

Biothreat 2 Screen Assay Card

Hybridization Probe Assays

This reagent kit is designed to test for three separate DNA targets—**Smallpox** (Assay 1), **Plague** (Assay 2), and ***Clostridium botulinum* Type A** (Assay 3)—from two unknown liquid or dry samples. These protocols are to be performed manually and have been simplified to reduce the risk of operator error.

⚠ WARNING: If the unknown sample to be tested is suspected to contain 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 when disposing of all waste materials that have come in contact with the suspected sample.

Kit PATH-ASY-0009—Contents

5 mL Reagent Grade Water (1)	5 mL Unknown Sample Bottles (2)	1 mL Syringes with Cannula Tips (4)
Sample Swab Pack (1)	Instruction Booklet (1)	Freeze-dried Reagents in a Foil Bag (1)
Transfer Pipettes Pack (1)	Loading Instructions Sticker (1)	

Note: A RAZOR® EX or RAZOR® instrument is required to run this assay.

Programming the Run Protocol

Before the sample is loaded into the pouch, verify that the run protocol for this test is loaded onto the instrument. If it is not and you are using a RAZOR, use the RAZOR desktop software to create the protocol and load it onto the instrument. Use the data in this card when creating the protocol for this particular test with the Protocol Wizard. For the RAZOR EX, you can load the protocol by scanning the square protocol bar code on the reagent box. If the bar code is damaged, use the generic bar codes that are located below. Times, temperatures, and results analyses are all included in the protocol bar code.

Loading Protocols for the RAZOR® EX

After the square protocol bar code has been scanned, scan the rectangular bar code on the pouch fitment. If the rectangular bar code is damaged, use the generic one below. **Note: You will only be able to use the generic bar code for one run. To re-use it, you have to delete the run.**

Note: Prepare sample before loading.

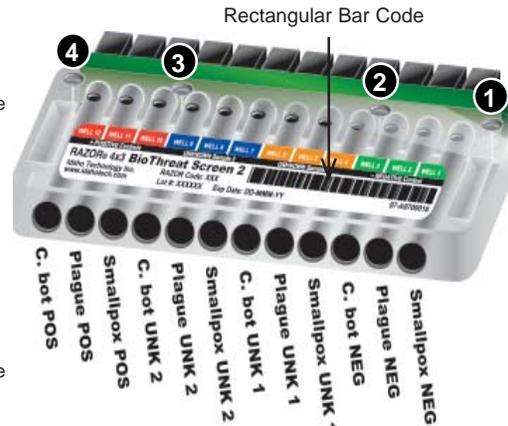


BIOTRT2B-BIO2B017



Kit Part Number: PATH-ASY-0009
Protocol Code: BIOTRT2B

- 1 Negative Port**
Add 0.5 mL reagent grade water
- 2 Unknown 1 Port**
Add 0.5 mL sample 1
- 3 Unknown 2 Port**
Add 0.5 mL sample 2
- 4 Positive Port**
Add 0.5 mL reagent grade water



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PATH-PRT-0040 Rev.03

Protocol Steps for the RAZOR®

Protocol Steps	Data to be Entered																																																																																				
Step 1: Protocol Identifier	Enter: 09H to identify this protocol. This identifying code matches the first three characters on the pouch. This will help you identify the protocol after it is loaded on the instrument.																																																																																				
Step 2: Protocol Parameters	Initial Hold Temperature: 93°C Denature Temperature: 91°C Anneal Temperature: 60°C																																																																																				
	Initial Hold Time: 120 s Denature Hold Time: 3 s Anneal Hold Time: 15 s																																																																																				
	Cycles: 55																																																																																				
Step 3: Select Organisms for the Protocol	A list of organisms is listed in the All Organisms column. Select Smallpox and click the Add button. Repeat for Plague and C. bot . All three will be added to the Organisms for this Protocol column. If Smallpox , Plague , or C. bot are not listed, see the <i>RAZOR Pouch Instruction Booklet</i> for instructions on how to add new organisms. Note: The target for Smallpox is "Tar1," Plague is "Tar1," and C. bot is "Tar1."																																																																																				
Step 4: Add Environmental Samples	Add two unknown samples by clicking the Add button and entering UNK1 . Repeat the steps and enter UNK2 .																																																																																				
Step 5: Assign an Organism to Each Sample Position	Assign Smallpox to positions 1, 4, 7, and 10 . Assign Plague to positions 2, 5, 8, and 11 . Assign C. bot to positions 3, 6, 9, and 12 .																																																																																				
Step 6: RAZOR Pouch Definition	Fill out the definition as shown in the image. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <table border="1"> <thead> <tr> <th colspan="6">Razor Bag Definition</th> </tr> <tr> <th>Pos</th> <th>Organism</th> <th>Target</th> <th>Type</th> <th>Env. Sample</th> <th>Concentration</th> </tr> </thead> <tbody> <tr><td>1</td><td>Smallpox</td><td>Tar1</td><td>NEG</td><td></td><td></td></tr> <tr><td>2</td><td>Plague</td><td>Tar1</td><td>NEG</td><td></td><td></td></tr> <tr><td>3</td><td>C. bot</td><td>Tar1</td><td>NEG</td><td></td><td></td></tr> <tr><td>4</td><td>Smallpox</td><td>Tar1</td><td>UNK</td><td>UNK1</td><td></td></tr> <tr><td>5</td><td>Plague</td><td>Tar1</td><td>UNK</td><td>UNK1</td><td></td></tr> <tr><td>6</td><td>C. bot</td><td>Tar1</td><td>UNK</td><td>UNK1</td><td></td></tr> <tr><td>7</td><td>Smallpox</td><td>Tar1</td><td>UNK</td><td>UNK2</td><td></td></tr> <tr><td>8</td><td>Plague</td><td>Tar1</td><td>UNK</td><td>UNK2</td><td></td></tr> <tr><td>9</td><td>C. bot</td><td>Tar1</td><td>UNK</td><td>UNK2</td><td></td></tr> <tr><td>10</td><td>Smallpox</td><td>Tar1</td><td>POS</td><td></td><td></td></tr> <tr><td>11</td><td>Plague</td><td>Tar1</td><td>POS</td><td></td><td></td></tr> <tr><td>12</td><td>C. bot</td><td>Tar1</td><td>POS</td><td></td><td></td></tr> </tbody> </table> </div>	Razor Bag Definition						Pos	Organism	Target	Type	Env. Sample	Concentration	1	Smallpox	Tar1	NEG			2	Plague	Tar1	NEG			3	C. bot	Tar1	NEG			4	Smallpox	Tar1	UNK	UNK1		5	Plague	Tar1	UNK	UNK1		6	C. bot	Tar1	UNK	UNK1		7	Smallpox	Tar1	UNK	UNK2		8	Plague	Tar1	UNK	UNK2		9	C. bot	Tar1	UNK	UNK2		10	Smallpox	Tar1	POS			11	Plague	Tar1	POS			12	C. bot	Tar1	POS		
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Step 7: RAZOR Metacalls	This step displays an image of the conditions required for an unknown to be called positive. You do not need to enter any data in this step. Click Finish to save the protocol.																																																																																				
NOTE:	Before interpreting results on machine's LED screen, remember assays correlate to the channels shown in diagram to right. <div style="text-align: right; margin-top: 10px;">  </div>																																																																																				