Material Modification of Abacus Diagnostics ABAcard® p30 Test

Purpose

The ABAcard p30 test (Abacus Diagnostics) is an immunochromatographic test for the presence of Prostate Specific Antigen (PSA or p30) that was validated by the SDPD Crime Laboratory in 1999 and has been approved for the confirmation of semen stains since that time. Due to supply chain issues related to the SARS COVID-19 pandemic, Abacus Diagnostics was unable to obtain the plastics necessary for the manufacture of the Abacus p30 cards and redesigned the tests using alternate plastic housings. The new design required a different volume for the test (80µL vs. the previous 200µL), requiring an evaluation of the material modification.

The new lots of ABAcard p30 can be differentiated by the format of the lot numbers. The original, validated lots, referred to herein as "ABAcard p30 (old)" had the format of three letter month followed by the year (e.g. NOV 2023). The new, modified lots, referred to herein as "ABAcard p30 (new)" have the format of YYYY-MM-DD (e.g. 2025-02-28).

This material modification was part of a wider evaluation of immunochromatographic tests including those from alternate manufacturers and testing kits for blood and saliva. The material modification data was taken from the sensitivity experiments comparing ABAcard p30 (old) to ABAcard p30 (new). Current SDPD protocol incudes extraction of semen stains in PCR grade water. ABAcard p30 (new) tests include an extraction buffer that is not used by SDPD. This material modification compared the new test cards with stains extracted in water and extracted in the buffer.

Materials and Methods

SERI Semen Standard and 2 additional samples of semen ("Semen 1" and "Semen 2") were serially diluted tenfold (1/10 – 1/1,000,000) in PCR grade water. The six dilutions were tested using 200µL for ABAcard p30 (old) and 80µL for ABAcard p30 (new).

Semen stains were prepared from tenfold serial dilutions (1/10 – 1/1,000). For ABAcard p30 (old), dried semen stains were extracted in 350µL PCR grade water and 200µL was tested. For ABAcard p30 (new), the dried semen stains were alternatively extracted in 350µL PCR grade water or 750µL of the extraction buffer supplied by the manufacturer in the testing kit; 80µL was used for ABAcard p30 (new).

Results

In general, ABAcard p30 (new) performed better than or the same as ABAcard p30 (old) in the sensitivity experiments. Extraction with ABAcard p30 (new) in water was generally as good or better than extraction in the supplied buffer.

The data from the cards is present at the end of this document, but can is summarized in the following tables.

Serial Dilutions of Semen

Semen Standard Dilutions	1/10	1/100	1/1,000	1/10,000	1/100,000	1/1,000,000
ABAcard p30 (old)	+	+	+	-	-	-
ABAcard p30 (new)	+	+	+	+	-	-

Semen Stain 1 Dilutions	1/10	1/100	1/1,000	1/10,000	1/100,000	1/1,000,000
ABAcard p30 (old)	+	+	+	-	-	-
ABAcard p30 (new)	+	+	+	+	-	-

Semen Stain 2 Dilutions	1/10	1/100	1/1,000	1/10,000	1/100,000	1/1,000,000
ABAcard p30 (old)	+	+	+	-	-	-
ABAcard p30 (new)	+	+	+	-	-	-

Extractions of Semen Stains

Semen Standard Dilutions	1/10	1/100	1/1,000
ABAcard p30 (old)	+	+	-
ABAcard p30 (new - water)	+	+	+
ABAcard p30 (new - buffer)	+	+	+

Semen Stain 1 Dilutions	1/10	1/100	1/1,000
ABAcard p30 (old)	+	-	-
ABAcard p30 (new - water)	+	+	+
ABAcard p30 (new - buffer)	+	+	+

Semen Stain 2 Dilutions	1/10	1/100	1/1,000
ABAcard p30 (old)	+	-	-
ABAcard p30 (new - water)	+	+	+
ABAcard p30 (new - buffer)	+	+	-

Conclusions

ABAcard p30 (new) demonstrates sensitivity that is on par with current methods. Extraction of semen stains in 350µL PCR grade water demonstrated improvement with ABAcard p30 (new) over current methods. Extraction with 750µL of the

supplied extraction buffer did not show improvement using ABAcard p30 (new) over extraction in 350µL PCR grade water.

Based on the results of this study, ABAcard p30 (new) testing using 80µL of extract from samples extracted in 350µL of PCR grade water is suitable for casework.

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