitors. 4. Dilute the collected sample 1:10 and repeat the run.

Pouch Loading Problems

Problem	Potential Cause	Resolutions
The liquid is not pulled into the pouch from the syringe.	The inlet port was not punctured.	You may need to push the syringe harder into the port to puncture the inlet membrane.
	The plungers may be twisted or facing the wrong direction.	 Note: Leave the syringe in the port. Wait 1 min. to see whether the liquid gets pulled into the well, then check that the pouch plungers are facing the correct direction. If they are not, turn them so the arrows point to the center (parallel with the fitment).
	The pouch has lost vacuum.	If a channel or channels fail to pull liquid, check the pouch or packaging for defects and contact BioFire Defense Customer Support. Use another pouch for the test.
White freeze-dried pellets do not resuspend.	Pouch may have lost vacuum, resulting in no liquid being pulled in.	See the last resolution in the previous problem section.
	The channel may be blocked.	 Note: Leave the syringe in the port. Wait 1 min. to see whether liquid gets pulled into the well, then check that the pouch plungers are facing the correct direction. If they are not, turn them so the arrows point to the center (parallel with the fitment). Try to bend the fitment while the syringe is still in the port.
	If the liquid is pulled in, reagent pellets may need several minutes to resuspend.	Gently shake the pouch.

Problem	Potential Cause	Resolutions
Air instead of liquid is pulled into pouch.	The syringe may have air.	Check the syringe. Before loading it, push a small drop of liquid out of the tip into the sample bottle and look for bubbles in the syringe. Use a new syringe to fill each port. Use another pouch for the test if only air was pulled into the pouch.

Decontamination

The following table lists the items that are needed for decontamination. For detailed instructions on how to perform a complete decontamination on the RAZOR Instrument, consult the *RAZOR Operator's Manual*.

10% bleach solution in a spray bottle	DNAZap™, or equivalent DNA degrading system
Water in a squeeze or spray bottle	Paper towels
95% ethanol in a squeeze bottle	Lens paper
Lens cleaner	

 **Note:** If a live agent has been used on or detected with the instrument, fumigation may be needed (i.e., ethylene oxide). Contact BioFire Defense Customer Support for more information.

Leaking Pouch

If a pouch is damaged after a sample has been added to it, ensure no one uses any potentially contaminated areas or instruments and follow the steps below to decontaminate and dispose of the pouch correctly.

1. Dispose of any potentially contaminated gloves.
2. Put on a clean pair of gloves and dispose of the potentially contaminated lab coat. Put on a new lab coat.
3. Discard the pouch in a containment or biohazard waste bin.
4. Change gloves.
5. Follow decontamination procedures in the *RAZOR Operator's Manual* for cleaning the affected instrument and area.

Instrument Decontamination

Refer to the *RAZOR Operator's Manual* for information about decontaminating the instrument.

Nearest Neighbors Test - The 10[®] Test Kit

The 10 target pouch contains PCR tests to detect DNA for the following organisms:

Organism	Common Name	Organism	Common Name
<i>Bacillus anthracis</i>	Anthrax	<i>Francisella tularensis</i>	Tularemia
<i>Brucella</i> spp.	Brucella	<i>Ricinus communis</i>	Ricin
<i>Clostridium botulinum</i>	Botulism	<i>Salmonella</i> spp.	Salmonella
<i>Coxiella burnetii</i>	Q fever	<i>Variola</i>	Smallpox
<i>Escherichia coli</i> O157	E. coli O157	<i>Yersinia pestis</i>	Plague

Each of the 10 assays was tested against the following strains and was detected appropriately:

Organism Strains*	Assays	Detected?
<i>Bacillus anthracis</i> Ames	<i>Bacillus anthracis</i>	Yes
<i>Brucella melitensis</i> 16M	<i>Brucella melitensis</i>	Yes
<i>Clostridium botulinum</i> Type A	<i>Clostridium botulinum</i>	Yes
<i>Coxiella burnetii</i> 9 mile	<i>Coxiella burnetii</i>	Yes
<i>Escherichia coli</i> O157:H7	<i>Escherichia coli</i> O157	Yes
<i>Francisella tularensis</i> Schu 4	<i>Francisella tularensis</i>	Yes
<i>Ricinus communis</i>	<i>Ricinus communis</i>	Yes
<i>Salmonella</i> Saintpaul	<i>Salmonella</i> spp.	Yes
<i>Variola</i> DNA [†]	<i>Variola</i>	Yes
<i>Yersinia pestis</i> India	<i>Yersinia pestis</i>	Yes

*All assays were tested against the strains, and only the appropriate target assays were detected.

[†]Variola is only tested as DNA since organism is not available.

Each of the 10 assays was tested against the following nearest neighbors (phylogenetically related species or other biothreat pathogens) and were found to show no cross reactivity.

<i>Bacillus anthracis</i> Ames	<i>Francisella philomiragia</i>
<i>Bacillus brevis</i>	<i>Francisella tularensis</i> Schu 4
<i>Bacillus cereus</i>	<i>Helicobacter pylori</i>
<i>Bacillus circulans</i>	<i>Klebsiella pneumonia</i>
<i>Bacillus licheniformis</i>	<i>Ochrobactrum anthropi</i>
<i>Bacillus megaterium</i>	<i>Ochrobactrum spp. isolates</i>
<i>Bacillus subtilis</i>	<i>Pseudomonas aeruginosa</i>
<i>Bacillus thuringiensis</i> : al hakam	<i>Ricinus communis</i>
<i>Brucella melitensis</i> 16M	<i>Rickettsia prowazekii</i>
<i>Burkholderia mallei</i>	<i>Salmonella Saintpaul</i>
<i>Campylobacter jejuni</i>	<i>Shigella dysenteriae</i>
<i>Citrobacter freundii</i>	<i>Shigella flexneri</i>
<i>Clostridium botulinum</i> Type A	<i>Staphylococcus aureus</i>
<i>Clostridium perfringens</i>	<i>Variola DNA</i>
<i>Coxiella burnetii</i> 9 mile	<i>Vaccinia</i>
<i>Escherichia coli</i> O111 ISO: ED031 EHEC2-18	<i>Vibrio cholerae</i>
<i>Escherichia coli</i> O157:H7	<i>Yersinia enterocolitica</i>
<i>E. coli</i> O26:H11 ISO: DEC10C EHEC2-11	<i>Yersinia frederiksenii</i>
<i>E. coli</i> O26:NM ISO: RDEC-1 EHEC2-15	<i>Yersinia pestis</i> India
<i>E. coli</i> O70:H11 ISO: DEC10J EHEC2-17	<i>Yersinia pseudotuberculosis</i>
<i>E. coli</i> O91:H21 ISO: 23/67 STEC1-5	
<i>Enterococcus faecium</i>	

Nearest Neighbors Test - Other Test Kits

The Anthrax kit contains PCR tests to detect DNA for the following organisms:

Organism	Common Name	Targets		
<i>Bacillus anthracis</i>	Anthrax	Target 2: pXO1	Target 3: pXO1	Target 4: pXO2

The Food Screen kit contains PCR tests to detect DNA for the following organisms:

Organism	Common Name	Organism	Common Name
<i>Campylobacter</i> spp.	Campylobacter	<i>Listeria monocytogenes</i>	Listeria
<i>Salmonella</i> spp.	Salmonella		

The Water Screen kit contains PCR tests to detect DNA for the following organisms:

Organism	Common Name	Organism	Common Name
<i>Cryptosporidium</i>	Cryptosporidium	<i>Escherichia coli</i> O157	E. coli O157
<i>Salmonella</i> spp.	Salmonella		

This RAZOR Sim10 kit contains PCR tests to detect DNA for the following two training assays:

Organism	Common Name	Organism	Common Name
<i>Bacillus globigii / atrophaeus</i>	Bg	<i>Saccharomyces cerevisiae</i>	Yeast

These organisms were tested against the following nearest neighbors (phylogenetically related species or other biothreat pathogens). The exception was *Campylobacter* Target 1, which tested positive against *Campylobacter jejuni*.

<i>Bacillus brevis</i>	<i>Enterococcus faecium</i>
<i>Bacillus cereus</i>	<i>Francisella philomiragia</i>
<i>Bacillus circulans</i>	<i>Helicobacter pylori</i>
<i>Bacillus licheniformis</i>	<i>Klebsiella pneumonia</i>
<i>Bacillus megaterium</i>	<i>Pseudomonas aeruginosa</i>
<i>Bacillus subtilis</i>	<i>Rickettsia prowazekii</i>
<i>Bacillus thuringiensis</i> : al hakam	<i>Shigella dysenteriae</i>
<i>Burkholderia mallei</i>	<i>Shigella flexneri</i>
<i>Campylobacter jejuni</i>	<i>Staphylococcus aureus</i>
<i>Citrobacter freundii</i>	<i>Vaccinia</i>
<i>Clostridium perfringens</i>	<i>Vibrio cholerae</i>
<i>Escherichia coli</i> O111 ISO: ED031 EHEC2-18	<i>Yersinia enterocolitica</i>
<i>E. coli</i> O26:H11 ISO: DEC10C EHEC2-11	<i>Yersinia frederiksenii</i>
<i>E. coli</i> O26:NM ISO: RDEC-1 EHEC2-15	<i>Yersinia pseudotuberculosis</i>
<i>E. coli</i> O70:H11 ISO: DEC10J EHEC2-17	
<i>E. coli</i> O91:H21 ISO: 23/67 STEC1-5	

Warranty

RAZOR pouches are covered under a limited warranty against reagent failures or defects that may occur during manufacturing. If you experience any problems that may indicate a defective pouch, please contact BioFire Defense Customer Support at (+1-801-262-3592) with the following information:

1. RAZOR pouch part number
2. Lot number
3. Lot expiration date

Symbol's Glossary

The following symbols can be found on the instrument, on pouch kits, or throughout this manual. Use the definitions below as a guideline to interpreting the symbols.

ISO 7000 Graphical Symbols for Use on Equipment – Registered Symbols							
3082 	Manufacturer	2492 	Batch Code (Lot Number)	2607 	Use-By Date (YYYY-MM-DD)		
1641 	Operator's Manual	0632 	Temperature Limit	0659 	Biological Risks		
W017 	Caution, Hot Surface		0434A 	Caution			
Underwriter's Laboratory Listing Mark for Canada and the United States			USB Implementers Forum				
	Underwriter's Laboratory Listing Mark			USB cable			
Manufacture Symbols (BioFire Defense, LLC)							
	NOTE - explains how to operate the instrument more efficiently.						



79 West 4500 South, Suite 14, Salt Lake City, Utah 84107 USA
1-801-262-3592 | www.BioFireDefense.com

*For additional information regarding our
products and applications, please contact
our Customer Service Department
at BioFire Defense.*

