



Abacus Diagnostics, Inc.

ABAcad_o p30 Test For The Forensic Identification of Semen

For Forensic Use

Immunoassay for the qualitative detection of p30 for the forensic identification of semen.

Catalog # 308332 (25 Test/kit)

Technical Information sheet

Intended Use

ABAcad_o p30 test is designed to qualitatively detect p30 for the forensic identification of semen. p30 is an accepted marker for detecting semen in criminal cases including vasectomized or azoospermic individuals.

Summary

In 1971 Hara et al. first described a protein in the seminal fluid, named gamma-seminoprotein. In 1978, Sensabaugh et al. characterized the protein in detail, found that its molecular weight corresponds to 30,000 Dalton and named it p30. In 1980 first immunometric assays were developed and Graves and Sensabaugh demonstrated that p30 is a reliable forensic marker for the identification of semen. The range of p30 is 200,000 to 5.5 million nanogram per ml of semen. The sensitivity of ABAcad_o p30 test is 4 ng/ml and therefore seminal fluid diluted up to 1 in a million should also be detectable. Various methods of detection of p30 include Ouchterlony double diffusion, crossover electrophoresis, rocket immunoelectrophoresis, radial immunodiffusion, and ELISA. A disadvantage of all the above conventional methods is that they are either not sensitive enough or cumbersome and time consuming to perform in forensic laboratories. Abacus Diagnostics' ABAcad_o p30 is, however, very sensitive with results only within 10 minutes.

Principle Behind This Test

In this test procedure, 200 µl of sample is added to the sample well 'S', and allowed to soak in. If p30 is present in the semen specimen, it will react with the mobile monoclonal antihuman p30 antibody and a mobile antigen antibody complex is thus formed. This mobile antibody-antigen complex migrates through the absorbent device towards the test area 'T'. In the test area 'T', a monoclonal antihuman p30 antibody is immobilized. This immobilized antibody captures the above complex so that an antibody-antigen-antibody sandwich is formed. The conjugated pink dye particles concentrate in a narrow zone on the membrane. When the p30 concentration in the sample exceeds 4 ng/ml the pink dye particles will form a pink colored band in the test area 'T' indicating a positive test result. As an internal positive control, p30 antibody-dye conjugates cannot bind to the antibody in the test area 'T', but are captured by an immobilized anti immunoglobulin antibody present in the control area 'C' forming a complex. The captured pink dye particles will thus form a band in the control area 'C', indicating that the test has worked properly and proper procedures have been followed. Thus, presence of two colored lines, one in the test area 'T' and other in the control area 'C', indicates a positive result, while a line only in the control area 'C' would indicate a negative result (provided no "high dose hook effect").

Reagents And Materials Provided

1. Test Device (25 pcs, each sealed individually in a test pouch)
2. A Dropper and a desiccant sealed inside each of the test pouch.
3. Test Instructions

Materials Required But Not Included

1. Clock or timer.
2. Centrifuge

Stability, Storage and Shelf Life

ABAcad_o p30 Detection Test should be stored below 82°F (28°C). The test can be stored in the sealed pouch below 82°F (28°C) until the expiration date as printed on the sealed test pouch. Do not Freeze. Do not use the test after the expiration date.

Sample Collection, Preparation and Storage

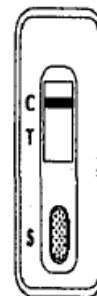
- The frozen specimens/swabs/stains must be thawed completely and brought to 2-8 °C.
- Extraction of specimens from swab or stain may be performed in 750 µL of HEPES buffered saline for 2 hours at 2-8 °C. Distilled water or other buffers suitable for further DNA extraction may be used as well. This procedure recovers approximately 99% of the extractable p30 on the swab.
- Centrifuge the above sample for 3 minutes after the above extraction step. Remove 300 µl of supernatant for testing purposes. This aliquot may be stored between 2-8 °C if not used immediately. Immediately before use with ABAcad_o p30 test, the sample should be brought back to room temperature. Remaining sample may be used for further DNA analysis without affecting the DNA yield.

Test Protocol

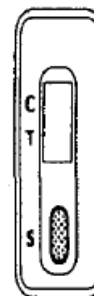
1. Allow the sample to warm to room temperature if it has been refrigerated.
2. Remove the device and the dropper from the sealed pouch.
3. Label the device with the case number.
4. Add 200 µL (or 8 drops with the dropper) of sample to the sample well 'S' of the test device.
5. Read result at 10 minutes. Positive results can be seen as early as 1 minute depending upon the p30 concentration. For negative results, one must wait for full 10 minutes.



Positive



Negative



Invalid

1. **Positive.** If there are two pink lines, one each in the test area 'T' and in the control area 'C', the test result is positive and indicates that the p30 level is at or above 4 ng/ml.
2. **Negative.** If there is only one pink line (in the control area 'C'), the test result is Negative. This may indicate that (a) No p30 is present above 4 ng/ml or (b) Presence of "High Dose Hook Effect". Presence of "High Dose Hook Effect" may give false negative result due to the presence of high concentration of p30 in the sample, as for example in undiluted seminal fluid. In such cases the sample may be retested using a 10 to 10,000 fold dilution.
3. **Invalid.** If there is no pink line visible in the control area 'C', the test is inconclusive. Repeat the test and reexamine the test procedure carefully.

PRECAUTIONS

- For the in vitro qualitative detection of p30 for the forensic identification of semen only.
- Do not use beyond the expiration date which appears on the sealed pouch.
- Disposable gloves should be worn while handling kit reagents or specimens. Wash your hands after the test.
- A fresh transfer pipette for each specimen should be used.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are being handled.

NGZSS

