Seratec® PSA Semiquant and a-Amylase Tests				
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Seratec® PSA Semiquant and a-Amylase Tests

1 Sample Preparation and Antigen Extraction (for both tests):

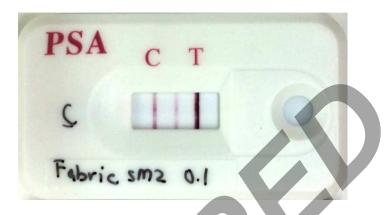
- 1.1 Make a 1/4 cutting for swabs, or ~ 3 mm x 3 mm for stains.
- 1.2 Add the cuttings to separately labeled 1.5 mL Eppendorf tubes.
- 1.3 Add 0.5 mL Phosphate Buffered Saline (PBS) solution to each sample. Record the PBS lot number.
- 1.4 Place the tubes on the Thermomixer. Shake at 300 RPM at room temperature (25°C) for 5 to 30 minutes.
- 1.5 Note: The same extract may be used for both Seratee® PSA Semiquant and Seratec® α -Amylase testing.

2 Seratec® PSA Semiquant Testing:

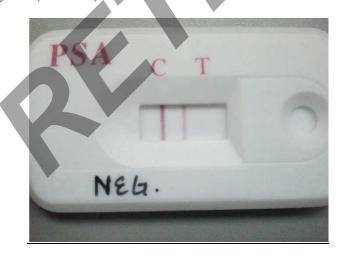
- 2.1 Record the cassette lot number. Remove the cassette from the foil pouch and label the cassette. The provided dropper may be discarded. *Do not use a cassette if the foil pouch has been opened.*
- 2.2 Prepare a 0.5 dilution by adding 100 μ L of each extract to 100 μ L PBS in a separately labeled Eppendorf tube.
- 2.3 Aliquot the full 200 µL of each 0.5 dilution into the test chamber of a new Seratec® PSA Semiquant card.
- 2.4 Read results at **10 minutes**. Record the results for the Internal Standard and Control by indicating positive or negative. Record the results for the test region by indicating positive or negative.
 - 2.4.1 <u>Note</u>: Positive results may be indicated if the lines appear prior to 10 minutes; however, negative results can only be indicated after 10 minutes.

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- 2.5 Interpretation of overall Seratec® PSA Semiquant Test:
 - 2.5.1 Positive (three lines):



- 2.5.1.1 A line appears in both the Internal Standard and Control regions, and
- 2.5.1.2 A positive line appears within the test region. *Note: weak or strong positive may be indicated within the exam notes.*
- 2.5.2 Negative (two lines):



- 2.5.2.1 Line appears in both the Internal Standard and Control regions, and
- 2.5.2.2 No line appears in the test region.

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2.5.3 Fail:

- 2.5.3.1 A line does not appear in either the Internal Standard and/or Control regions.
- 2.5.3.2 An incomplete line appears in the Internal Standard, Control, and/or Test Region.



An example of an incomplete line at the Test Region

2.5.3.3 If a test fails, the test must be repeated by performing Steps in section 2, on a new Seratec® PSA Semiquant card.

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3 Seratec[®] α-Amylase Testing:

- 3.1 Record the cassette lot number. Remove the cassette from the foil pouch and label the cassette. The provided dropper may be discarded. *Do not use a cassette if the foil pouch has been opened.*
- 3.2 Aliquot 200 μ L of each extract (no dilution) directly into the test chamber of the Seratec® α -Amylase card.
- Read results at **10 minutes**. Record the results for the Control by indicating positive or negative. Record the results for the test region by indicating positive or negative.
 - 3.3.1 <u>Note</u>: Positive results may be indicated if the lines appear prior to 10 minutes; however, negative results can only be indicated after 10 minutes.
- 3.4 Interpretation of overall Seratec® α-Amylase Test:
 - 3.4.1 Positive (two lines):



- 3.4.1.1 A line appears in Control region, and
- 3.4.1.2 A positive line appears within the test region. *Note: weak or strong positive may be indicated within the exam notes.*

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3.4.2 Negative (one line):



- 3.4.2.1 A line appears in Control region, and
- 3.4.2.2 No line appears in the test region.
- 3.4.3 Fail:
 - 3.4.3.1 A line does not appear in the Control region.
 - 3.4.3.2 An incomplete line appears in the Control, and/or Test Region.
 - 3.4.3.3 If a test fails, the test must be repeated by performing Steps in section 3, on a new Seratec® α -Amylase card.