Seratec® PSA Semiquant and α-Amylase Tests

**IMPORTANT:** While semen contains a large quantity of PSA, positive results from the PSA Semiquant test does not confirm the presence of semen. Similarly, saliva contains a large quantity of α-Amylase, however, positive results from the α-Amylase test does not confirm 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 the sample into a tube of 0.5 mL Phosphate Buffered Saline (PBS) solution, replacing the reagent LIMS label with the new sample label.

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 μL of each extract to 100 μL 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.

**Note:** 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):
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 μL 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.
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, Seratec® α-Amylase Testing, on a new Seratec® α-Amylase card.