SA Scientific™

SAS™ hCG Products FAQ

1. **What are common causes of Faint Lines?**
   - The addition of too much sample.
   - Sample is near the cutoff value.
   - Sample has a matrix affect.

2. **What are common causes of False Positives?**
   - Patient may have antibodies to the antibodies used in the test.
   - Patient may have hCG elevated due to prescription drugs or hormone therapy.
   - Patient may have elevated hCG due to an undiagnosed medical condition.
   - Reading the results of the test after 15 minutes
   - Precipitates may be present in the sample requiring centrifugation

3. **What are the most common causes of False Negatives?**
   - Applying specimen drop wise with an unqualified pipette delivery system may cause the following.
     - Too much specimen may be added to sample well which may cause flooding of the test and cause the antigen to flow around the test line area.
     - Too little specimen may be applied to the sample well. This will cause the background not to clear. Specimens near the minimal detectable threshold may not be observed.
   - Not using first morning urine specimen.
   - hCG concentrations are below the minimal detectable threshold of the SAS™ hCG test. When pregnancy is still suspected, a fresh serum or early morning urine should be collected 48 hours later and tested.

   The SAS™ hCG tests provide a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.

4. **What are the most common migration issues?**
   - Insufficient sample pipetted into device.
   - Sample may be too viscous.
   - Matrix effect between the sample and the test device.

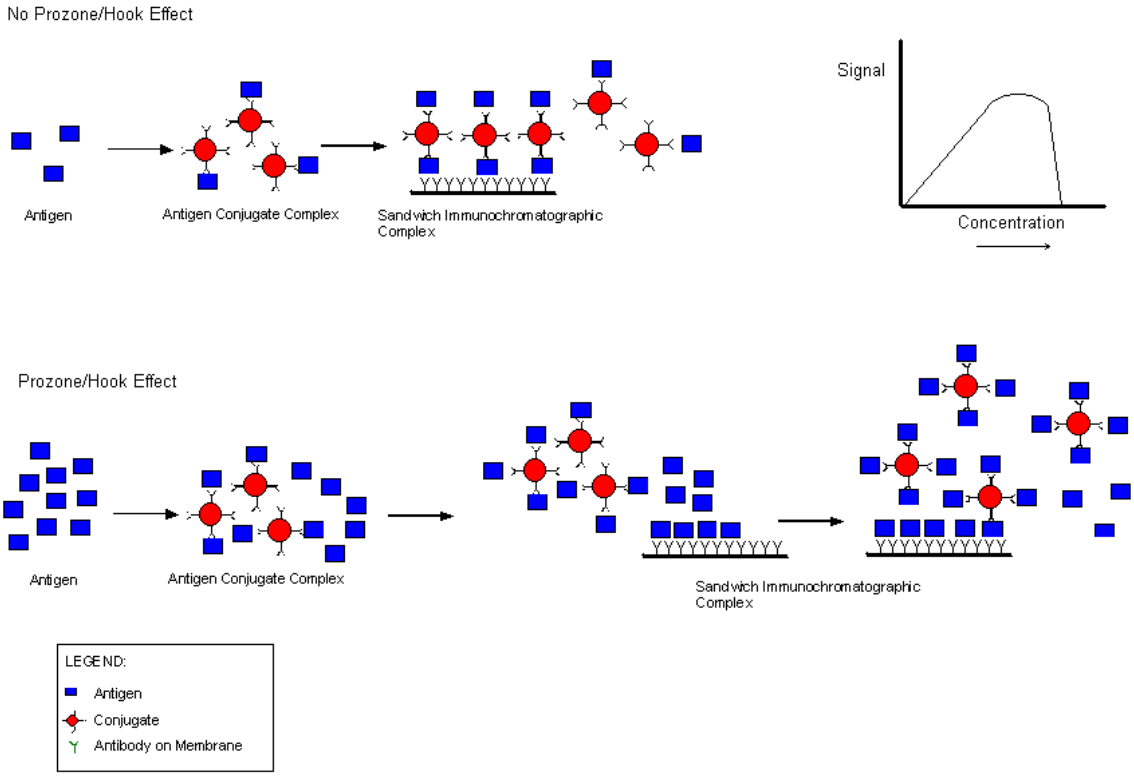
5. **What is the Prozone or Hook Effect?**
   Prozone or Hook Effect is the condition by which large quantities of antigen in an immunoassay system impair antigen-antibody binding, resulting in low antigen determination.

Prozone/Hook Effect FAQ

1. **What is a Prozone/Hook Effect?**

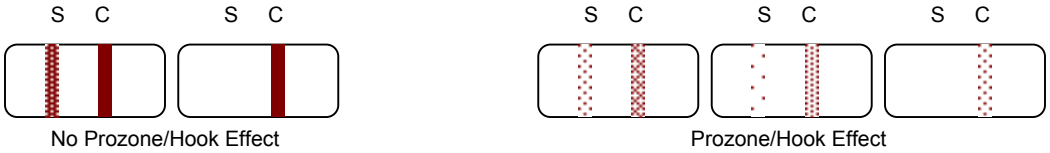
   Prozone/Hook Effect occurs when excess antigen binds the antibody at the test line, therefore not allowing the binding of the conjugate-antigen colored complex to the antibody on the test line (See Drawing Below). Light specimen and control lines characterize an assay having a Prozone/Hook Effect.

   This phenomenon is mainly found in immunoassays in which three components (antigen, conjugate, and capture antibody) are incubated together. Dilution of the antigen sample with saline or PBS will enhance the signal intensity.



2. How do you recognize a Prozone/Hook Effect in an immunochromatographic assay?

Prozone/Hook Effect is characterized by either a light or non-existent test (specimen) line and a light control line. See illustration below.



3. Can you correct for Hook Effect?

Yes, simply dilute the sample 1:2 or 1:4 with PBS or Saline, and perform the assay once again.

4. Are references available to read more on Prozone/Hook Effect?

Yes, please see list below.

1. Butch AW. [Letter]. Clin Chem 2000: 1720-1721.
2. Dahlmann N et al. "Hook Effect" In a Patient with a Gonadotropin-Secreting Tumor [Letter]. Clin Chem 1990; 36: 168.
3. Diamandis EP and Christopoulos TK. Immunassay. New York, pp. 230-231
4. Ermens AM, et al. Dilution Protocols for Detection of Hook Effects/Prozone Phenomenon [Letter]. Clin Chem 2000; 46: 1719-1720.
5. Hussa RO. The Clinical Marker hCG. West Port, Conn. , 1987.
6. Wu JT, Christensen SE. Effect of different test designs of immunoassays on "hook effect" of CA 19-9 measurement. J. Clin Lab Anal 1191; 5:228-32.