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

<u>IMPORTANT</u>: While semen contains a large quantity of PSA, positive results from the PSA Semiquant test <u>does not confirm</u> the presence of semen. Similarly, saliva contains a large quantity of α -Amylase, however, positive results from the α -Amylase test <u>does not confirm</u> the presence of saliva. Care must be taken with the interpretation, reporting, and testimony of such results.

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 Record the PBS lot number. Add 0.5 mL Phosphate Buffered Saline (PBS) solution to each sample.
- 1.4 Place the tubes on the Thermomixer. Shake at 300 RPM at room temperature (25°C) for 5 to 30 minutes.

Note: The same extract may be used for both Seratec® PSA Semiquant(Section 2) and Seratec® α-Amylase testing (Section 4).

2 Seratec® PSA Semiquant Testing:

The Seratec PSA Semiquant Test effectively detects the presence of high concentrations of PSA. While PSA stands for "Prostate Specific Antigen," this is a misnomer – PSA is not specific to the prostate gland. Therefore, care must be taken with the interpretation and reporting of results. A positive result only confirms the presence of high concentrations of PSA. A positive result does not confirm the presence of semen.

- 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.

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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.

<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.

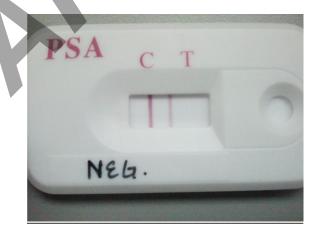
- 3 Interpretation of overall Seratec® PSA Semiquant Test:
- 3.1 Positive for PSA (three lines):



- 3.1.1 A line appears in both the Internal Standard and Control regions, and
- **3.1.2** A positive line appears within the test region.

Note: weak or strong positive may be indicated within the exam notes.

3.2 Negative for PSA (two lines):



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- 3.2.1 Line appears in both the Internal Standard and Control regions, and
- 3.2.2 No line appears in the test region.
- 3.3 Fail:
 - 3.3.1 A line does not appear in either the Internal Standard and/or Control regions.
 - 3.3.2 An incomplete line appears in the Internal Standard, Control, and/or Test Region.



An example of an incomplete line at the Test Region

3.3.3 If a test fails, the test must be repeated by performing steps in Section 2, "Seratec® PSA Semiquant Testing", on a new Seratec® PSA Semiquant card.

4 Seratec[®] α-Amylase Testing:

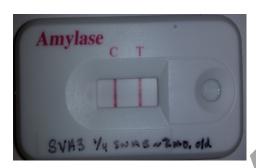
- 4.1 Record the cassette lot number. Remove the cassette from the foil pouch and label the cassette. The provided dropper may be discarded. *Do not use a cassette if the foil pouch has been opened.*
- 4.2 Aliquot 200 μ L of each extract (no dilution) directly into the test chamber of the Seratec® α -Amylase card.
- 4.3 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.

Note: 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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5 Interpretation of overall Seratec® α-Amylase Test:

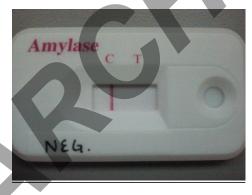
5.1 Positive for Amylase (two lines):



- 5.1.1 A line appears in Control region, and
- 5.1.2 A positive line appears within the test region.

Note: weak or strong positive may be indicated within the exam notes.

5.2 Negative for Amylase (one line):



- 5.2.1 A line appears in Control region, and
- 5.2.2 No line appears in the test region.
- 5.3 Fail:
 - 5.3.1 A line does not appear in the Control region.
 - 5.3.2 An incomplete line appears in the Control, and/or Test Region.
 - 5.3.3 If a test fails, the test must be repeated by performing steps in Section 4, <u>Seratec® α -Amylase Testing</u>, on a new Seratec® α -Amylase card.